Regulatory Environment of the Healthcare Industry

Presenters

Mark L. Mattioli, Esq.
Greenberg Traurig

Todd A. Zigrang
MBA, MHA, FACHE, ASA
HEALTH CAPITAL CONSULTANTS, LLC

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Presenter Bio

Mark L. Mattioli, Esq. is a shareholder in the Philadelphia office of Greenberg Taurig, Mr. Mattioli provides regulatory, transactional, and compliance guidance to hospitals, physicians and other healthcare providers in a variety of areas, including antitrust, healthcare reform, managed care contracting, reimbursement, fraud and abuse (Stark and Anti-Kickback), health information privacy and security and medical staff credentialing. Mr. Mattioli has extensive experience in consulting with healthcare clients and in litigating matters in health law and other highly regulated industries. He has litigated numerous cases involving healthcare entities in antitrust, False Claims Act, breach of privacy, and commercial disputes with other providers.

Mark also advises hospital, health care providers and health plan clients regarding health and information privacy and security under HITECH and HIPAA, governmental investigations, development of joint ventures, provider contracting issues and medical staff bylaw and disciplinary issues. Mark proactively counsels clients as they confront inquiries, audits and investigations from governmental agencies, including the Department of Justice, Office of Inspector General and the Department of Health and Human Services.

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Presenter Bio

Todd A. Zigrang, MBA, MHA, FACHE, ASA is the President of **HEALTH CAPITAL CONSULTANTS** (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 1,000 transactions and joint ventures involving acute care hospitals and health systems; physician practices; ambulatory surgery centers; diagnostic imaging centers; accountable care organizations, managed care organizations, and other third-party payors; dialysis centers; home health agencies; long-term care facilities; and, numerous other ancillary healthcare service businesses. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the co-author of "The *Adviser's Guide to Healthcare – 2nd Edition*" (AICPA, 2015), numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies*; *Business Appraisal Practice*; and, *NACVA QuickRead*. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

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The American Society of Appraisers is an international organization of appraisal professionals, founded in 1952 to provide a comprehensive, profession wide organization for appraisers and valuation engineers.

As a comprehensive body, the ASA pursues accurate valuation for all classes of property and hence examines multiple levels of economic activity. As such, the ASA seeks to foster cooperation between professionals of several valuation disciplines, and this spirit of cooperation may help engender multidisciplinary approaches to the art and science of valuation.

Mission of the Healthcare Special Interest Group (HSIG)

The *Healthcare Special Interest Group* (HSIG) is a Subcommittee of the ASA's International Education Committee and dedicated to the advancement of multidisciplinary education in healthcare valuation.

HSIG views the field of healthcare valuation as a complex area affecting multiple disciplines and requiring unique approaches for study and solutions. At the same time, the field also holds much promise for those willing to pursue new, multidisciplinary answers in this ever-changing healthcare market environment.

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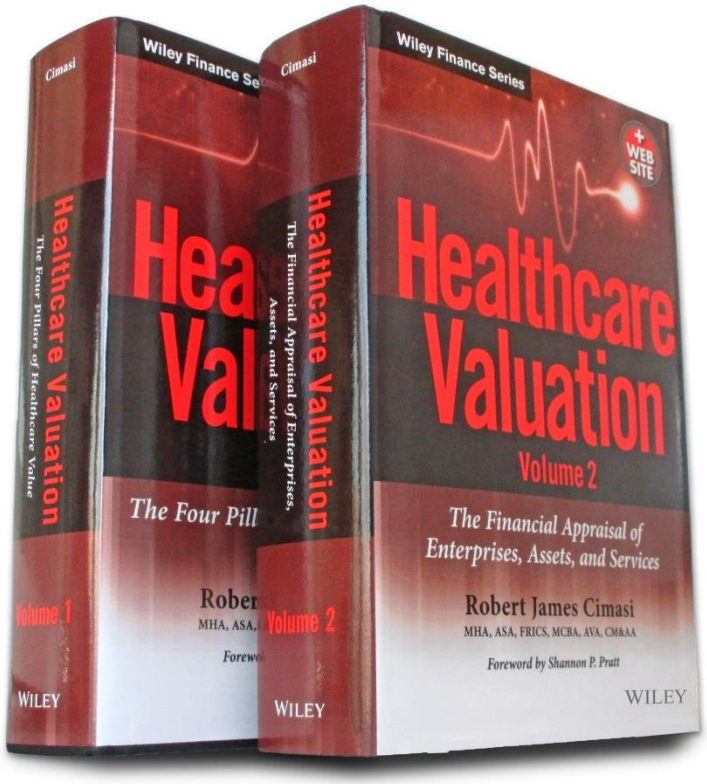
In-Person Course Session Textbook



The course session textbook page reference appears, for your reference, at the top left-hand corner of each slide.

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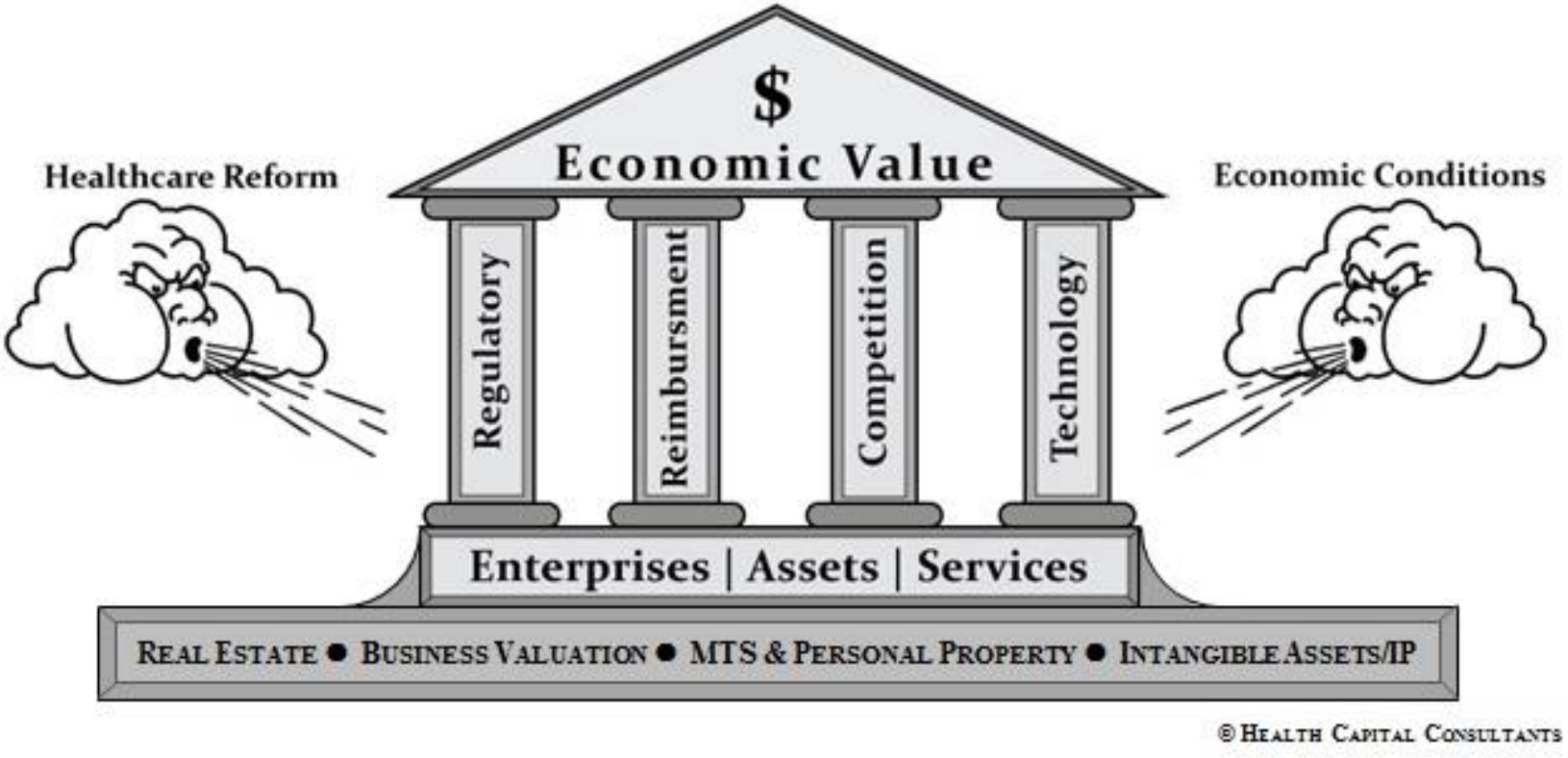
Overview of the Presentation

- Tax Regulations
- Fraud & Abuse Regulation & Enforcement
- Competition
- Privacy Laws
- Safety Regulations
- Licensure, Certification, & Accreditation
- Other Federal & State Regulations
- The Patient Protection & Affordable Care Act (ACA)
- Concluding Remarks

The Four Pillars



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Overview

- Historically, the medical profession was relatively free from government regulation
  - The profession had control over its organization; standards of practice; and the markets in which it operated
- More recently, the rise of the *"corporatization of medicine"* has led to *"[e]mployers and the government becom[ing] critical intermediaries in the system because of their financial role, and they are using their power to reorient the system"*

"The Adviser's Guide to Healthcare, 2nd Edition" By Robert J. Cimasi & Todd A. Zigrang, New York, New York: AICPA, 2015, p. 282; "The Social Transformation of American Medicine" By Paul Starr, New York, NY: Basic Books, Inc., 1982, p. 445.

Valuation Issues Arising from Regulatory Concerns

- Establishing the existence of certain tangible and intangible assets within a healthcare enterprise
- Whether (and under which circumstances) it is legally permissible for those assets to be acquired
- Selection of the applicable valuation methodologies, approaches, and techniques related to establishing the *Fair Market Value* of healthcare enterprises, assets, and services

Tax Regulations

501(c)(3) Tax Exempt Organizations

The 3-Legged Stool of Tax Exempt Organizations:

- *"Charitable purpose"* and community benefit
- Prohibition against excess benefit transactions and *"inurement of private benefit"*
- Charitable purpose and community benefit must be legally permissible

"Exemption Requirements" I.R.C. § 501(c)(3).

501(c)(3) Tax Exempt Organizations

- *"Charitable Organizations"* are Tax Exempt
  - Must be *"organized and operated exclusively for"* exempt purposes
  - No earnings to private shareholders or individuals
  - No excess benefit transactions or inurement of private benefit
- Affordable Care Act's (ACA) Additional Requirements
  - Community Health Needs Assessments (CHNA)
  - Financial Assistance Policy (FAP)

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"Exemption Requirements" I.R.C. § 501(c)(3); "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 9007, 124 Stat. 119, 856-57 (March 23, 2010) (to be codified at 42 U.S.C. § 501).

Prohibition Against Excess Benefit Transactions & "Inurement of Private Benefit"

- **Excess Benefit Transaction**: "…*transaction in which an economic benefit is provided by an applicable tax-exempt organization, directly or indirectly, to or for the use of any disqualified person, if the value of the economic benefit provided [by the organization] exceeds the value of the consideration received for providing such benefits"*
- Compensation arrangements involving tax exempt organizations may include financial incentives
- Can include assets or services
- If an organization is engaged in an excess benefit transaction, the IRS may impose intermediate excise taxes as punishment

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"Excess benefit transaction" 26 CFR 53.4958-4(a)(1) (2012).

Prohibition Against Excess Benefit Transactions & "Inurement of Private Benefit"

IRS factors to consider in ensuring the incentive arrangement is legally permissible:

- Whether the compensation arrangement was established by an independent board of directors or independent compensation committee
- Whether the state not for profit laws and fiduciary responses were considered
- Whether the incentive arrangement results in a total compensation arrangement that is reasonable
- Whether the exempt organiation and physician are at arm's length (e.g., the physician does not have a significant impact on the management or control of compensation)
- Whether there is a reasonable ceiling on the amount a physician may earn included in the arrangement

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"Excess benefit transaction" 26 CFR 53.4958-4(ii) (2012).

Prohibition Against Excess Benefit Transactions & "Inurement of Private Benefit"

IRS factors to consider in ensuring the incentive arrangement is legally permissible (continued):

- Whether the arrangement will reduce charitable services or benefits of the organization
- Whether the arrangement utilizes quality of care/patient satisfaction metrics
- If the compensation arrangement is tied to net revenues of a physician, whether the arrangement reflects the charitable purpose of the organization
- Whether the arrangement creates a joint venture between the organization and group of physicians

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"Excess benefit transaction" 26 CFR 53.4958-4(ii) (2012).

Prohibition Against Excess Benefit Transactions & "Inurement of Private Benefit"

IRS factors to consider in ensuring the incentive arrangement is legally permissible (continued):

- Whether the arrangement operates as a means to distribute profits to controlling members of the organization
- Whether the arrangement serves a business purpose of the organization
- Whether the arrangement would result in no abuse or unwarranted benefits, or includes devices to guard against such
- Whether the compensation incentive is tied to services a physician actually performs

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"Excess benefit transaction" 26 CFR 53.4958-4(ii) (2012).

Prohibition Against Excess Benefit Transactions & "Inurement of Private Benefit"

- **Inurement of Private Benefit**: When an exempt organization is "*…organized or operated for the benefit of private interests…*"
- **"Private Benefit" Test**: Ensures that any transaction between an exempt organization and a private person is conducted at arms-length and that any benefit to the private person is *insubstantial* when compared to the community benefit produced by the transaction

"Inurement/Private Benefit - Charitable Organizations" Internal Revenue Services, February 2, 2012, http://www.irs.gov/charities/charitable/article/0,,id=123297,00.html (Accessed 8/7/2012).
"Exemption from tax on corporations, certain trusts, etc." 26 U.S.C. § 501(c)(3).
"Exempt Healthcare Organizations: Meeting Commercial Reasonableness Thresholds" By Robert James Cimasi and Michael Meissner, Consultants' Training Institute, December 12, 2012, p. 22.

Bona Fide Employees vs. Form 1099 Independent Contractors

- IRS definition of "*employees*" versus "*1099 independent contractors*" is significant for fraud and abuse regulations governing healthcare providers
- 11 factor test, broken into 3 general categories:
  - *Behavioral control*
  - *Financial control*
  - *Type of relationship between the parties*
- Not necessary that all 11 factors be met, and no single factor is dispositive in determining employment status

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Employer's Supplemental Tax Guide (Supplement to Publication 15 (Circular E), Employer's Tax Guide" Publication 15-A, Department of the Treasury, Internal Revenue Service, 2012, p. 7.

IRS Determinations of Employee Status

Behavioral Control	
1	Instructions that the business gives to the worker
2	Training that the business gives to the worker
Financial Control	
1	The extent to which the worker has unreimbursed business expenses
2	The extent of the worker's investment
3	The extent to which the worker makes his or her services available to the relevant market
4	How the business pays the worker
5	The extent to which the worker can realize a profit or loss
Type of Relationship	
1	Written contracts describing the relationship the parties intended to create
2	Whether or not the business provides the worker with employee-type benefits, such as insurance, a pension plan, vacation pay, or sick pay
3	The permanency of the relationship
4	The extent to which services performed by the worker are a key aspect of the regular business of the company

"Employer's Supplemental Tax Guide (Supplement to Publication 15 (Circular E), Employer's Tax Guide" Publication 15-A, Department of the Treasury, Internal Revenue Service, 2012, p. 7.

Provider Taxes

- Funneled back to providers in increased Medicaid reimbursement rates
  - States can retain federally matched funds
- States may not tax providers more than 25%
- 49 States and Washington, D.C. have some type of provider tax (Alaska is only state not using provider taxes)

"Prohibition on use of voluntary contributions, and limitation on use of provider-specific taxes to obtain Federal financial participation under Medicaid" 42 U.S.C. 1396b(w)(2010); "Health Provider and Industry State Taxes and Fees" National Conference of State Legislatures, February 2016, http://www.ncsl.org/research/health/health-provider-and-industry-state-taxes-and-fees.aspx (Accessed 4/15/2016).

Ad Valorem Taxes

- *"According to the value"*
- Fixed or calculated proportion of the property's value *"as assessed or appraised on a regular basis"* by state and local authorities
- Also applicable to imported goods

"State and Local Taxation" 71 Am. Jur. 2d, § 18 (2010).

Excise, Sales, & Use Taxes

- Effective January 1, 2020 – 40% excise tax imposed on employees with **high-cost health coverage**
  - Employer-sponsored health insurance that provides employee an excess benefit above determined thresholds
  - Thresholds include:
    - For employees with self-only coverage, the product of $10,200 and the health cost adjustment percentage for such employees
    - For employees with any other type coverage, the product of $27,500 and the health cost adjustment percentage for such employees

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"Patient Protection and Affordable Care Act, Sec. 9001, 10901" Pub. Law 111-148, 124 Stat. 119 (March 23, 2010), p. 847-853, 862-866, 1015-1016, as amended by "Health Care and Education Reconciliation Act, Sec.1401" Pub. Law 111-152 (March 30, 2010), p. 1059-1060, 1064-1065; "Consolidated Appropriations Act, 2016" H.R. 2029, 114th Cong., Division P, Title I, § 101(a) (December 18, 2015).

Excise, Sales, & Use Taxes

ACA Excise Tax on Medical Devices

- Originally effective January 1, 2013; suspended from January 2016 through December 2017
- Device *manufacturer, producer, or importer* must pay a tax equivalent to 2.3% of medical device's sale price
- *"Retail Exemption"* for devices *"generally purchased by the general public,"* e.g., eyeglasses, contact lenses, and hearing aids
- Safe harbor provision for other certain categories of medical devices (e.g., some lab tests and some *"over the counter"* devices)

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"Patient Protection and Affordable Care Act, Sec. 9001, 10901" Pub. Law 111-148, 124 Stat. 119 (March 23, 2010), p. 862-866, 1015-1016, as amended by "Health Care and Education Reconciliation Act, Sec.1401" Pub. Law 111-152 (March 30, 2010), p. 1059-1060, 1064-1065; "Consolidated Appropriations Act, 2016" H.R. 2029, 114th Cong. Division Q, Title I, Subtitle C, Part 2, § 174 (January 6, 2015); "Medical Device Excise Tax: Frequently Asked Questions" Internal Revenue Service, February 3, 2014, http://www.irs.gov/uac/Medical-Device-Excise-Tax:-Frequently-Asked-Questions (Accessed 9/4/2014).

Fraud & Abuse
Regulation & Enforcement

The Anti-kickback Statute

- A felony for any person to *"knowingly and willfully"* solicit or receive, or to offer or pay, any *"remuneration"*, directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program
  - Affordable Care Act – *"With respect to violations of [the Anti-Kickback Statute] a person need not <u>have actual knowledge</u> of this section or specific intent to commit a violation of this section"* [emphasis added]
- Punishable by up to five years in prison and/or criminal fines up to $25,000

"Chapter 15: Covered Medical and Other Health Services," Medicare Benefit Policy Manual, Centers for Medicare and Medicaid Services, Department of Health and Human Services, Aug. 7, 2009, Section 30, 150-250, http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf (Accessed 9/21/09);
"Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b);
"Hanlester Network v. Shalala" 51 F.3d 1390 (9th Cir. 1995);
"Patient Protection and Affordable Care Act, Sec. 10606" Pub. Law 111-148, 124 Stat. 119 (March 23, 2010), p. 689.

One Purpose Test

- *U.S. v. Greber* – If *one purpose* of the arrangement with, or payment to, physicians is to induce a physician's use of services, then the Anti-Kickback Statute is violated, even if the arrangement or payment was also intended to compensate the physician for legitimate professional services
- *Advocate Health Care* - Hospitals not precluded from purchasing physician practices as long as payment for the practice and its assets is not in excess of *Fair Market Value*

"U.S. v. Greber," 760 F.2d 68 3d Cir. (1985), p. 2-3; "U.S. ex rel. Obert-Hong v. Advocate Health Care," 211 F. Supp. 2d 1045 (N.D. Ill. 2002); "The Hypocrisy of the One Purpose Test in Anti-Kickback Enforcement Law" By Eugene E. Elder, BNA Health Law Reporter, Vol. 4, no. 15 (July 26, 2000), p. 546.

Recent OIG Fraud Alerts

Indications from OIG on application of Anti-kickback Statute

Date	Title
2015	Physician Compensation Arrangements May Result in Significant Liability
2014	Laboratory Payments to Referring Physician
2013	Physician-Owned Entities
2010	Telemarketing by Durable Medical Equipment Suppliers (Updated)
2003	Telemarketing By Durable Medical Equipment Suppliers
2000	Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer
1999	Physician Liability for Certifications in the Provision of Medical Equipment & Supplies & Home Health Services
1998	Fraud and Abuse in Nursing Home Arrangement With Hospices
1996	Provision of Services in Nursing Facilities
1995	Home Health Fraud Medical Services to Nursing Homes
1994	Joint Venture Relationships Routine Waiver of Part B Co-payments/Deductibles Hospital Incentives to Referring Physicians Prescription Drug Marketing Practices Arrangements for the Provision of Clinical Lab Service

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"Special Fraud Alerts" Office of Inspector General, U.S. Department of Health & Human Services, http://oig.hhs.gov/compliance/alerts/index.asp (Accessed 9/4/2014).

Anti-Kickback Safe Harbors

- HHS has authority to create a list of payment and business practices that are guaranteed to not be considered as kickbacks, bribes, or rebates under Medicare and Medicaid
- Shields arrangements from regulatory liability and protects transactional arrangements unlikely to result in fraud or abuse
  - Intended to *"permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy"*

"Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions" Department of Health and Human Services, Fed. Register, Vol. 54, (Jan. 23, 1989); "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64, No. 223 (November 19, 1999), p. 63518; "OIG Advisory Opinion No. 07-10" Department of Health and Human Services, Washington, D.C., September 20, 2007, p. 1, 2; "OIG Advisory Opinion No. 08-14" Department of Health and Human Services, Washington D.C., October 2, 2008, p. 5; "OIG Advisory Opinion No. 09-05" Department of Health and Human Services, Washington, D.C., May 21, 2009, p. 9; "OIG Advisory Opinion No. 09-07" Department of Health and Human Services, Washington, D.C., June 30, 2009, p. 6; "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions" Department of Health and Human Services, Fed. Register, Vol. 54, (Jan. 23, 1989).

List of Safe Harbors

- Returns on investment interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of a Practice
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing Organizations (GPO)
- Waiver of Beneficiary Coinsurance and Deductible Amount
- Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
- Price Reductions Offered to Health Plans

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42 C.F.R. Section 1001.952(a)-(y).

List of Safe Harbors, continued

- Practitioner Recruitment
- Obstetrical Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Services Organizations (CHSO)
- Referral Arrangements for Specialty Services
- Price Reductions Offered to Eligible Managed Care Organizations
- Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations
- Ambulance Replenishing
- Health Centers
- Electronic Prescribing Items and Services
- Electronic Health Record Items and Services
- Ambulatory Surgery Centers (ASC)

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42 C.F.R. Section 1001.952(a)-(y).

Continuation of Anti-Kickback Statute

- Advisory Opinion Process
  - Submit a written request containing certain specified information:
    - Technical requirements pursuant to 42 CFR 1008
    - Describing the Issues and the Arrangement
    - Signed certification
  - An original and two copies of the request need to be sent via US mail, overnight courier or hand delivered to the Chief of the Industry Guidance Branch

"Advisory Opinions FAQ." Office of Inspector General, http://oig.hhs.gov/faqs/advisory-opinions-faq.asp (Accessed 9/10/15).

Intersection Between Valuation Opinions & Legal Opinions

- *Legal opinions* seek written opinions on a deal, but the lawyers will not opine on the valuation (e.g., whether price exceeds *Fair Market Value*)
- *Valuation opinions* analyze the value of the subject enterprise, asset, or service
  - *Valuation opinions* do *not* give any legal advice

Stark Law

- Federal prohibition against physician self-referral
- Prohibits physicians from referring Medicare or Medicaid patients to an entity for *Designated Health Services* (DHS) if the physician, or an immediate family member, has a *financial relationship* with that entity

"Health Care Fraud and Abuse: Practical Perspectives" Edited by Linda A. Baumann, Washington, DC: American Bar Association, 2002, p. 52; "Limitation on certain physician referrals," 42 U.S.C. 1395nn(a), (2012).; 42 C.F.R. 411.353 (2008).

Designated Health Services

List of Designated Health Services
Clinical laboratory services
Physical therapy, occupational therapy, and speech-language pathology services
Radiology and certain other imaging services, including: • Magnetic resonance imaging • Computerized axial tomography scans • Ultrasound services
Radiation therapy services and supplies
Durable medical equipment and supplies
Parenteral and enteral nutrients, equipment, and supplies
Prosthetics, orthotics, and prosthetic devices and supplies
Home health services
Outpatient prescription drugs
Inpatient and outpatient hospital services

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"Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(h)(6).

Differences between Stark and Anti-Kickback Statute

- Stark addresses *financial incentives* related to *referral*; Anti-kickback Statute addresses the *financial relationship* between providers
- Stark applies only to *Medicare* and *Medicaid*; Anti-kickback Statute applies to *all* federally-funded state healthcare programs
- Penalties are different – No criminal penalties under Stark

Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b); 42 U.S.C. 1395nn, Social Security Act Sec. 1877, "Limitations on Certain Physician Referrals", http://www.cms.hhs.gov/PhysicianSelfReferral/Downloads/section_1877.pdf (Accessed 10/21/09); "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b); "Limitations on certain physician referrals," 42 U.S.C. 1395nn(a), (2012).

Differences Between Stark and Anti-Kickback Statute

Anti-Kickback

- Intent-based
- Criminal liability
- Broader application- implicates more relationships
- Safe-Harbors- "Should"

Stark

- Strict liability
- Civil liability
- Applies only to financial relationships with "physicians" or immediate family members
- Exceptions- "Must"

Differences between Anti-kickback Statute and Stark

	Anti-kickback Statute	Stark Law
Referrals	From anyone	From a physician
Items/Services	Any items/services	Designated health services
Intent	Willful action, but no actual knowledge of violation required	No intent required Intent required for civil monetary penalties for knowing violations
Penalties	Criminal and civil penalties	Civil penalties only
Exceptions	Voluntary safe harbors	Mandatory exceptions
Federal Health Care Programs	All	Medicare/Medicaid

"Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), http://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf (Accessed 10/7/13).

Stark Law Exceptions

- Any financial relationship between a healthcare entity and a physician providing DHS must fall within an exception to be legally permissible
- Promotes practice integration and protects arrangements where there is little risk of abuse
- 37 exceptions to Stark that fall under 3 categories:
  - Exceptions that apply to both ownership/investment interests and compensation arrangements
  - Exceptions that apply only to ownership/investment interests
  - Exceptions that apply only to compensation arrangements

"Health Care Fraud and Abuse: Practical Perspectives" Edited by Linda A. Baumann, Washington, DC: American Bar Association, 2002, p. 106; 42 C.F.R. 411.355-411.357; "Limitations on certain physician referrals," 42 U.S.C. 1395nn(a)-(e), (2012); "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule" Federal Register, Vol. 80, No. 220 (November 16, 2015).

Stark Law Exceptions

- Group Practice Arrangements with a Hospital Exception
- Payments by a Physician Exception
- Fair Market Value Compensation Exception
- Remuneration Provided by a Hospital to a Physician Exception
- Physician Services Exception
- Prepaid Plans Exception
- Physician Incentive Plan Exception
- Risk-sharing arrangements
- Compliance Training
- Obstetrical malpractice insurance subsidies
- Ownership/Investment Interests in:
  - Publicly-Traded Securities Exception
  - Rural Area Exception
  - "Whole" Hospital Exceptions
  - Hospitals Located in Puerto Rico Exception
- Rental of Office Space Exception
- Rental of Equipment Exception
- Bona Fide Employment Exceptions
- Isolated Transactions Exception
- Electronic Prescribing Items and Services Exception
- Electronic Health Records Items and Services Exception

"Limitations on certain physician referrals," 42 U.S.C. 1395nn(a)-(e), (2012); "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule" Federal Register, Vol. 80, No. 220 (November 16, 2015).

Stark Law Exceptions

- Personal Service Arrangement Exception
- Medical Staff Incidental Benefits Exception
- Indirect Compensation Arrangements Exception
- In-office Ancillary Services Exception
- Services Furnished by an Organization to Enrollees Exception
- Services Provided by Academic Medical Centers Exception
- Nonmonetary Compensation Exception
- Retention Payments in Underserved Areas Exception
- Compensation of Nonphysician Practitioner
- Implants Furnished by an ASC Exception
- EPO and other dialysis drugs in ESRD
- Preventative screening services, immunizations, vaccines
- Eyeglasses and lens following cataract surgery
- Specialty Hospital Exceptions
- Intra-Family Members in Rural Areas Exception
- Physician Recruitment Exception
- Charitable Donations by a Physician Exception
- Community-Wide Health Information Systems Exception
- Timeshare Arrangements

"Limitations on certain physician referrals," 42 U.S.C. 1395nn(a)-(e), (2012); "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule" Federal Register, Vol. 80, No. 220 (November 16, 2015).

Provider Self-Referral Disclosures under Stark

- ACA required CMS to create Self-Referral Disclosure Protocol (SRDP)
- Financial incentives to providers to self-disclose *actual* or *potential* Stark violations
- CMS settled 69 violations of the physician self-referral statute from 2011-2015
- OIG established a distinct Self-Disclosure Protocol for violations of AKS in 1998, and revised the Self-Disclosure Protocol in April of 2013
- CMS finalizes changes associated with PFS Payments including the Physician Quality Reporting System, the Physician Value-Based Payment Modifier, and the Medicare Electronic Health Record Incentive Program starting in 2016

"Self-Referral Disclosure Protocol," Centers for Medicare & Medicaid Services, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html (Accessed 10/7/13); "Self-Referral Disclosure Protocol Settlements" Centers for Medicare & Medicaid Services, https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/self-referral-disclosure-protocol-settlements.html (Accessed 4/15/2016); "Self-Disclosure Information," Office of Inspector General, U.S. Department of Health and Human Services, http://oig.hhs.gov/compliance/self-disclosure-info/index.asp (Accessed 10/7/13); "Updated OIG's Provider Self-Disclosure Protocol" Office fo Inspector General, U.S. Department of Health and Human Services, https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf (Accessed 9/4/2014); "Proposed policy, payment, and quality provisions changes to the Medicare Physician Fee Schedule for Calendar Year 2016," Centers for Medicare & Medicaid Services, July 8, 2015, https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2015-fact-sheets-items/2015-07-08.html (Accessed 9/10/15).

False Claims Act (FCA)

- When one *"knowingly presents, or causes to be presented, to an officer or employee of the United States government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval, e.g.,* ***upcoding****"*
- Civil penalties for false claims violations
- Whistleblower Provision (Qui Tam)
- State FCA statutes – Can expand/alter provisions of federal law (state claims reviewed by OIG)

"False Claims Act" 31 U.S.C. 3729(a) (2006). "State False Claims Act Reviews," Office of Inspector General, U.S. Department of Health and Human Services, http://oig.hhs.gov/fraud/falseclaimsact.asp (Accessed 08/03/12); "State False Claims Act Requirements for Increased State Share of Recoveries," Social Security Act § 1909.

Recent Trends and Cases

- 2014 – over $5.7 billion in recoveries under the FCA
- FY 2015 – over $1.9 billion in settlements and judgments for FCA violations brought by the government and *qui tam* relators
  - Several settlements alone have approached $500 million

"2015 Mid-Year False Claims Act Update," By Robert C. Blume et al., Gibson Dunn, July 8, 2015, http://www.gibsondunn.com/publications/pages/2015-Mid-Year-False-Claims-Act-Update.aspx (Accessed 9/8/15); "Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2015" Department of Justice & Department of Health and Human Services, February 2016, http://oig.hhs.gov/publications/docs/hcfac/FY2015-hcfac.pdf (Accessed 4/15/2016).

Fraud Enforcement Recovery Act (FERA)

- Signed in May 2009
- No specific intent needed to defraud
- Government need only show a person acted *"knowingly"* by:
  - Having actual knowledge of the information
  - Acting in *deliberate ignorance* of the truth or falsity of the information
  - Acting in *reckless disregard* of the truth or falsity of the information

"Fraud Enforcement and Recovery Act, Sec. 4" Pub. Law 111-21, 123 Stat. 1617 (May 20, 2009), p. 1623-1624.

Health Care Fraud Prevention & Enforcement Action Team (HEAT)

- Mission
  - Gather resources across government to help prevent waste, fraud & abuse in Medicare & Medicaid
  - Reduce skyrocketing health care costs & improve quality of care
  - Highlight best practices by providers & public sector employees who are dedicated to ending waste, fraud & abuse in Medicare
  - Build upon existing partnerships between DOJ & HHS to reduce fraud & recover taxpayer dollars
- HEAT helped recover $2.4 billion in taxpayer dollars in 2015
  - With a total return of more than $29 billion to the Medicare Trust Funds since its inception

"Heat Task Force Official Website," stopmedicarefraud.gov (Accessed 9/23/10). "Sebelius: New Fraud Prevention Team Will Turn Up Heat," By Ben Amirault, Health Leaders Media, May 21, 2009, http://www.healthleadersmedia.com/content/233446/topic/WS_HLM2_FIN/Sebelius-New-Fraud-Prevention-Team-will-Turn-up-Heat.html (Accessed 5/21/09); "Departments of Justice and Health and Human Services announce record-breaking recoveries resulting from joint efforts to combat health care fraud" U.S. Department of Health & Human Services, February 26, 2014, http://www.hhs.gov/news/press/2014pres/02/20140226a.html (Accessed 4/21/14); "Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2015" Department of Justice & Department of Health and Human Services, February 2016, http://oig.hhs.gov/publications/docs/hcfac/FY2015-hcfac.pdf (Accessed 4/15/2016).

Medicare Fraud Strike Force

- A multi-agency team of investigators at all governmental levels
- Part of HEAT
- Established in May 2009
- Nine locations
- Designed to combat Medicare fraud through using Medicare data analysis techniques and focusing on community policing

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"Medicare Fraud Strike Force Charges 89 Individuals for Approximately $223 Million in False Billing" Department of Justice Office of Public Affairs, May 14, 2013, http://www.justice.gov/opa/pr/2013/May/13-crm-553.html (Accessed 10/7/13); "Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2015" Department of Justice & Department of Health and Human Services, February 2016, http://oig.hhs.gov/publications/docs/hcfac/FY2015-hcfac.pdf (Accessed 4/15/2016); "Heat Task Force" https://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/index.html (Accessed 4/15/2016).

Dodd-Frank Act

- Creates new protections and incentives for whistleblowers in any type of financial fraud, including false claims
  - "Bounty" provision
- Expands the Sarbanes-Oxley Act (SOX)

"Dodd-Frank: Picking Up Where SOX Fell Short" By Lynne Ann Anderson and Meredith R. Murphy, New Jersey Labor and Employment Law, Posted on DrinkerBiddle.com, Spring 2012, http://www.drinkerbiddle.com/Templates/media/files/Outside%20Publications/2012/picking-up-where-sox-fell-short.pdf (Accessed 8/7/12), p. 19.

Fair Market Value (FMV) Defined

- **FMV** – The value in arm's-length transactions, consistent with the *General Market Value*
- **General Market Value** – *"…the price that an asset would bring as a result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party…"*

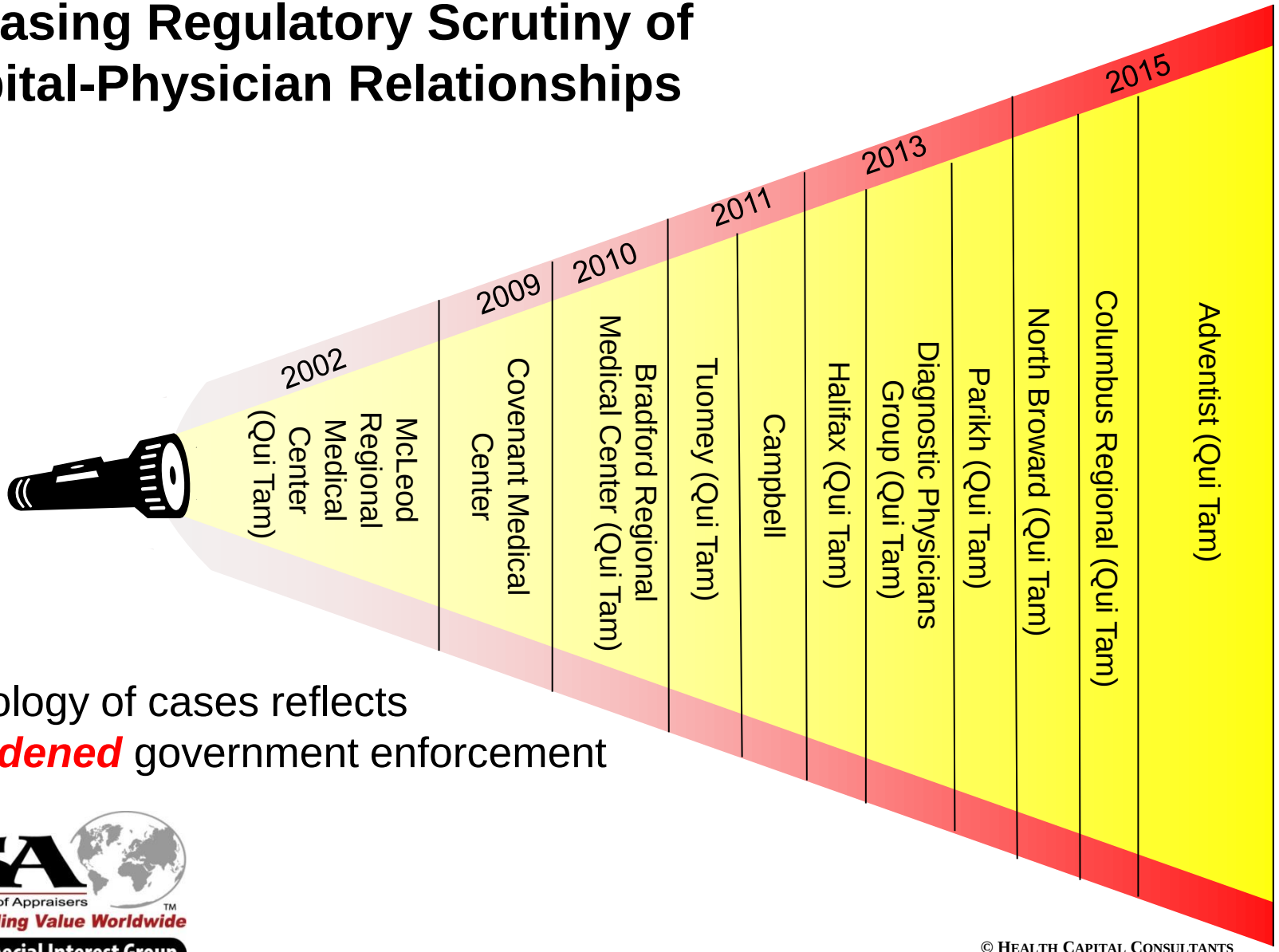
"Program Integrity; Medicare and State Health Care Programs; Permissive Exclusions," 42 CFR 1001.952(b)(5), (2009), p. 735; "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III): Final Rule" Federal Register Vol. 72, No. 171 (September 5, 2007), p. 51081; The Stark Law (as stated in the U.S. code) also equates the terms Fair Market Value and General Market Value, to wit: "The term 'fair market value' means the value in arm's length transactions, consistent with the general market value." From "Limitation on Certain Physician Referrals" 42 U.S. 1395nn (April 4, 2012).

Fair Market Value (FMV) Defined

- **U.S. ex rel. Obert-Hong v. Advocate Health Care** footnote - FMV may differ from traditional economic valuation formulae, which take into account referrals
  - Because Anti-kickback Statute prohibits any inducement for referrals, they must be excluded from any calculation of fair value
- **American Lithotripsy Society v. Thompson** - Proving that an arrangement is FMV is imperative in complying with Stark's requirements
  - *"Payment exceeding fair market value is in effect deemed payment for referrals"*
- In court, FMV determination may be based on a *"battle of the experts"*

"U.S. ex rel. Obert-Hong v. Advocate Health Care," 211 F.Supp.2d 1045, 1049 (N.D. Ill. 2002); "Am. Lithotripsy Soc'y v. Thompson," 215 F.Supp.2d 23, 27 (D.D.C. 2002).

Increasing Regulatory Scrutiny of Hospital-Physician Relationships



Chronology of cases reflects ***emboldened*** government enforcement

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Relevant Fraud & Abuse Case Law

U.S. ex rel. Richard Raugh v. McLeod Regional Medical Center

- *"[t]he claims for services referred, ordered or arranged by those physicians were alleged to be false in three respects:*
  - *First, Section 1877 of the Social Security Act, 42 USC 139nn (also known as Stark II), prohibited McLeod from billing Medicare for items or services referred or ordered by physicians with whom it had such financial relationships.*
  - *Second, McLeod forfeited its right to submit those claims to the federal health care programs by paying remuneration intended to induce those and other referrals in violation of the Anti-Kickback Statute, 42 USC 1320a-7(b).*
  - *And third, McLeod certified falsely on Medicare cost reports that the services identified or summarized were not provided or procured through payment directly or indirectly of a kickback or billed in violation of federal law*."

"McLeod Regional Medical Center to Pay U.S. Over $15 Million to Resolve False Claims Act Allegations," U.S. Dept. of Justice, Press Release, November 1, 2002, Accessed at http://www.justice.gov/opa/pr/2002/November/02_civ_634.htm (Accessed 10/3/2012).

Relevant Fraud & Abuse Case Law

U.S. v. Covenant Medical Center

- Five of Covenant's physicians were reportedly among the highest-paid physicians in the entire U.S., making as much as $2.1 million, despite Covenant's tax exempt status
  - Amounts significantly exceeded the 75th percentile for physician compensation in respective specialties
- Significant discrepancies between the compensation paid to the five Covenant physicians, as compared to the compensation paid to physicians in the region and around the country

"Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations" Press Release, United States Department of Justice, August 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 9/11/09); "Covenant to pay feds $4.5M to settle fraud allegations" Waterloo Cedar Falls Courier, August 25, 2009, http://www.wcfcourier.com/articles/2009/08/25/news/breaking_news/doc4a94156271f78380125347.txt (Accessed 9/11/09).

Relevant Fraud & Abuse Case Law

U.S. v. Bradford Regional Medical Center

- Two physicians and the Medical Center had a direct financial relationship through non-compete clause of a sublease agreement for a nuclear camera
- Court used a FMV analysis to determine legal impermissibility of the sublease arrangement, applying Stark's definition of FMV and *"value or volume"* standard
- Significant exchange was the non-compete payments that required the physicians to not engage in the nuclear camera business

"Executive Summary of Report of Charles T. Day, CPA" Case 1:04-cv-00186-MBC, September 10, 2008, p. 17.

Relevant Fraud & Abuse Case Law

U.S. v. Bradford Regional Medical Center

- Court remarked:
  - *"A 'fair market value' to the doctors to get out of the nuclear camera business was roughly the amount of money they would make by staying in the business and referring their patients to their own camera"*
  - *"to the hospital, 'fair market value' … was roughly the amount of money they would expect to gain from the doctors no longer referring their patients to their own camera"*
  - *"While the value agreed upon by parties who are in a position to refer business to each other and who take into account anticipated referrals will be a fair value **as between the parties**, such an arrangement is not 'fair market value' under the Stark Act"*

"Executive Summary of Report of Charles T. Day, CPA" Case 1:04-cv-00186-MBC, September 10, 2008, p. 48-50.

Relevant Fraud & Abuse Case Law

U.S. ex rel. Drakeford v. Tuomey

- Hospital paid 19 part-time physicians an amount beyond FMV by taking into account the *volume* or *value* of referrals
  - 10-year contract for part-time employment
  - Productivity bonus
  - Incentive bonus
- Physician productivity fell between the 50th and 75th percentile, but compensation was over the 90th percentile
- Provides insight into what constitutes reasonable wRVU compensation
  - Government – Compensation per wRVU should not exceed the 75th MGMA percentile without substantial justification

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Tuomey Healthcare Sys., Inc., No. 10-1819, 2012 U.S. Ct. App. WL 1059849, at *6.

Relevant Fraud & Abuse Case Law

U.S. v. Campbell

- Recruitment initiative
  - Included *"entering into part-time employment contracts with local community cardiologists in private practices, who had patients they could refer to University Hospital for cardiac-related procedures."*
- Providers incur potential *Stark* liability *as individuals* by referring patients to healthcare entities with whom they have a financial relationship if fixed compensation amount can be seen as an *remuneration* for patient referrals in the absence of services performed by the physician as called for in the employment agreement

"U.S. v. Campbell," 2011 U.S. Dist. LEXIS 1207 p. 4.

Relevant Fraud & Abuse Case Law

U.S. ex rel. Baklid-Kunz v. Halifax

- Kickbacks paid to providers through incentives and pooled compensation
  - Physicians compensated two to four times their respective annual base salary
  - Incentives equivalent to 15% of the hospital's oncology program's operating margin
- Neurosurgeons paid over $2 million annually (greater than 100% of the 90th percentile of neurosurgeon compensation) and annual bonuses over $1 million
- **March 10, 2014** - Halifax settled with the U.S. government for $85 million

"United States Government Intervenes in Health Care Fraud Suit Against Halifax Hospital After Two Years of Investigating Fraud and Stark Allegations," September 19, 2011.
"DOJ asks Halifax Health to pay up to $600 million in whistleblower case" The Pathology Blawg, June 6, 2013, http://pathologyblawg.com/medical-news/doj-asks-halifax-health-pay-up-600-million-whistleblower-case/ (Accessed 10/3/2013).
"Damages in whistle-blower Medicare fraud case against Halifax Hospital could hit $1B" By Marni Jameson, Orlando Sentinel, July 5, 2013, http://articles.orlandosentinel.com/2013-07-05/health/os-whistleblower-medicare-fraud-halifax-20130705_1_elin-baklid-kunz-damages-marlan-wilbanks (Accessed 10/3/2013).

Relevant Fraud & Abuse Case Law

U.S. ex rel. Heesch v. Diagnostic Physicians Group

- The Clinic's compensation to the physician group allegedly included a percentage of the money collected from Medicare for tests and procedures the providers referred to the Clinic
- Government alleged that physicians *"received a financial benefit from ordering tests at [the Clinic] that they did not receive from referring tests to other clinics and hospitals"*
  - Physicians were *"compensated for order tests outside their specialties"*

"The United States' Complaint in Intervention" in "U.S. ex rel. Heesch v. Diagnostic Physicians Group" Civil Action No. 11-0364-KD-B, S.D. Ala., (Aug. 8, 2013), p. 29. "US Joins False Claims Act Lawsuit Alleging Illegal Physician Compensation by Mobile, Ala. Health Firm" US. Department of Justice Office of Public Affairs, http://www.justice.gov/opa/pr/2013/July/13-civ-768.html, July 8, 2013, (Accessed 10/7/13).

Relevant Fraud & Abuse Case Law

U.S. ex rel. Parikh v. Citizens Medical Center

Court Order – Motion to Dismiss

- Citizen's Medical Center allegedly paid bonuses and financial incentives to physicians who referred patients for treatment
  - Physicians' income more than doubled when they became employed by Citizen's Medical Center
  - Citizen's Medical Center allegedly lost money on the physicians' practices

"United States ex rel. Parikh v. Citizens Medical Center, et al., Memorandum and Order," Civil Action No. 6:10-CV-64 (S.D.T.X. September 20, 2013), p. 1, 28.

Relevant Fraud & Abuse Case Law

U.S. ex rel. Parikh v. Citizens Medical Center

Court Order – Motion to Dismiss

- *"if true, [the allegations] provide a strong inference of the existence of a kickback scheme"*
- *"Even if the cardiologists were making less than the national median salary for their profession, the allegations that they began making substantially more money once they were employed by Citizens is sufficient to allow an inference that they were receiving improper remuneration"*
- *"This inference is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive – a motive Relators identify as a desire to induce referrals"*

"United States ex rel. Parikh v. Citizens Medical Center, et al., Memorandum and Order," Civil Action No. 6:10-CV-64 (S.D.T.X. September 20, 2013), p. 1, 28.

Relevant Fraud and Abuse Case Law

U.S. ex rel. Barker v. Columbus Regional Health System

- Two lawsuits filed by the same relator; together, both lawsuits allege Columbus Regional allowed its physicians to **upcode** for evaluation and management (E&M) services, compensation *in excess of FMV*, and medical directorship arrangements that were not *commercially reasonable*
- Columbus Regional alleged to have given medical directorships to four oncologists in one physician practice, when only ten of the physicians in that practice saw patients
- Columbus Regional alleged to have paid one oncologist, Dr. Andrew Pippas, in excess of a 2:1 compensation to collections ratio
  - Base pay for Dr. Pippas determined by number of work RVUs performed

"United States ex rel. Barker v. Columbus Regional Healthcare System et al.," Case No. 4-14-cv-304 (M.D.Ga. December 29, 2014), Relator's Complaint, p. 12, 14, 27; "United States ex rel. Barker v. Columbus Regional Healthcare System et al.," Case No. 4-12-cv-108 (M.D. Ga., May 10, 2013), Relator's Amended Complaint, p. 11.

Relevant Fraud and Abuse Case Law

U.S. ex rel. Barker v. Columbus Regional Health System

- Complaint discusses reports provided by outside consultants regarding whether compensation paid to Dr. Pippas fit within FMV
  - Reports issued in 2008, 2009, and 2013
  - None of the reports analyze the commercially reasonableness of the compensation paid to Dr. Pippas, nor the commercial reasonableness of his medical directorship
- Parties settled the case in September 2015 for $25 million, with the possibility of further payments up to $10 million

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"United States ex rel. Barker v. Columbus Regional Healthcare System et al.," Case No. 4-14-cv-304 (M.D.Ga. December 29, 2014), Relator's Complaint, p. 15-17, 23-24; "Georgia Hospital System and Physician to Pay More than $25 Million to Settle Alleged False Claims Act and Stark Law Violations" U.S. Department of Justice, September 4, 2015, http://www.justice.gov/opa/pr/georgia-hospital-system-and-physician-pay-more-25-million-settle-alleged-false-claims-act-and (Accessed 9/16/15).

Relevant Fraud and Abuse Case Law

US ex rel. Payne v. Adventist Health System, and US ex rel. North Broward Hospital

- Doctors paid above 90th MGMA percentile despite performance below 50th Percentile
- Payment based upon complicated formula that took into account value of DHS referrals
- Payment must be limited to FMV of work performed by Physician
- Hospitals lost up to $200 million on group
- Government Recovered $115 Million & $69.5 Million

"United States ex rel. Reilly v. North Broward Hospital District, et al.," Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 8, 29-31; "Florida Hospital District Agrees to Pay United States $69.5 Million to Settle False Claims Act Allegations" U.S. Department of Justice, September 15, 2015, http://www.justice.gov/usaosdfl/pr/floridahospitaldistrictagreespayunitedstates695millionsettlefalseclaimsact (Accessed 9/16/15); "United States ex rel. Payne et al. v. Adventist Health System et al.," Case No. 3:12cv856-W (W.D.N.C. February 13, 2013), Relator's Amended Complaint, p. 60, 68; "Adventist Health System Agrees to Pay $115 Million to Settle False Claims Act Allegations" U.S. Department of Justice, September 21, 2015, http://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations (Accessed 9/22/15).

Relevant Fraud and Abuse Case Law

U.S. ex rel. Reilly v. North Broward Hospital District

Relator's Third Amended Complaint

- Complaint alleges North Broward employed physicians at a loss, which losses were offset by inpatient and ancillary fees generated by referrals
- Complaint alleges North Broward compensated employed physicians:
  - *"(1) at levels which exceeded the fair market value of their personal services,*
  - *(2) at levels which were not commercially reasonable if the physicians were not in a position to generate referral business for Broward Health, and*
  - *(3) at levels which were determined and paid based in part on the volume and value of inpatient and outpatient referrals by such physicians to Broward Health hospitals and clinics*." [emphasis added]

"United States ex rel. Reilly v. North Broward Hospital District, et al.," Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 8.

Relevant Fraud and Abuse Case Law

U.S. ex rel. Reilly v. North Broward Hospital District

- North Broward allegedly tracked the volume and value of referrals by employed physicians in "*Contributive Margin Reports*"
- The complaint alleges that these reports track "*the revenue from every admission, every ancillary, anything that's done to patients of employed physicians*."
- The complaint alleges that employing physicians at a loss "*is only sustainable by anticipating and allocating hospital referral profits to cover the massive direct losses from excessive physician compensation*."
- North Broward settled the case for $69.5 million in September 2015

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"United States ex rel. Reilly v. North Broward Hospital District, et al.," Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 8, 29-31; "Florida Hospital District Agrees to Pay United States $69.5 Million to Settle False Claims Act Allegations" U.S. Department of Justice, September 15, 2015, http://www.justice.gov/usaosdfl/pr/floridahospitaldistrictagreespayunitedstates695millionsettlefalseclaimsact (Accessed 9/16/15).

Relevant Fraud and Abuse Case Law

U.S. ex rel. Payne et al. v. Adventist Health System et al.

- Complaint alleges Adventist hospitals employed physicians at a loss, knowing that referrals from employed physicians would offset those losses
  - "Compensating the doctors whose practices they have purchased at levels that not only exceed what (Adventist) can rationally pay while maintaining a physician practice that could be economically viable on its own merits, but that even more dramatically exceed what (Adventist's) employee physicians could reasonably expect to earn if those physicians had continued to own and operate the business themselves." [Complaint, p. 56]
- Complaint alleges Adventist could bear the losses only because Adventist hospitals tracked physician referrals
- Relator is former risk manager of Park Ridge Health, an Adventist-affiliated hospital in Hendersonville, NC

"United States ex rel. Payne et al. v. Adventist Health System et al.," Case No. 3:12cv856-W (W.D.N.C. February 13, 2013), Relator's Amended Complaint, p. 56-57.

Relevant Fraud and Abuse Case Law

U.S. ex rel. Payne et al. v. Adventist Health System et al.

Relator's Amended Complaint

- Park Ridge Agreement with Southeastern Sports Medicine (SESM)
  - Professional Services Agreement with Park Ridge, wherein SESM physicians would exclusively practice at Park Ridge locations in return for payment per RVU
  - Park Ridge lost $2.9 million in 2011 under this agreement with SESM
  - Park Ridge gained $3.6 million from inpatient and ancillary referrals from SESM from January-September 2011
- Lawsuit settled in September 2015 for $115 million

"United States ex rel. Payne et al. v. Adventist Health System et al.," Case No. 3:12cv856-W (W.D.N.C. February 13, 2013), Relator's Amended Complaint, p. 60, 68; "Adventist Health System Agrees to Pay $115 Million to Settle False Claims Act Allegations" U.S. Department of Justice, September 21, 2015, http://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations (Accessed 9/22/15).

FMV & Commercial Reasonableness

- An arrangement must simultaneously be at *Fair Market Value* and be *Commercially Reasonable* to be deemed legally permissible
  - **Fair Market Value** - Looks to the reasonableness of the range of dollars paid for a product or service
  - **Commercial Reasonableness** - Looks to the reasonableness of the business arrangement generally

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"Tread Carefully When Setting Fair Market Value: Stark Law Must Be Considered" Joyce Frieden, November 1, 2003, http://findarticles.com/p/articles/mi_m0CYD/is_/ai_110804605 (Accessed 9/26/08).

Determining Commercial Reasonableness

- Some questions to consider:
  - Is it necessary to have a physician perform that service?
  - Is it necessary to have a physician of that specialty perform that service?
- Both the level of services and the consideration paid must be *Commercially Reasonable* for the arrangement to survive regulatory scrutiny

"Exempt Healthcare Organizations: Meeting Commercial Reasonableness Thresholds" By Robert James Cimasi and Michael Meissner, Consultants' Training Institute, December 12, 2012, p. 22.

Definitions of Commercial Reasonableness

HHS

- Arrangement appears to be *"…a sensible prudent business arrangement, from the perspective of the particular parties involved, even in the absence of any potential referrals"*

Stark II, Phase II

- *"An arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential for DHS referrals"*

"Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships," Centers for Medicare and Medicaid Services, Federal Register, Vol. 63, Nol. 6, (January 9, 1998), p. 1700; "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule," Centers for Medicare and Medicaid Services, Federal Register, Vol. 69, No. 59, (March 26, 2004), p. 16093.

Definitions of Commercial Reasonableness

IRS

- Factors considered when determining the *commercial reasonableness* of a physician compensation arrangement:
  - Specialized training and experience of the physician
  - The nature of duties performed and the amount of responsibility
  - Time spent performing duties
  - Size of the organization
  - National and local economic conditions

"Business Expenses," Department of the Treasury, Internal Revenue Service, Publication 525 (2014), p. 7.

Definitions of Commercial Reasonableness

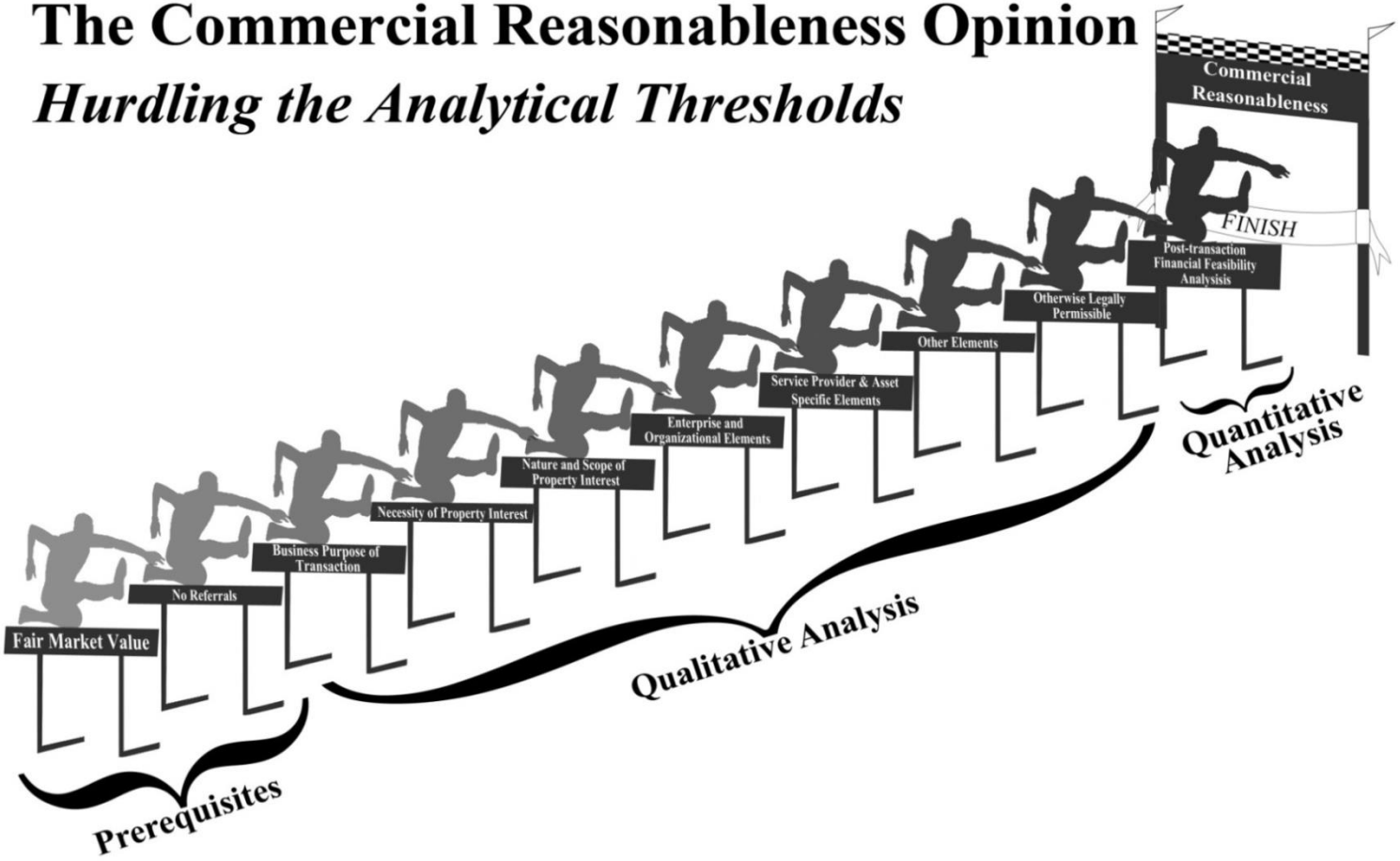
IRS

- Factors considered when determining the *commercial reasonableness* of a physician compensation arrangement:
  - Salary ranges for equivalent physicians in comparable organizations
  - History of pay for the employee
  - Availability of similar services in the geographic area

"Business Expenses," Department of the Treasury, Internal Revenue Service, Publication 525 (2014), p. 7.

The Commercial Reasonableness Opinion

Hurdling the Analytical Thresholds



Commercial Reasonableness

Transaction Prerequisites

- Does the consideration paid for any aspect of the transaction fall within range of the *FMV* (or fall substantially below FMV)?
- Is the transaction a sensible, prudent business agreement even in the absence of any potential referrals?
  - Compensation must not be based on the *"volume or value"* of referrals

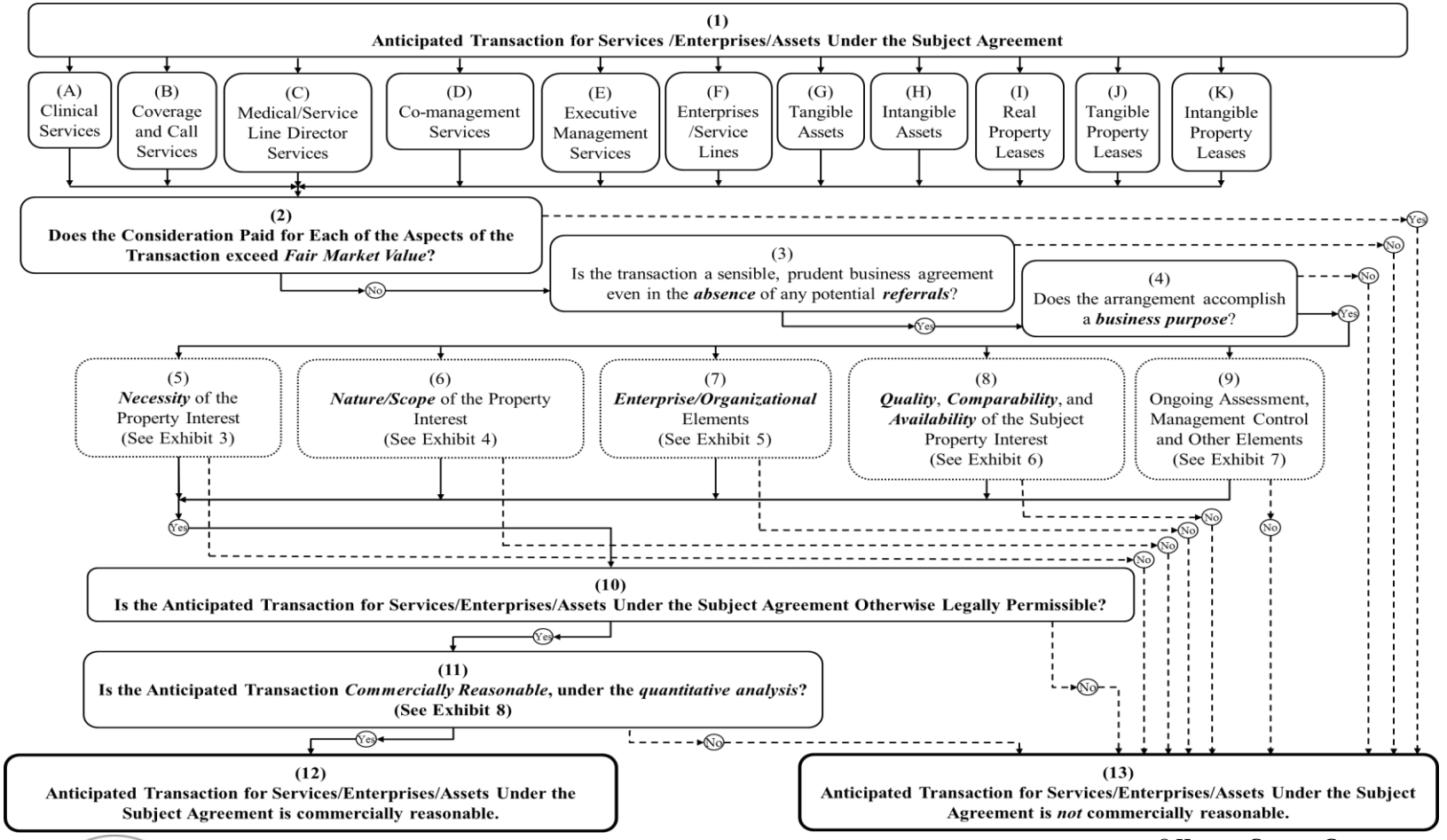
"Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b); "Hanlester Network v. Shalala" 51 F.3d 1390 (9th Cir. 1995); "Program Integrity; Medicare and State Health Care Programs; Permissive Exclusions," 42 CFR 1001.952(b)(5), (2009).

Commercial Reasonableness

Qualitative Factors

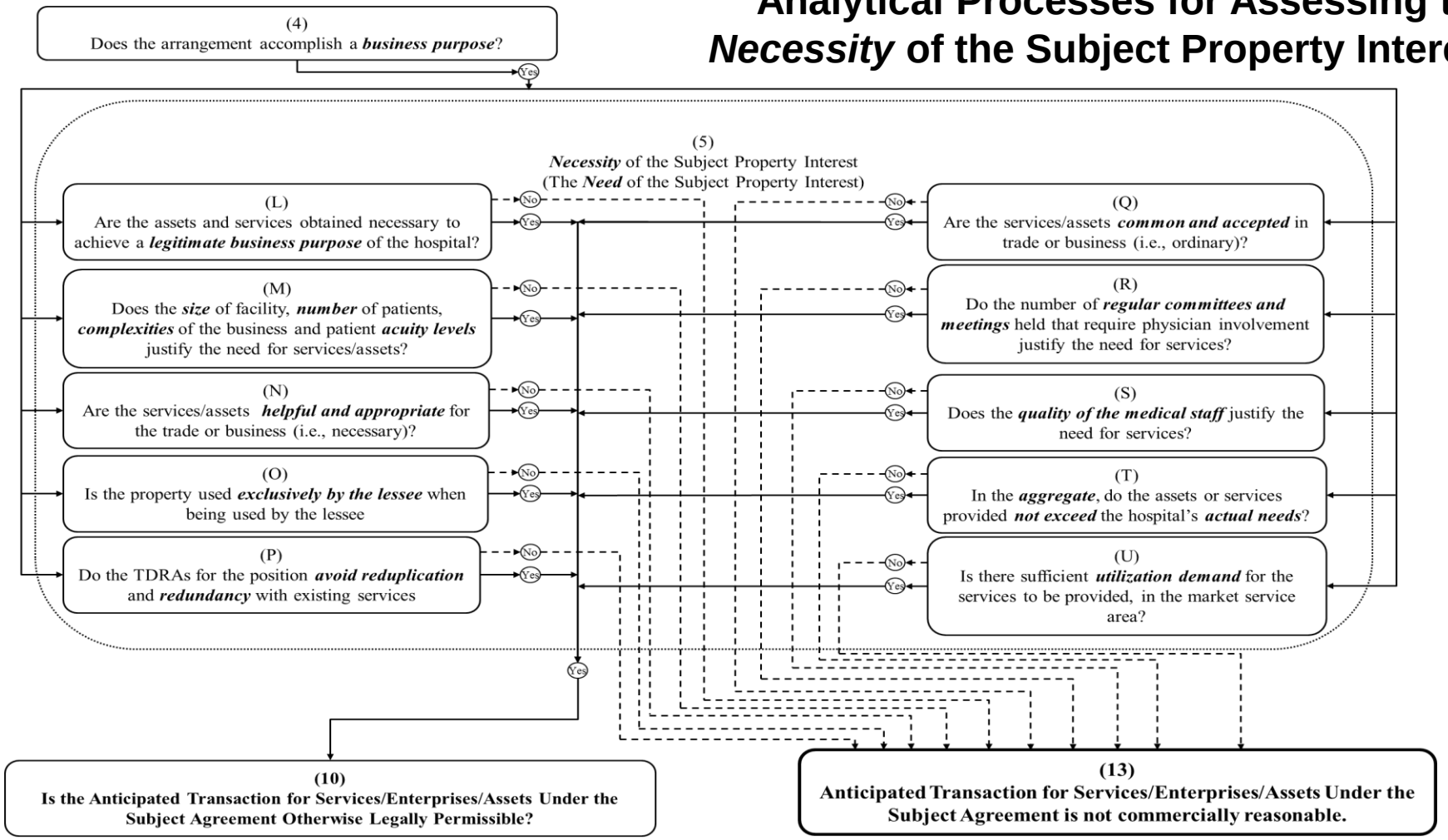
- Does the arrangement accomplish a business purpose?
  - Necessity of subject property interest
  - Nature/Scope of subject property interest
  - Enterprise/Organizational elements
  - Quality, comparability, & availability of subject property interest
  - Ongoing assessment, management control & other elements
- Is the anticipated transaction for services/enterprises/assets under the subject agreement otherwise legally permissible?

Qualitative Analytical Steps in Commercial Reasonableness Threshold

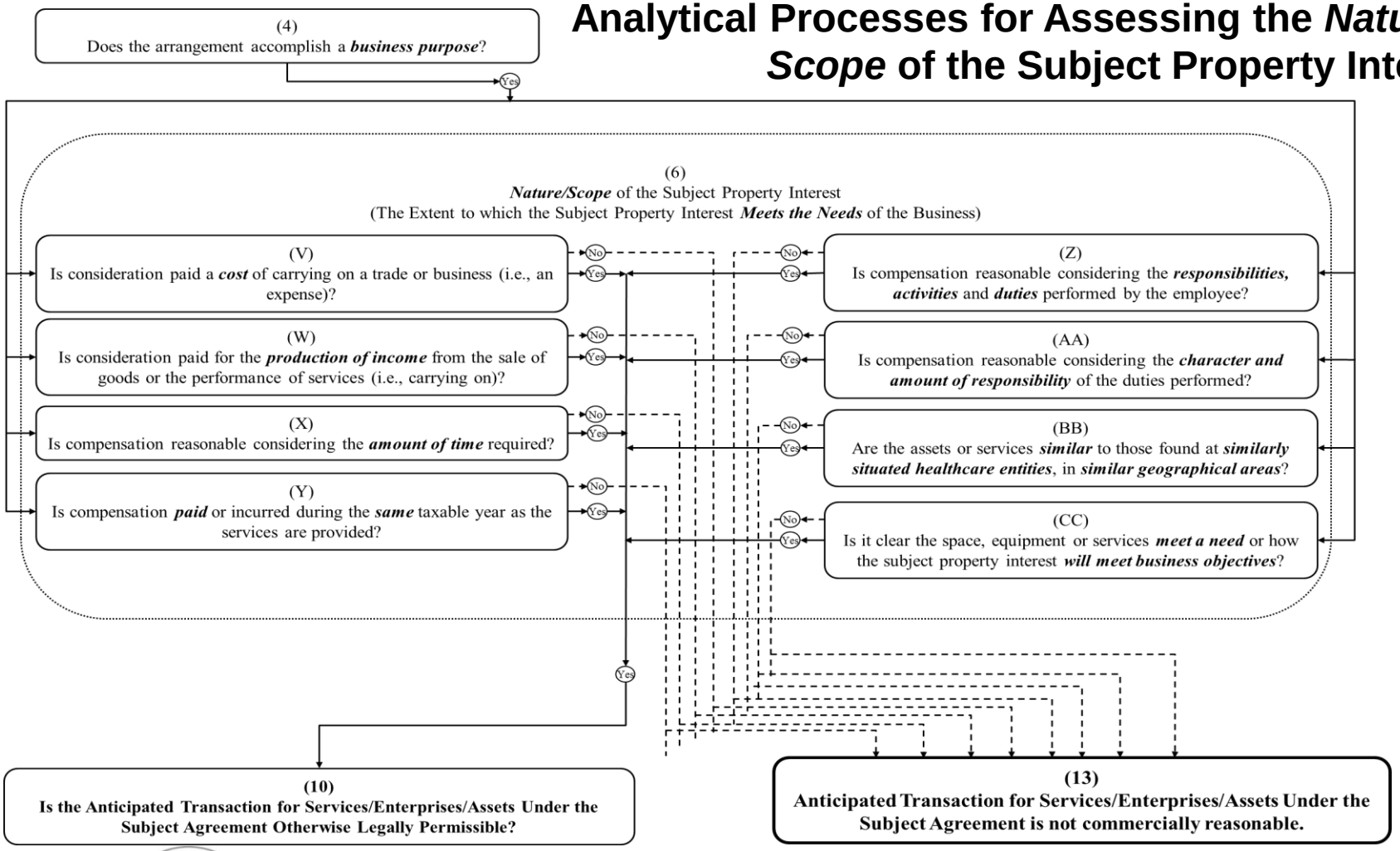


Textbook Reference
Vol. 2●Ch. 16●*Commercial Reasonableness*
Page 948-952
Healthcare Valuation
Financial Appraisal of Enterprises, Assets & Services
by Robert James Cimasi

Analytical Processes for Assessing the *Necessity* of the Subject Property Interest

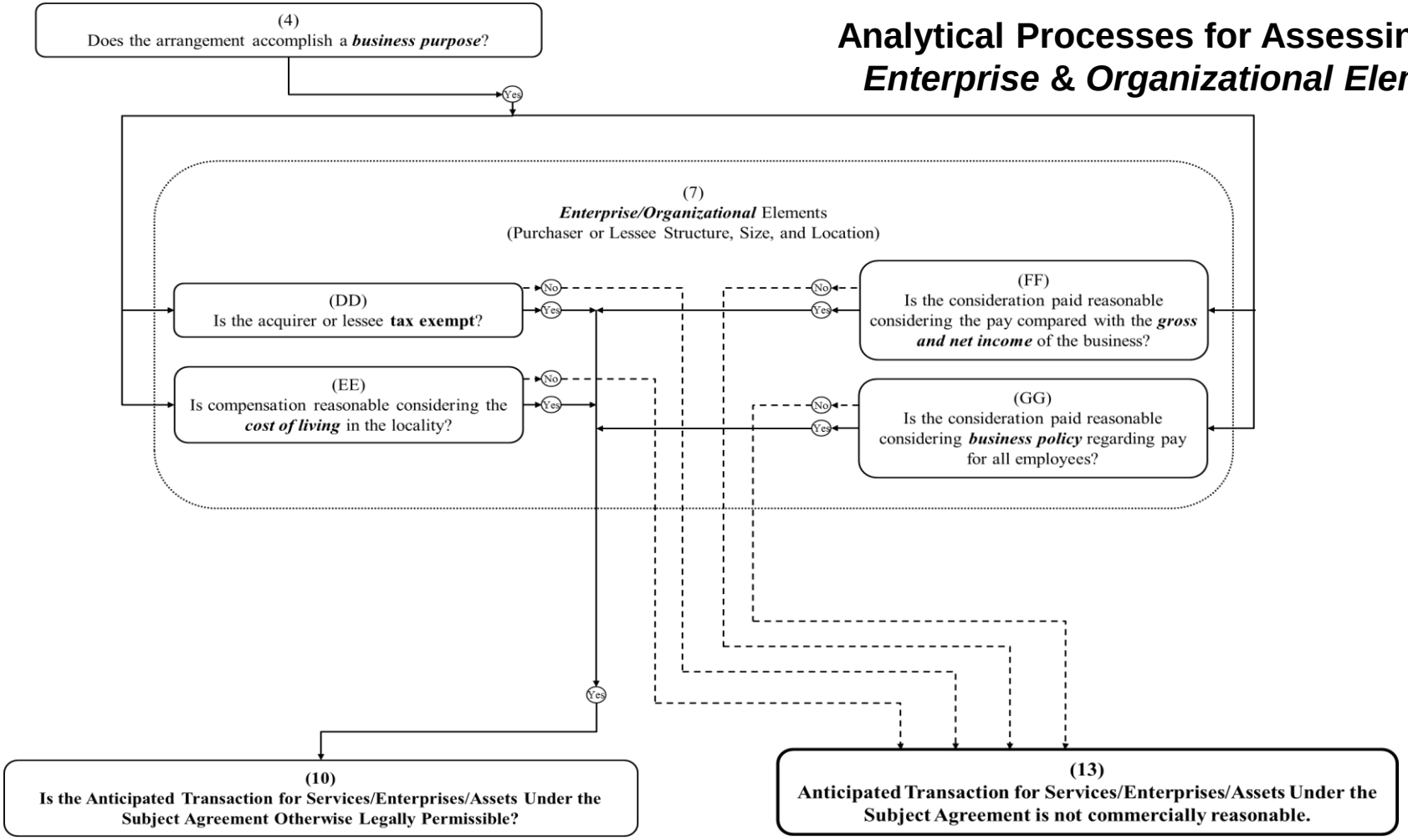


Analytical Processes for Assessing the *Nature & Scope* of the Subject Property Interest

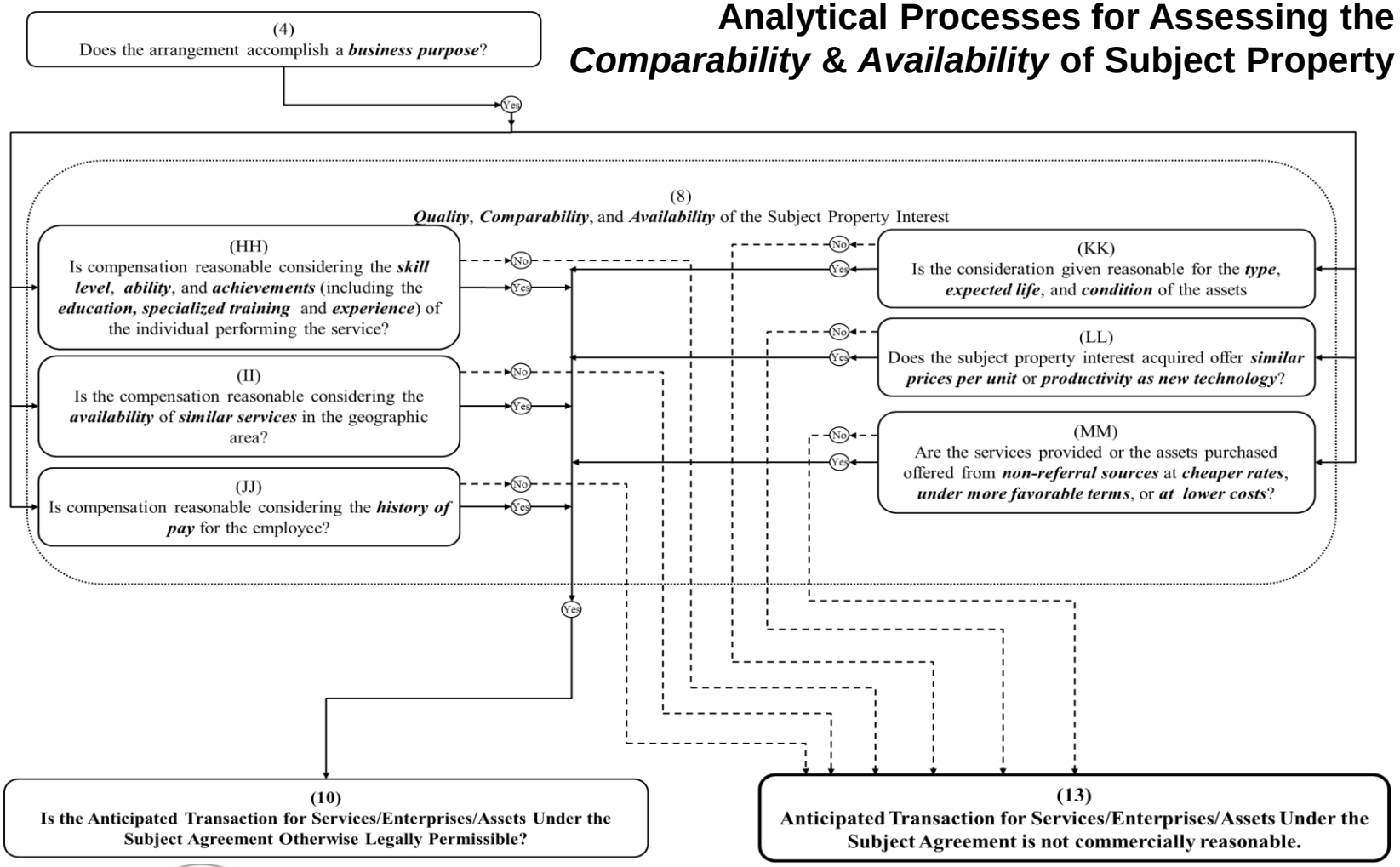


Textbook Reference
Vol. 2●Ch. 16●*Commercial Reasonableness*
Page 954-955
Healthcare Valuation
Financial Appraisal of Enterprises, Assets & Services
by Robert James Cimasi

Analytical Processes for Assessing the *Enterprise & Organizational Elements*



Analytical Processes for Assessing the *Quality, Comparability & Availability* of Subject Property Interest



Textbook Reference
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Healthcare Valuation
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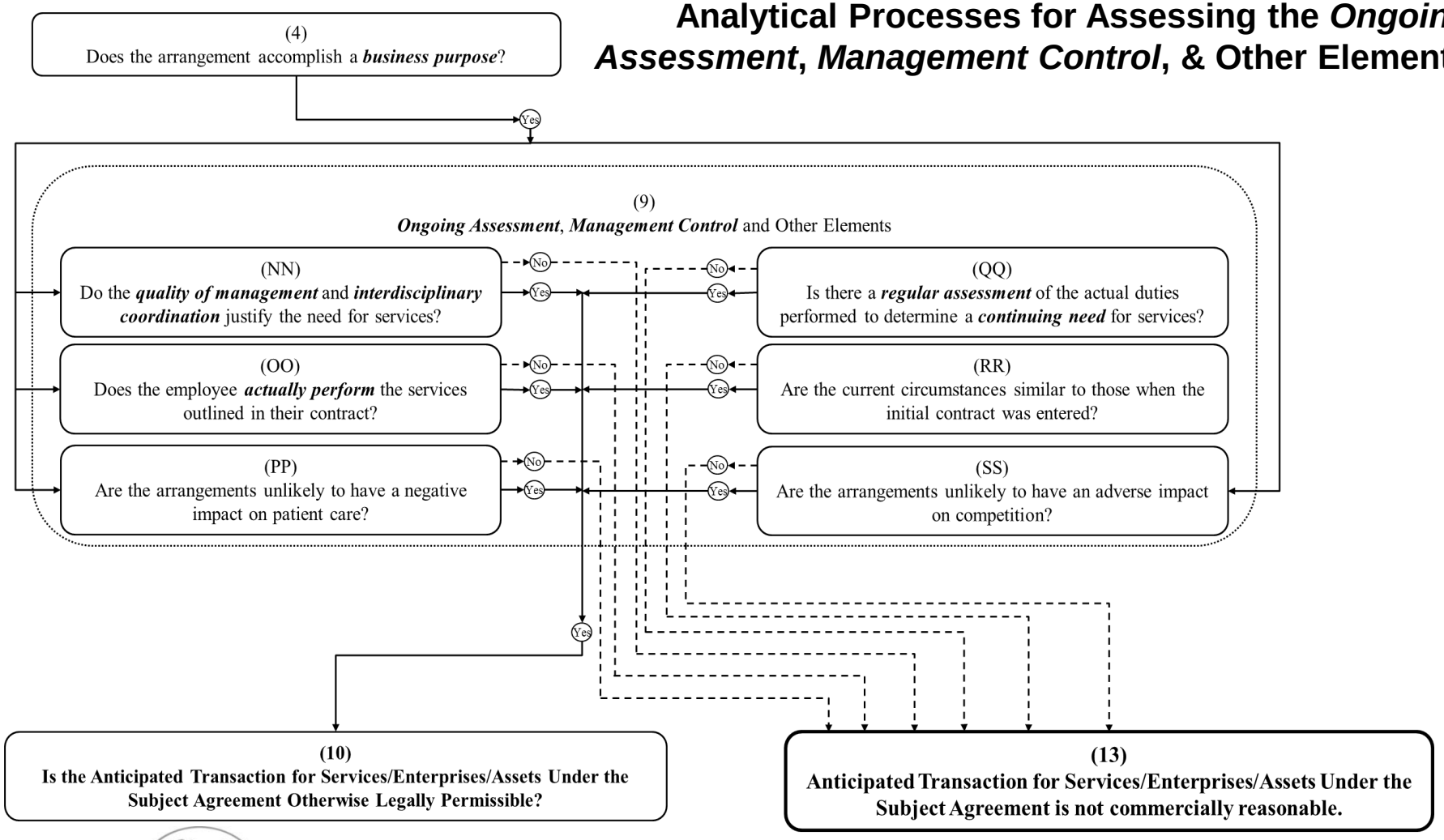
Analytical Processes for Assessing the *Ongoing Assessment*, *Management Control*, & Other Elements

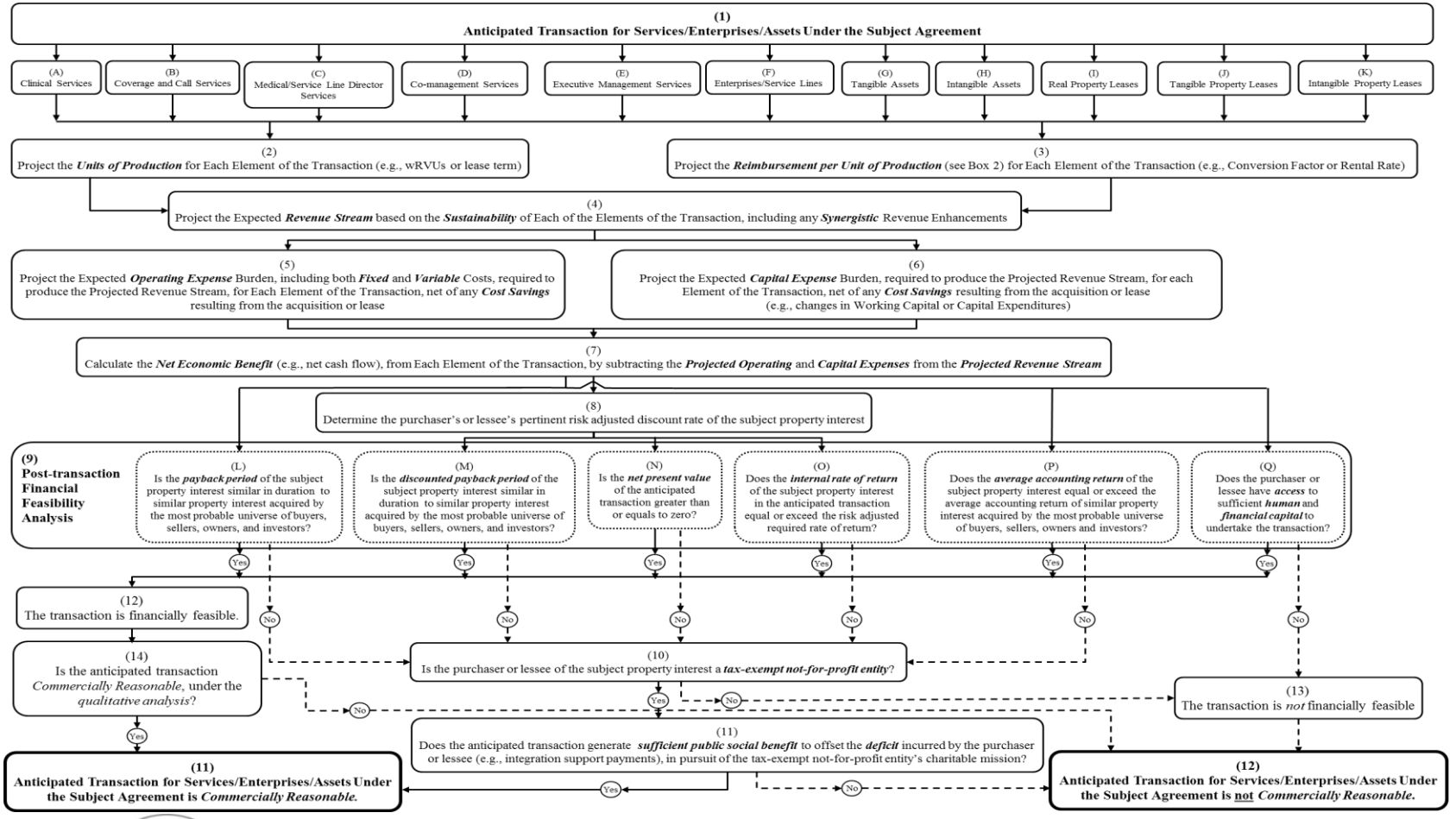


Commercial Reasonableness

Quantitative Factors/Post-Transaction Financial Feasibility Analysis

- Payback period & discounted payback period
- Net present value analysis
- Internal rate of return
- Average accounting rate of return

Quantitative Analytical Steps in the Commercial Reasonableness Threshold



Post-Transaction Financial Feasibility Analysis

		TTM	Common Size		PAY 1	Common Size	PAY 2	Common Size	PAY 3	Common Size	PAY 4	Common Size	PAY 5
Revenue													
Professional Revenue	(2)	$10,978,453		(12)	$11,921,167		$12,225,054		$12,536,685		$12,856,213		$13,183,937
wRVUs	(3)	171,770		(13)	174,404		177,079		179,795		182,552		185,352
Reimbursement per wRVU	(4)	$63.91		(14)	$68.35		$69.04		$69.73		$70.42		$71.13
wth in Utilization Demand/Market Share				(15)	1.53%		1.53%		1.53%		1.53%		1.53%
Growth in Reimbursement				(16)	6.95%		1.00%		1.00%		1.00%		1.00%
Technical Revenue	(5)	$3,097,624		(17)	$3,794,377		$5,216,891		$5,349,934		$5,486,357		$5,626,229
Units	(6)	16,622		(18)	16,876		17,135		17,398		17,665		17,936
Reimbursement per Unit	(7)	$186.36		(19)	$224.84		$304.46		$307.50		$310.58		$313.68
wth in Utilization Demand/Market Share				(20)	1.53%		1.53%		1.53%		1.53%		1.53%
Growth in Reimbursement				(21)	20.65%		35.41%		1.00%		1.00%		1.00%
Total Revenue		$14,076,077	100.00%	(8)	$15,715,544	100.00%	$17,441,945	100.00%	$17,886,618	100.00%	$18,342,570	100.00%	$18,810,166
Total Non-MD Comp Expenses		$8,453,719	60.06%	(22)	$7,581,780	48.24%	$7,775,066	44.58%	$7,973,280	44.58%	$8,176,521	44.58%	$8,384,958
Physician Compensation Related Expenses													
Physician Shareholder Salaries	(9)	$5,315,152	37.76%	(23)	$7,837,716	49.87%	$7,957,930	45.63%	$8,079,987	45.17%	$8,203,887	44.73%	$8,329,719
Physician Benefits		$840,385	5.97%	(24)									
Health Care		$0	0.00%	(24)	$186,550	1.19%	$186,550	1.19%	$186,550	1.19%	$186,550	1.19%	$186,550
Taxes		$0	0.00%	(24)	$203,615	1.30%	$208,769	1.33%	$210,539	1.34%	$212,335	1.35%	$214,160
Pension		$0	0.00%	(24)	$156,754	1.00%	$159,159	1.01%	$161,600	1.03%	$164,078	1.04%	$166,594
CME & Meals		$0	0.00%	(24)	$49,000	0.31%	$49,000	0.31%	$49,000	0.31%	$49,000	0.31%	$49,000
Dues & Subscriptions		$0	0.00%	(24)	$24,250	0.15%	$24,250	0.15%	$24,250	0.15%	$24,250	0.15%	$24,250
Signing Bonus		$0	0.00%	(25)	$208,000	1.32%	$208,000	1.19%	$208,000	1.16%	$208,000	1.13%	$208,000
Quality Incentive Bonus		$0	0.00%	(26)	$416,000	2.65%	$416,000	2.39%	$416,000	2.33%	$416,000	2.27%	$416,000
Total MD Comp Related Expenses		$6,155,537	43.73%		$9,081,885	57.79%	$9,209,658	52.80%	$9,335,926	52.20%	$9,464,100	51.60%	$9,594,273
Total Operating Expenses	(10)	$14,609,256	103.79%		$16,663,665	106.03%	$16,984,724	97.38%	$17,309,206	96.77%	$17,640,621	96.17%	$17,979,231
Net Operating Income Before Adjustments	(11)	($533,179)	-3.79%		($948,121)	-6.03%	$457,222	2.62%	$577,412	3.23%	$701,949	3.83%	$830,935
Cumulative Cash Flow				(29)	($2,748,121)		($2,290,899)		($1,713,487)		($1,011,538)		($180,603)
Initial Investment				(27)	($1,800,000)								
Payback Period		5.17											

Fraud & Abuse Regulatory Agencies

- Office of Inspector General (OIG)
- Centers for Medicare and Medicaid Services (CMS)
- Internal Revenue Service (IRS)
- Department of Justice (DOJ), through the development of initiatives such as the *Fraud Enforcement and Recovery Act* (FERA) and *Healthcare Enforcement Action Team* (HEAT)
- Federal District Attorneys
- State Attorneys General (AGs)

Fraud & Abuse Reimbursement Monitoring Programs

Recovery Audit Contractors (RAC)

- Tasked with improving payment accuracy and increased program transparency by identifying improper Medicare payments to providers based on three categories of errors:
  - Payment for medically unnecessary services
  - Payment for incorrectly coded services
  - Payment for services not supported by sufficient documentation

"Implementation of Recovery Auditing at the Centers for Medicare and Medicaid Services: FY 2010 Report to Congress" Centers For Medicare and Medicaid Services, 2011, p. 2-4.

Fraud & Abuse Reimbursement Monitoring Programs

Audit Medicaid Integrity Contractors (Audit MICs)

- CMS created Audit MICs to administer a Medicaid Integrity Program and oversee contracted entities
- CMS selects audit targets using a selection process that identifies potential fraud using data analysis of Medicaid payments
- Audit MICs are assigned targets and, if they find more evidence of fraud, they refer the cases to OIG for investigation

"Early Assessment of Audit Medicaid Integrity Contractors" By Daniel R. Levinson, Office of the Inspector General, March 2012, OEI-05-10-00210, p. 1-5.

Fraud & Abuse Reimbursement Monitoring Programs

Comprehensive Error Rate Testing (CERT) Program

- Created by CMS to determine improper *Medicare fee-for-service payments*
- CMS uses the CERT program's results to provide Congress with an estimate of the annual amount of improper Medicare payments made to providers during a given year

"Review of CERT Errors Overturned Through the Appeals Process for Fiscal Years 2009 and 2010" By Daniel R. Levinson, Office of the Inspector General, March 2012, A-01-11-00504, p. 1.

Fraud & Abuse Reimbursement Monitoring Programs

Medicare-Medicaid (Medi-Medi) Data Match Program

- Goal – To analyze Medicare and Medicaid claims data *collectively* in order to identify potentially fraudulent billing activities that might not have been observed when analyzing claims data *separately*
- State participation is voluntary, and states must fund their own program
- OIG – Program *"produced limited results and few fraud referrals"*

"The Medicare-Medicaid (Medi-Medi) Data Match Program" By Daniel R. Levinson, Office of the Inspector General, April 2012, OEI-09-08-00370, p. 1-2, 17.

Fraud & Abuse Reimbursement Monitoring Programs

ACA Fraud Identification Programs

- Strengthening of prison sentences through Federal Sentencing Guidelines
- Promotion of Transparency through Physician Payments Sunshine Act
  - Transactions between companies and physicians must be publicly reported

"Patient Protection and Affordable Care Act, Sec. 10606" Pub. Law 111-148, 124 Stat. 119 (March 23, 2010), p. 689, 1006-1008; "Doctors Face New Scrutiny Over Gifts: New Health Law Calls for Increased Disclosures" By Peter Loftus, The Wall Street Journal, August 22, 2013, http://online.wsj.com/article/SB10001424127887323455104579014812178937016.html?dsk=y&cb=logged0.6060728852902819 (Accessed 9/4/13).

Fraud & Abuse Reimbursement Monitoring Programs

Independent Monitoring OIG Guidance

- Developed by the Association of Healthcare Internal Auditors, American Health Law Association, Health Care Compliance Association, and the HHS OIG
- Addresses:
  - Roles of, and relationships between, the organization's audit, compliance, and legal departments
  - Mechanism and process for issue-reporting within an organization
  - Approach to identifying regulatory risks
  - Methods of encouraging enterprise-wide accountability for achievement of compliance goals and objectives

"Practical Guidance for Health Care Governing Boards on Compliance Oversight," Office of Inspector General, U.S. Department of Health and Human Services, Association of Healthcare Internal Auditors, American Health Lawyers Association, Health Care Compliance Association, April 20, 2015.

Importance of Creating an Internal Compliance Program

7 Fundamental Elements of an Effective Compliance Program

- Implementing written policies, procedures and standards of conduct
- Designating a compliance officer and compliance committee
- Conducting effective training and education
- Developing effective lines of communication
- Conducting internal monitoring and auditing
- Enforcing standards through well-publicized disciplinary guidelines
- Responding promptly to detected offenses and undertaking corrective action

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""Health Care Compliance Program Tips," Health Care Prevention and Enforcement Action Team, Office of Inspector General, http://oig.hhs.gov/compliance/provider-compliance-training/files/Compliance101tips508.pdf (Accessed 9/10/15).

Competition

Antitrust Regulations

The Sherman Act

- Prohibits any *"contract, combination. . .or conspiracy, in restraint of trade or commerce"*

The Clayton Act

- Prohibits:
  - Price discrimination
  - Exclusive dealing arrangements
  - Mergers and joint ventures that could create a monopoly
- Example – *FTC v. Phoebe Putney*

"Monopolies and Combinations in Restraint of Trade" 15 U.S.C.A. §1-7 (2012).

Antitrust Regulations

- ProMedica (2014 – appealed in 2015)
  - The 6th Circuit Court of Appeals sided with the FTC by order ProMedica to divest St. Luke's in Maumee, OH
  - This would reduce competition leading to higher prices for patients
- St. Luke's in Idaho (2015)
  - The Court considered whether St. Luke's acquisition of a medical group was anti-competitive

"ProMedica takes antitrust battle to Supreme Court," By Lisa Schencker, Modern Healthcare, January 6, 2015 http://www.modernhealthcare.com/article/20150106/NEWS/301069958 (Accessed 9/8//15).

Antitrust Regulations

Section 5 – Federal Trade Commission (FTC) Act

- Prohibits *"unfair methods of competition in or affecting commerce,"* and gives the FTC authority to bring enforcement actions against anti-competitive practices
- Goal – To ensure a competitive marketplace in which consumers will have high quality, cost-effective healthcare and a wide range of choices

"Federal Trade Commission; Promotion of Export Trade and Prevention of Unfair Methods of Competition" 15 U.S.C.A. §41-58 (2012).
"Statements of Antitrust Enforcement Policy in Health Care" U.S. Department of Justice and the Federal Trade Commission, August, 1996, http://www.justice.gov/atr/public/guidelines/0000.htm#CONTNUM_61 (Accessed 09/19/12) p. 3-4;).

Monopoly

- Abuse of monopoly power prohibited by Sherman Act
- FTC examines potentially illegal arrangements under a rule of reason analysis
- *"Safety zone"* for certain ACOs

"Sherman Antitrust Act" 15 U.S.C. § 2. "Federal Trade Commission, Department of Justice Issue Final Statement of Antitrust Policy Enforcement Regarding Accountable Care Organizations" Federal Trade Commission, Press Release, October 20, 2011, http://www.ftc.gov/opa/2011/10/aco.shtm (Accessed 7/15/12);).

Concerted Refusal to Deal (Group Boycott)

- *Wilk v. American Medical Association* – Associations refusing to deal with chiropractors and calling the chiropractic profession *"unscientific quackery"* was a boycott that created an *"unreasonable restraint of trade"*

- *DOJ and State of Idaho* – Settlement after allegations that orthopedic surgeons conspired to receive more fees by denying worker's compensation insurance and threatening Blue Cross

- Broken messenger model cases

"Wilk, et al. v. American Medical Association, et al." 895 F.2d 352 (February 7, 1990), p. 356-58.
"U.S. and State of Idaho v. Idaho Orthopaedic Society, et al." Civil Case No. 10-268-S.EJL (D.C. Idaho, August 30, 2010); "Idaho Orthopedists Charged with Engaging in Group Boycotts and Denying Medical Care to Injured Workers" U.S. Department of Justice, Press Release (May 28, 2010), http://www.justice.gov/atr/public/press_releases/2010/259181.htm (Accessed 9/20/12);).

Predatory Pricing and Price Fixing

- *Alta Bates Medical Group* – 600-physician member IPA allegedly conspired to coordinate collective negotiations on fee-for-service contracts by disallowing individual IPA members from participating in the negotiations on the individual reimbursement rates they would receive until the IPA had approved the negotiated prices

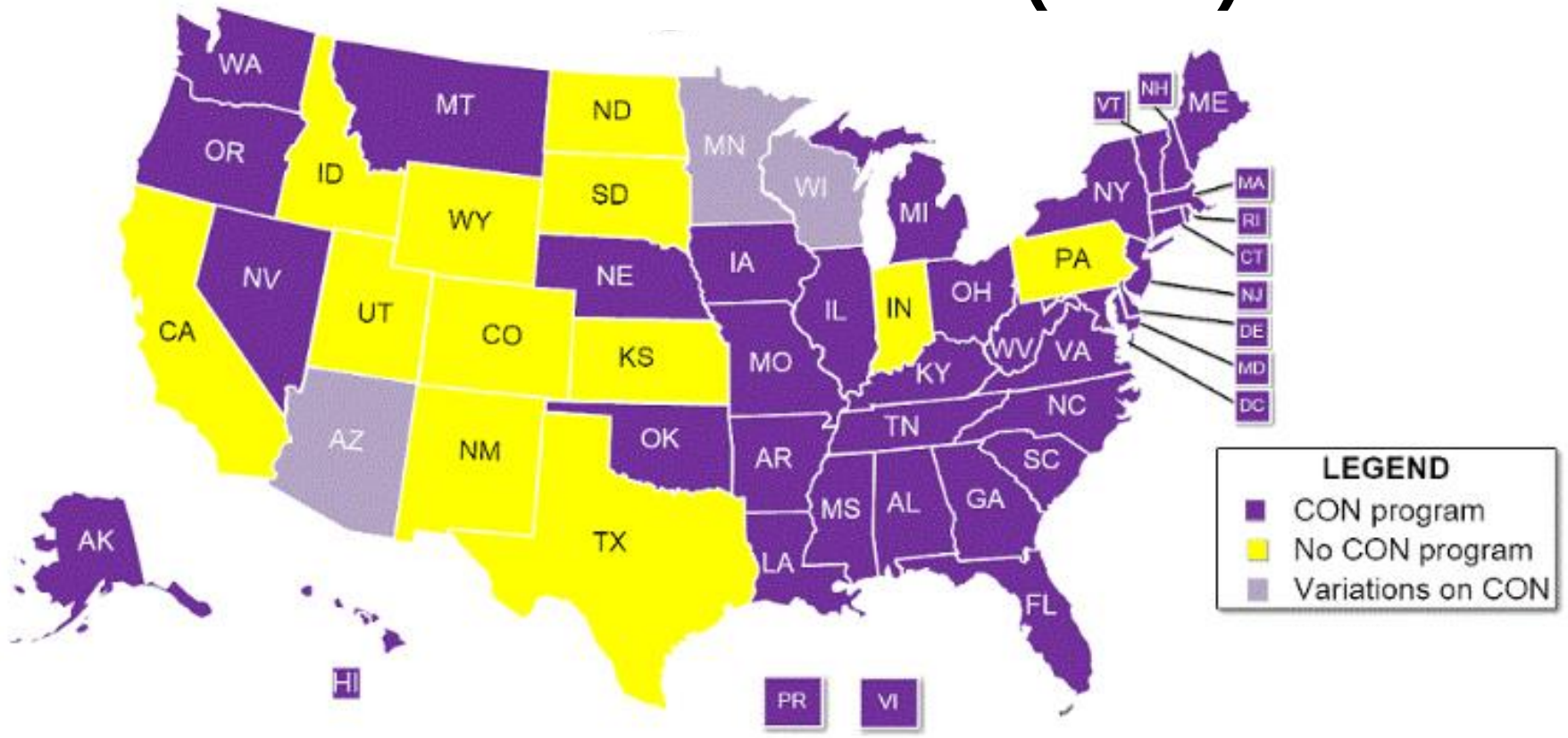
"FTC Settles Price-Fixing Allegations Against San Francisco IPA, American Health Lawyers Association, June 5, 2009, http://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/2009/June%202009/June%2005%202009/FTCSettlesPrice- FixingAllegationsAgainstSanFranciscoIPA.aspx (Accessed 10/2/12); "Commission Approves FY 2008 HSR Premerger Notification Report; FTC Approves Final Consent Order in Matter Concerning Alta Bates Medical Group," News Release, FTC, July 14, 2009, http://www.ftc.gov/opa/2009/07/hsr.shtm (Accessed 10/2/12);).

Certificate of Need (CON)

- State government determines where, when, and how capital expenditures will be made for public healthcare facilities, services and major equipment
- Aimed at restraining health care facility costs and allowing coordinated planning of new services and construction
- Originated to regulate the number of beds in hospitals and nursing homes, and to prevent overbuying of expensive equipment
- 35 states (and Washington DC) still retain some type of CON program, law, or agency

"Certificate of Need: State Health Laws and Programs," National Conference of State Legislatures, March, 2012, http://www.ncsl.org/issues-research/health/con-certificate-of-need-state-laws.aspx (Accessed 9/20/12); "State Certificate of Need (CON) Health Laws, 2013", Compiled by NCSL November 2013, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx, (Accessed 9/4/2014); "State certificate-of-need laws weather persistent attacks" By Lisa Schencker, Modern Healthcare, January 23, 2016, http://www.modernhealthcare.com/article/20160123/MAGAZINE/301239964 (Accessed 4/15/2016).

Certificate of Need (CON)



"Certificate Of Need: State Health Laws And Programs" National Conference of State Legislatures, January 2016, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx (Accessed 5/3/2016).

Any Willing Provider Statutes

- Require health insurance plans to accept any healthcare provider into their network that is willing to agree to the plan's terms and conditions, including reimbursement rates
- Vary by state as to type of organization they regulate and which providers they affect
  - Some states provide protection only to pharmacists or pharmacies; others regulate coverage of physicians, dentists, hospitals, mid-level providers, allied health professionals, etc.
- As of November 2014, 27 states had some type of *"any willing provider"* statute

"Any Willing or Authorized Providers", National Conference of State Legislators, http://www.ncsl.org/research/health/any-willing-or-authorized-providers.aspx, (Accessed 9/4/2014).

Covenants Not to Compete

- May be agreements between buyers and sellers, as well as employers and employees
  - Example - Desirable for hospitals in order to prevent an employed physician from establishing a competing medical practice upon termination of his hospital employment, or following a physician's sale of his practice to another healthcare enterprise, such as a medical group practice
- Some states have passed legislation prohibiting the use of *non-compete agreements* among certain healthcare providers

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"Restrictive Covenants in Professional Employment Contracts" By Robert R. Roper, American Journal of Roentgenology, March 28, 1989.

Most Favored Rate Clauses

- Also known as *Most Favored Nation (MFN) Clauses*
- Seller promises buyer that it will not offer another buyer better rates before offering those better rates to the first buyer
- Example - Blue Cross Blue Shield of Michigan (BCBSM)
  - BCBSM agreed to pay hospitals a higher rate in exchange for the hospitals charging rival insurers at least as much as BCBSM, sometimes more
  - Plaintiffs won approval of a $30 million settlement that BCBSM violated antitrust laws by using *most favored nation* clauses in its contract

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"Most Favored Nations Provision (MFN)," Practical Law, Thomson Reuters, http://us.practicallaw.com/8-382-3637 (Accessed 9/23/15). "Controversial $30M Blue Cross Antitrust Settlement Approved," By Matthew Bultman, Law 360, April 1, 2015, http://www.law360.com/articles/638293/controversial-30m-blue-cross-antitrust-settlement-approved (Accessed 9/10/15).

State Regulations
How/When Payors Pay Providers

Ohio	California	Texas	Arizona
Prompt Payment of Claims - Has 30 days to process a claim if no supporting documents are needed - Has 45 days if there is a request for supporting documents	Prompt Payment of Claims - Has 45 working days to process a claim for an HMO - Has 30 days to process a claim for other health service plans	Prompt Payment of Claims - Has 30 days to process a claim for electronic claims - Has 45 days to process a claim for non-electronic claims	Prompt Payment of Claims - Has 30 days to process a claim or interest payments are required

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"Prompt Pay Statutes," AMBA, http://www.ambanet.net/PromptPayState.pdf (Accessed 9/17/15).

Privacy Laws

Health Insurance Portability & Accountability Act of 1996 (HIPAA)

- Possession of confidential healthcare information is regulated on a federal level
- Most widely used for safeguarding the privacy of Protected Health Information (PHI)
- HIPAA Privacy Rule – Provides standards for use and disclosure of individuals' PHI
  - Goal - To assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well-being

"Summary of the HIPAA Privacy Rule," OCR Privacy Brief, United States Department of Health and Human Services, May 2003, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 6/17/09), p.1, 4, 9.

HIPAA & Data Breaches

- OhioHealth (July 2015)
  - A misplaced unencrypted flash drive caused OhioHealth to issue a data breach notification letter
  - Information on flash drive: patient names, medical record numbers, names of insurance companies, physician names, addresses, dates of birth, referral and treatment dates, types of procedures conducted, clinical information, Social Security numbers
- Anthem (2015)
  - Cyber attack drained 80 million records from Anthem's data
  - Included: names, taxpayer IDs, birthdays, medical IDs, addresses, email addresses, employment data

"OhioHealth Missing Flash Drive Leads to Health Data Breach," By Sara Heath, Health IT Security, July 29, 2015, http://healthitsecurity.com/news/ohiohealth-missing-flash-drive-leads-to-health-data-breach (Accessed 9/10/15); "US health insurer Anthem drained of 80 million records," By Lisa Vaas, naked security, February 6, 2015, https://nakedsecurity.sophos.com/2015/02/06/us-health-insurer-anthem-drained-of-80-million-records/ (Accessed 9/10/15).

Red Flags Rule

- Requires many businesses and organizations to implement a written Identity Theft Prevention Program
  - Designed to detect the warning signs, i.e. *"red flags"*, of identity theft in day-to-day operations, take steps to prevent the crime, and mitigate the damage it inflicts
- Enforced by the FTC, the federal bank regulatory agencies, and the National Credit Union Administration

"Identify Theft Red Flags and Address Discrepancies Under the Fair and Accurate Credit Transactions Act of 2003; Final Rule" 16 CFR 681, Federal Trade Commission, November 9, 2007, p. 63719. "Fighting Fraud with the Red Flag Rules: A How-To Guide for Business" Federal Trade Commission, ftc.gov/redflagsrule, March 2009, p. 1.

Health Information Technology for Economic & Clinical Health (HITECH) Act

- Incorporated into the American Recovery and Reinvestment Act of 2009
- Intended to promote widespread adoption of health IT
- Allows patients to request an electronic copy of their medical records as well as an audit trail that shows all disclosures of their PHI
- Prohibits the sale of a patient's PHI without their authorization
- Requires individuals to be notified if there is an unauthorized disclosure or use of their PHI

"Stimulus Package Includes New HIPAA Security Rules: Small Practices Face Greatest Financial Impact," By Sheri Porter, AAFP News Now, March 18, 2009, http://www.aafp.org/online/en/home/ (6/17/2009); "American Recovery and Reinvestment Act of 2009," Pub. L. No. 111-5, 123 Stat. 115 (Feb. 17, 2009).

Patient Safety and Quality Improvement Act (PSQIA) of 2005

- Voluntary reporting system for medical errors
  - Goal – To enhance the data available to assess and resolve patient safety and health care quality issues
- Provides federal privilege and confidentiality protections for patient safety information
- The confidentiality provisions will improve patient safety outcomes by creating an environment where providers may report and examine patient safety events without fear of increased liability risk

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"Health Information Privacy: Understanding Patient Safety Confidentiality" U.S. Department of Health and Human Services, http://www.hhs.gov/ocr/privacy/psa/understanding/index.html (Accessed 2/4/10); "Patient Safety and Quality Improvement; Final Rule" 42 C.F.R. Part 3, Centers for Medicare and Medicaid Services, November 21, 2008, p. 70732-34.

Custodial Rights to Patient Charts

- Patient rights with respect to their medical records
  - Right to view and obtain much of their health information and to have corrections made
  - Right of access to inspect and obtain a copy of their PHI from the entity with access to such information
- Providers have right to the custody of patient medical charts and records and patient recall lists
  - Charts and records constitute an intangible asset of the physician practice that may be transferred and valued

"Personal Health Records and the HIPAA Privacy Rule" U.S. Department of Health and Human Services, http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/healthit/phrs.pdf (Accessed 8/14/13).

Safety Regulations

Clinical Laboratory Improvement Amendments (CLIA)

- Passed in 1988 following a public outcry after numerous reports of inaccurate Pap smear results
- Goal - To improve the *accuracy, reliability, and timeliness* of laboratory test results

CMS Initiatives to Improve Quality of Laboratory Testing Under the CLIA Program, CMS, July 2006. "Problems in Health Care Law" Robert D. Miller and Rebecca C. Hutton, Eighth Edition, Mississauga, ON, Jones and Bartlett Publishers, 2004, p. 327.

Occupational Safety & Health Act (OSHA)

- Enacted to establish and enforce standards for occupational health and safety
- Standards developed for various industries are mandatory for all covered employers
- Mandates that each state enact legislation to implement the standards and procedures promulgated by the Department of Labor

"Problems in Health Care Law" Robert D. Miller and Rebecca C. Hutton, Eighth Edition, Mississauga, ON, Jones and Bartlett Publishers, 2004, p. 327.

United States Nuclear Regulatory Commission (NRC)

- An independent agency created by Congress in 1974
- Tasked with ensuring the safe use of radioactive material for civilian purposes through a combination of regulatory requirements, licensing, safety oversight, operational evaluation, and support activities

"About NRC," United States Nuclear Regulatory Commission, April 28, 2009, http://www.nrc.gov/about-nrc.html (Accessed 9/1/09).

Environmental Laws

- Hazardous Waste
  - The Resource Conservation and Recovery Act (RCRA) of 1976 provided the EPA with *". . .the authority to control hazardous waste from the 'cradle-to-grave'…[which] includes the generation, transportation, treatment, storage, and disposal of hazardous waste"*
  - Medical waste disposal is often more specifically regulated on a state level, with all 50 U.S. states having some type of state regulation governing the disposal of medical waste

Summary of the Resource Conservation and Recovery Act, EPA, http://www.epa.gov/lawsregs/laws/rcra.html; "Where You Live: State Medical Waste Programs," U.S. Environmental Protection Agency, September 14, 2012, http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm (Accessed 9/14/2012).

Food and Drug Administration (FDA)

- Regulates food, dietary supplements, pharmaceuticals, vaccines, blood products and other biologics, medical devices, electronic products, cosmetics, veterinary products, and tobacco products
- Both pharmaceuticals and medical devices are required to have approval from the FDA prior to commercialization of the pharmaceutical or medical device
  - The future economic benefit from the patent cannot be realized until after the approval is gained from the FDA

"What Does FDA Regulate," U.S. Food and Drug Administration," www.fda.gov (Accessed 11/6/12).

Licensure, Certification, & Accreditation

Licensure of Healthcare Facilities

- Intended to ensure that patients receive quality healthcare
- All 50 states require hospitals and skilled nursing facilities to be licensed
- Minimum requirements for licensing nursing home facilities vary little between states

State Licensure of Facilities" Thomson Reuters, 50 State Regulatory Surveys: Health Care: Long Term Care, June 2012; "Medicare and Medicaid Fraud and Abuse" By Alice G. Gosfield, 2012 Edition, Thomson Reuters, 2012, p. 31; "Agreements with States" 42 U.S.C. § 1395aa (2010); "Effect of Accreditation" 42 U.S.C. § 1395bb (2010).

Medicare and Medicaid Certification of Healthcare Facilities

- Must meet the eligibility requirements for program participation, including certification of compliance with the *Conditions of Participation* (CoP)
  - Based on a survey conducted by a state agency on behalf of CMS
- Organization must be *"deemed"* to satisfy the health and safety standards component of the Medicare certification process to be certified

"Facts about federal deemed status and state recognition" The Joint Commission, June 19, 2012, http://www.jointcommission.org/assets/1/18/Facts_about_Federal_Deemed_Status.pdf (Accessed 09/14/12).

Accreditation of Healthcare Facilities

- Granted by private authorities - not legally mandated
- Some states accept certain accreditation as a basis for full or partial licensure as part of an effort to reduce duplicative hospital inspections

"Problems in Health Care Law, Ninth Edition" Robert D. Miller, Jones and Bartlett, 2006, p. 59 -6.

Accreditation Bodies

The Joint Commission

- Provides accreditation for ambulatory care centers, behavioral health centers, critical access hospitals, home care, general hospitals, laboratory services, long-term care facilities, office-based surgery centers, and international healthcare providers

American Osteopathic Association

- Accrediting body for osteopathic healthcare facilities and medical schools

"Problems in Health Care Law, Ninth Edition" Robert D. Miller, Jones and Bartlett, 2006, p. 59 -60; "The Joint Commission Code of Conduct" The Joint Commission, 2009, http://www.jointcommission.org/NR/rdonlyres/5B9CE6DD-FA09-465E-BDA8-C1FBCE03A555/0/TJCCodeofConduct09.pdf (Accessed 02/10/10); "State Recognition Details" The Joint Commission, http://www.jointcommission.org/state_recognition/state_recognition_details.aspx?ps=25 (Accessed 09/18/12).

Accreditation Bodies

National Committee on Quality Assurance (NCQA)

- Accrediting body for managed care plans

Accreditation Association for Ambulatory Health Care

- Evaluates:
  - Federally qualified health centers (FQHCs)
  - Office-based surgery centers
  - ASCs
  - Hospitals

"About NCQA" National Committee for Quality Assurance, http://www.ncqa.org/tabid/675/Default.aspx, (Accessed on June 29, 2009); "AAAHC Announces New Accreditation Program for Hospitals: Will Be Independent of Ambulatory Accreditation Program" Accreditation Association for Ambulatory Health Care, Press Release (April, 25, 2012), Accessed at http://www.aaahc.org/news/archives/2012/Hospital-Program/ (Accessed 9/12/12).

Emergency Medical Treatment & Active Labor Act (EMTALA)

- Enacted in 1986 by the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA '85)
- Requires any hospital that *participates in Medicare* and has an *emergency room* to provide a *"medical screening"* to any patient coming to the hospital's emergency department to determine if they have any potentially harmful medical conditions

"Examination and treatment for emergency medical conditions and women in labor" 42 U.S.C.A. §1395dd(e)(2), (December 8, 2003), p. 2534; "Agreements with providers of services; enrollment process," 42 U.S.C. § 1395cc, (October 21, 2011).

Occupancy Regulations

- In order for a healthcare facility, or any new building, to be operational, it must pass a building inspection by a licensing agency in order to secure a certificate of occupancy (CO) from the local municipal government

"Problems in Health Care Law" Robert D. Miller and Rebecca C. Hutton, Eighth Edition, Mississauga, ON, Jones and Bartlett Publishers, 2004, p. 62.

Licensure of Healthcare Professionals

- All 50 states and the District of Columbia mandate licensure of Allopathic Physicians (M.D.s), Osteopathic Physicians (D.O.s), Dentists, Registered Nurses, etc.
- State laws specify minimum qualifications to obtain licensure, and define circumstances under which a license may be revoked, suspended, or limited

"U.S. Health Law and Policy 2001: A Guide To The Current Literature" By Donald H. Caldwell Jr., Jossey-Bass, 2001, p. 253.

Board Certification

- The American Board of Medical Specialties (ABMS) is a nationally-recognized non-profit organization made up of 24 Member Boards that oversee doctor specialty certification in the U.S.
  - Medical specialty certification in the U.S. is a voluntary process
  - Board Certification demonstrates a physician's exceptional expertise in a particular specialty and/or subspecialty of medical practice

"American Board of Medical Specialties Board Certification Editorial Background" American Board of Medical Specialties, August 31, 2012, Accessed at www.abms.org (Accessed 9/12/12); "What Board Certification Means", by American Board of Medical Specialties, http://www.abms.org/About_Board_Certification/means.aspx (Accessed 4/22/10).

Board Certification – Primary Care

- Today most, if not all, doctors are considered specialists

	1975	1980	1985	1990	1995	2000	2013
Active Physicians	366,425	435,545	511,090	559,988	646,022	737,504	898,234
Primary Care	144,861	170,705	199,495	213,514	241,329	274,653	319,881
% of Active that are Primary Care	39.53%	39.19%	39.03%	38.13%	37.36%	37.24%	35.61%

	1975-1980	1975-1985	1975-1990	1975-1995	1975-2000	1975-2013
Percent Change	-0.86%	-1.27%	-3.55%	-5.51%	-5.80%	-9.92%
CAGR	-0.17%	-0.13%	-0.24%	-0.28%	-0.24%	-0.27%

"Physician Characteristics and Distribution in the US: 2015 Edition," Derek R. Smart, American Medical Association: 2015, p.288-290.

Nonphysician Scope of Practice

- Predicted shortage of primary care physicians as the population grows and millions of individuals become newly insured
- One proposed solution – Expand laws regarding the scope of practice of nonphysician practitioners (NPPs)
  - Examples: nurse practitioners and physician assistants
  - May allow physician practices to provide wider range of services
- In considering changes to licensure and scope-of-practice requirements, state legislatures will weigh concerns about patient safety
- Many states expanded have scope of services for NPPs

"Nurse Practitioners and Primary Care," Health Policy Brief, Health Affairs, October 25, 2012, p.1.

Tort Reform

- **Malpractice**: *"Professional misconduct or an unreasonable lack of skill"*
- While there have been efforts at federal tort reform, a *federal cap* on damages has yet to be signed into law
  - Many states have caps already in place

"Medical Liability/Malpractice Laws," National Conference of State Legislatures, August 15, 2011, http://www.ncsl.org/default.aspx?tabid=18516 (Accessed 4/15/2016).

Licensure of Health Insurance Plans

- State laws require insurers and insurance-related businesses to be licensed before selling their products or services
- Insurers who fail to comply with regulatory requirements are subject to license suspension or revocation
  - States may exact fines for regulatory violations
- Fundamental reason for government regulation – to protect American consumers
  - Insurance is more heavily regulated than other types of business because of the complexity of the contracts

"State Insurance Regulation," National Association of Insurance Commissioners and the Center for Insurance Policy and Research, 2011, p. 1-3. "Office-Based Anesthesia and Surgery: Creating a Culture of Safety" By Fred E. Shapiro and Richard D. Urman, American Society of Anesthesiologists, Vol. 75 No. 8, August 2011, p. 14.

Other Federal & State Regulations

Corporate Practice of Medicine Doctrine

- Created by the American Medical Association (AMA) to protect the public, as well as physicians
  - Bans unlicensed individuals and entities from engaging in the practice of medicine by restricting them from employing licensed physicians
- Regulated on a state level
- Fee-splitting

"Corporate Medicine in 21st Century Health Care," By John W. Jones, Esq., Physician's News Digest, June 2007, http://www.physiciansnews.com/law/607jones.html, (Accessed on July 9, 2009).

False/ Misleading Advertising

- Increased scrutiny by the FTC and State AGs/State Insurance Commissioners regarding how healthcare goods, services, and procedures are advertised or labeled
- In a 2006 push for more *transparent* drug labeling, the FDA and HHS released a final rule requiring manufacturers to assess the effect of any change in "*identity, strength, quality, purity, and potency*" of a drug as it relates to the safety and effectiveness of that drug

"Supplements and Other Changes to Approved New Animal Drug Applications" Federal Register, Vol 71, No. 239 (December 13, 2006), p. 74766.

Employment Retirement Income Security Act (ERISA)

- Protects individuals who participate in health benefit plans through private sector employers by providing rights to information and a grievance process for receiving benefits
- Does not require an employer to offer health benefits, but regulates those employers who *do* offer benefits and stipulates generally that employers allocate their benefits fairly

"ERISA and Healthcare Plan Enforcement" By FindLaw, (2010) http://employment.findlaw.com/employment/employment-employee-wages-benefits/employment-employee-wages-benefits-health-insurance-top/employment-employee-wages-benefits-erisa.html, (Accessed 8/28/13).

Consolidated Omnibus Budget Reconciliation Act (COBRA)

- Passed in 1986 as an amendment to ERISA
- Requires employers who employ 20 or more workers to offer continued healthcare insurance for a period after a "*qualifying event*"
- Provides certain retirees and their dependents the right to purchase a continuation of group health plan coverage from their previous employer-based plan

Pension Protection Act

- Established new funding requirements for defined benefit pensions
- Modified federal law provisions prescribing how the minimum permissible value of a lump-sum distribution from a defined benefit plan will be determined from 2008 onward
- Established conditions under which payment of lump sums from defined benefit plans will be restricted
- Removes *"Threshold Restriction"*
- Relaxes the Knowledge Standard
- Limited statutory application to non-cash charitable contributions

"Lump-Sum Distributions Under the Pension Protection Act" CRS Report for Congress, Patrick Purcell, Dec. 3, 2007, http://www.aging.senate.gov/crs/pension9.pdf.
"How to Avoid an IRS Valuation Audit and Staying Clear of Penalties" ASA, Michael Gregory and Robert James Cimasi, St. Louis, MO Jan 10, 2011.

Family Medical Leave Act (FMLA)

- For employees with families
- Employers with 50 or more employees must provide up to 12 weeks of unpaid leave for parents giving birth or adopting a child or for serious illness of the employee or dependent
- Stipulates that the employee receive their self-only health insurance at a premium equal to that of an active status employee

Leave Benefits: Family & Medical Leave" By United States Department of Labor, http://www.dol.gov/dol/topic/benefits-leave/fmla.htm (Accessed 8/27/10).

The Patient Protection & Affordable Care Act (ACA)

Individual Mandate

- The ACA requires U.S. citizens and legal residents to carry health insurance
- Individuals who refuse to buy insurance will face a tax penalty
  - By 2016, the tax penalty will be $695 per year or 2.5% of income, whichever is greater
- King v. Burwell

"Justices Uphold Individual Mandate, Set Limits on Medicaid Expansion." Jordan Rau and Julie Appleby, Kaiser Health News, Jun. 28 2012. http://www.kaiserhealthnews.org/stories/2012/june/28/supreme-court-upholds-individual-mandate.aspx.

Employer Mandate

- Under original ACA legislation, on January 1, 2014, employers would incur tax penalties if they had 50 or more employees and did not offer health insurance
- Mandate was delayed for at least one year
  - As a result, the Congressional Budget Office (CBO) estimated the U.S. Treasury would receive $10 billion less in revenue than originally projected
- Hobby Lobby, 2014 decision by Supreme Court

"Delay In Major Health Law Provision Raises Doubts At Critical Stage of Rollout", Jay Hancock and Julie Appleby, Kaiser Health News, July 2, 2013 http://www.kaiserhealthnews.org/stories/2013/july/02/analysis-employer-mandate-delay.aspx (Accessed 8/28/2013); "Supreme Court sides with employers over birth control mandate" By Robert Barnes, The Washington Post, June 30, 2014, https://www.washingtonpost.com/national/supreme-court-sides-with-employers-over-birth-control-mandate/2014/06/30/852e5c84-fc61-11e3-b1f4-8e77c632c07b_story.html (Accessed 4/15/2016).

Health Insurance Exchanges

- Established to create a more organized and competitive market for health insurance
  - Offer a choice of health plans
  - Establish common rules regarding the offering and pricing of insurance
  - Provide information to help consumers better understand the options available to them
- Serves individuals and smaller employers
- King v. Burwell – Chief Justice Robert's opinion

"Explaining Health Care Reform: Questions About Health Insurance Exchanges" Kaiser Family Foundation, April, 2010, http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7908-02.pdf (Accessed 8/28/2013).

Small Business Healthcare Affordability Tax Credits

- Provides a tax credit to small employers with fewer than 25 employees and average annual wages of less than $50,000 that purchase health insurance for employees
- Phase I: For tax years 2010 through 2013, tax credit is up to 35% of employer's contribution toward employee's health insurance premium if employer contributes at least 50% of the total premium cost or 50% of a benchmark premium

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"Small Business Health Care Tax Credit for Small Employers" Internal Revenue Service, June 26, 2014, http://www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-for-Small-Employers (Accessed 9/4/2014).

Small Business Healthcare Affordability Tax Credits

- Phase II: For tax years 2014 and later, for eligible small businesses that purchase coverage through the state exchange, tax credit is up to 50% of employer's contribution toward employee's health insurance premium if employer contributes at least 50% of the total premium cost
  - The credit will be available for two years
  - The full credit will be available to employers with 10 or fewer employees and average annual wages of less than $25,000
  - The credit phases-out as firm size and average wage increases

"Small Business Health Care Tax Credit for Small Employers" Internal Revenue Service, June 26, 2014, http://www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-for-Small-Employers (Accessed 9/4/2014).

Small Business Health Options Program (SHOP)

- State-based marketplace for individual policies sold by private insurers
  - In October 2014, small businesses in five states were able to register on SHOP exchanges. Currently, businesses in all 50 states are able to obtain plans on the SHOP exchange.
- Small employers limited to one plan from Federally Facilitated Exchanges

"Administration Delays Health Law Provision for Small Businesses", Kaiser Health News, April 2, 2013 http://www.kaiserhealthnews.org/daily-reports/2013/april/02/health-reform-small-business-exchange.asp (Accessed 8/28/2013); "Small Businesses in These Five States to Get Early Access to New Healthcare.gov Portal" By J.D. Harrison, The Washington Post, September 3, 2014, http://www.washingtonpost.com/business/on-small-business/small-businesses-in-these-five-states-to-get-early-accessto-new-healthcaregov-portal/2014/09/03/24500924-3304-11e4-a723-fa3895a25d02_story.html (Accessed 9/12/14).

No Denial Based on Pre-existing Conditions

- Perhaps the most significant provision of the ACA affecting health insurers
- Prohibits health insurers from excluding individuals on the basis of a pre-existing condition
- Required to provide dependent coverage for children up to age 26

"Patient Protection and Affordable Care Act, Sec. 1302, 2714" Pub. Law 111-148, 124 Stat. 119 (March 23, 2010), p. 132, 163-164.
"Health Care Reform Memo: April 12, 2010" Deloitte Center for Health Solutions, April 12, 2010, http://www.deloitte.com/view/en_US/us/Insights/Browse-by-Content-Type/Newsletters/health-care-reform-memo/6a8e7661b62f7210VgnVCM100000ba42f00aRCRD.htm (Accessed 5/19/2010).

Medical Loss Ratio (MLR)

- Limits the portion of premium dollars health insurers may spend on administration, marketing, and profits
  - Most insurance companies that cover individuals and small businesses must spend at least 80% of premium income on health care claims and quality improvement
  - Only 20% premium income spent on administration, marketing, and profit
    - MLR threshold is higher for large group plans, which must spend at least 85% of premium dollars on health care and quality improvement

"Explaining Health Care Reform: Medical Loss Ratio (MLR), Kaiser Family Foundation Feb, 29, 2010, http://kff.org/health-reform/fact-sheet/explaining-health-care-reform-medical-loss-ratio-mlr/ (Accessed 8/28/2013).

ACA Impact on Medicare

- Medicare is required to:
  - Provide a productivity adjustment and reductions to market basket updates for many providers
  - Make several concessions to expand primary care, coordinated care, and delivery system reform
  - Support quality initiatives
  - Add restrictions on revenue spending in 2014 for Medicare Advantage plans
  - Update disproportionate share payments (DSH)

ACA Impact on Medicare

- Medicare requirements, continued:
  - Enforce provisions to continuously reduce the gap between generic and brand-name drugs by 2020
  - Add restrictions on revenue spending in 2014 for Medicare Advantage plans
  - Update disproportionate share payments (DSH)

Medicaid Expansion

- SCOTUS invalidated the ACA provisions that mandated states to expand their Medicaid programs or lose all matching federal funds
- States now have the choice to:
  - Opt into the Medicaid expansion in exchange for significant federal assistance; or,
  - Maintain their Medicaid programs' status quo
- For those that expand Medicaid, anyone whose salary was 138% of Federal Poverty Level would be covered under Medicaid
- 47.6 million nonelderly Americans meet these criteria

"How will the Medicaid Expansion for Adults Impact Eligibility and Coverage? Kaiser Family Foundation, April 7, 2014, http://kff.org/health-reform/fact-sheet/how-will-the-uninsured-fare-under-the-affordable-care-act/ (Accessed 9/8/2015).

Medicare Shared Savings Program

- Intent
  - To promote accountability for a population of Medicare beneficiaries
  - Improve the coordination of FFS items and services, encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery
  - Incentivize higher value care
- ACO may share in a percentage of its savings if it meets certain safety and quality requirements

"Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations," Centers for Medicare and Medicaid Services, 42 CFR 425 Federal Register, Vol. 70, No. 67, (April 7, 2011), p. 19533.

Medicare Shared Savings Program

Next Generation ACOs

- New Tracks:
  - Risk sharing rates of 80%, which will increase to 85% in three years
  - *Full Performance Risk* – ACO bears 100% of the risk
  - Both tracks are subject to a 15% cap

Track 3 ACOs

- Track 1 – "one-sided" risk
  - ACO not held accountable for losses with a 50% share rate
- Track 2 – "two-sided" risk
  - Share in losses and savings of up to 60%
- Track 3
  - Share in losses and savings of up to 75%

"Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations," Centers for Medicare and Medicaid Services, 42 CFR 425 Federal Register, Vol. 70, No. 67, (April 7, 2011), p. 19533.

ACO Waivers

- Intended to enable ACOs to align performance (clinical and cost) with financial models to change the way care is delivered
- Types of Waivers:
  - ACO Pre-Participation Waiver
  - ACO Participation Waiver
  - Shared Savings Distributions Waiver
  - Compliance with Stark Law Waiver
  - Patient Incentive Waiver

ACO Waivers

- Uncertainty regarding longevity of ACO waivers
  - October 2015 – CMS issued its final rule implemented the waivers
  - Both CMS and OIG noted that further rules and modifications may be implemented

"Medicare Program; Final Waivers in Connection with the MSSP" Federal Register Vol. 80, No. 209 (October 29, 2015) p. 66742-43.

Clinically Integrated Networks (CINs)

- Networks of interdependent facilities and providers, which collaborate to develop and sustain clinical initiatives
- Forms of clinical integration
  - Care coordination for a specific clinical condition
  - Vertical integration
  - Horizontal integration
- Laws involved:
  - Stark, Anti-kickback Statute, federal tax exemption laws, antitrust laws, state insurance laws

"Developing an Effective Clinically Integrated Network," By Max Reibolt et al., Coker Group, July 2013. "Considerations for Clinical Integration," By Jason Godlwater, MA, MPA & Larry Yuhasz, Truven Health Analytics, December 2011, p. 3.

Bundled Payments for Care Improvement

- A demonstration program launched by CMS whereby healthcare organizations are compensated with a single payment for both:
  - The hospital ancillary and technical component services
  - The physician professional component services related to a single episode-of-care
- Goals
  - *Align incentives* among hospitals, physicians, & other providers
  - Achieve *higher quality, more coordinated care at a lower cost to Medicare*

"CMS Finalizes Bundled Payment Initiative for Hip and Knee Replacements" U.S. Department of Health and Human Services, November 16, 2015, http://www.hhs.gov/about/news/2015/11/16/cms-finalizesbundled-payment-initiative-hip-and-knee-replacements.html (Accessed 12/1/2015).

Concluding Remarks

Concluding Remarks

Pursuing Interdisciplinary Collaboration

Healthcare Industry Specific Appraisal Assignments

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Personal Property • Business Valuation • Intangible Assets/IP

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- Shared Clients
- Interdisciplinary Approach Yields Significant Benefit to Both ***Clients*** and ***Appraisers***

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Concluding Remarks
We Can (and should) All Work Together!

- To obtain the requisite background for forecasting the future performance of healthcare enterprises, assets, and services in the current dynamic era of healthcare reform, valuation professionals should develop and maintain an in-depth understanding of the history and the development of healthcare delivery, as well as, the unique dynamics of those often complex business arrangements that comprise newly emerging healthcare organizations and the various elements of property value involved in each.
- A multidisciplinary project team of appraisers has the potential to provide an enhanced scope and diversity of knowledge and breadth of experience to the benefit of both the ***appraisers*** and the ***client***.

Concluding Remarks
We Can (and should) All Work Together!

- When developing an understanding of the forces and stakeholders that have the potential to drive healthcare markets, valuation professionals must examine the subject enterprises, assets, and services as they relate to and within the context of:
- ***"The Four Pillars of the Healthcare Industry"***
  - Reimbursement
  - Regulatory
  - Competition
  - Technology
- These four elements serve as a conceptual framework for analyzing the viability, efficiency, efficacy, and productivity of the subject property interest(s)

Concluding Remarks

We Can All Work Together!

- More informed and uniform valuation practice would benefit the users of healthcare valuations and *improve public confidence in appraisers*
- To enhance competency, significant specialized education and training is an important benefit for healthcare appraisers and clients
- Given these issues, a multidisciplinary approach toward advanced education related to healthcare industry valuation is an important initiative of the ASA, as the premier multidisciplinary valuation society of professional appraisers

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			Session Details			Time				Speakers		
		Program Events	Course Title	Presentation Day	Time of Day	Date	Start	End	Duration	Presenter	Co-Presenter	
1	DAY 1	Registration and Breakfast		Friday	Morning	5/6/2016	7:30 AM	8:15 AM	45 Minutes			1
2		Session 1	*Overview of Healthcare Industry*	Friday	Morning	5/6/2016	8:15 AM	9:15 AM	1 Hour	Bob Cimasi, ASA		2
3		Session 2	*Regulatory Environment of the Healthcare Industry*	Friday	Morning	5/6/2016	9:15 AM	10:30 AM	1 Hour 15 Minutes	Mark Mattioli, Esq.	Todd Zigrang, ASA	3
4		Break		Friday	Morning	5/6/2016	10:30 AM	10:45 AM	15 Minutes			4
5		Session 2	*Regulatory Environment of the Healthcare Industry*	Friday	Morning	5/6/2016	10:45 AM	12:30 PM	1 Hour 45 Minutes	Mark Mattioli, Esq.	Todd Zigrang, ASA	5
6		Lunch		Friday	Afternoon	5/6/2016	12:30 PM	1:30 PM	1 Hour			6
7		Session 2	*Regulatory Environment of the Healthcare Industry*	Friday	Afternoon	5/6/2016	1:30 PM	2:15 PM	45 Minutes	Mark Mattioli, Esq.	Todd Zigrang, ASA	7
8		Session 3	*Impact of Competitive Forces*	Friday	Afternoon	5/6/2016	2:15 PM	3:15 PM	1 Hour	Roger Strode, Esq.	Todd Zigrang, ASA	8
9		Break		Friday	Afternoon	5/6/2016	3:15 PM	3:30 PM	15 Minutes			9
10		Session 3	*Impact of Competitive Forces*	Friday	Afternoon	5/6/2016	3:30 PM	5:00 PM	1 Hour 30 Minutes	Roger Strode, Esq.	Todd Zigrang, ASA	10
11	DAY 2	Breakfast		Saturday	Morning	5/7/2016	7:30 AM	8:00 AM	30 Minutes			11
12		Session 5	*Technology Development*	Saturday	Morning	5/7/2016	8:00 AM	11:00 AM	3 Hours	Col. Geoff Ling, MD, PhD	Bob Cimasi, ASA	12
13		Lunch		Saturday	Afternoon	5/7/2016	11:00 AM	12:00 PM	1 Hour 15 Minutes			13
14		Session 5	*Healthcare Reimbursement Environment in an Era of Reform*	Saturday	Morning	5/7/2016	12:00 PM	3:00 PM	3 Hours	Shari Ling, MD	Bob Cimasi, ASA	14
15		Break		Saturday	Afternoon	5/7/2016	3:00 PM	3:15 PM	15 Minutes			15
16		Session 6	*Q & A - Discussion Conclusion and Course Review*	Saturday	Afternoon	5/7/2016	3:15 PM	3:45 PM	30 Minutes	Bob Cimasi, ASA		16
17		Session 6	*Examination*	Saturday	Afternoon	5/7/2016	3:45 PM	4:45 PM	1 Hour			17