Can't See the Forest for the Trees

The Misapplication of Economic Theory to the Increasing Regulatory Trend Against Vertical Healthcare Integration

Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA
Chief Executive Officer, HEALTH CAPITAL CONSULTANTS

NACVA and the CTI's
Business Valuation and Healthcare Valuation Conference
September 19-21, 2016 | Washington, DC

DISCLAIMER

The information contained in this presentation is only intended for general purposes.

It is designed to provide authoritative and accurate information about the subject covered. It is sold with the understanding that the copyright holder is not engaged in rendering legal, accounting, or other professional service or advice. If legal or other expert advice is required, the services of an appropriate professional person should be sought.

The material may not be applicable or suitable for the reader's specific needs or circumstances. Readers/viewers may not use this information as a substitute for consultation with qualified professionals in the subject matter presented here.

Although information contained in this publication has been carefully compiled from sources believed to be reliable, the accuracy of the information is not guaranteed. It is neither intended nor should it be construed as either legal, accounting, and/or tax advice, nor as an opinion provided by the Consultants' Training Institute (CTI), the National Association of Certified Valuators and Analysts (NACVA), the Institute of Business Appraisers (IBA), the presenter, or the presenter's firm.

The authors specifically disclaim any personal liability, loss, or risk incurred as a consequence of the use, either directly or indirectly, of any information or advice given in these materials. The instructor's opinion may not reflect those of the CTI, NACVA, IBA, their policies, other instructors, or materials.

Each occurrence and the facts of each occurrence are different. Changes in facts and/or policy terms may result in conclusions different than those stated herein. It is not intended to reflect the opinions or positions of the authors and instructors in relation to any specific case, but, rather, to be illustrative for educational purposes. The user is cautioned that this course is not all inclusive.

The Consultants' Training Institute (CTI) is registered with the National Association of State Boards of Accountancy (NASBA) as a sponsor of continuing professional education on the National Registry of CPE Sponsors. State boards of accountancy have final authority on the acceptance of individual courses for CPE credit. Complaints regarding registered sponsors may be submitted through its web site: learningmarket.org.

Presenter Bio

Robert James Cimasi, MHA, ASA, MCBA, FRICS, CVA, CM&AA, serves as Chief Executive Officer of **HEALTH CAPITAL CONSULTANTS** (HCC), a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including valuation consulting and capital formation services; healthcare industry transactions, including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and certificate-of-need and other regulatory and policy planning consulting.

Mr. Cimasi is a nationally known speaker on healthcare industry topics and the author of numerous peer-reviewed articles, chapters in legal treatises and anthologies, and nationally published books, including: "*Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*" [2014 - John Wiley & Sons]; "*Accountable Care Organizations: Value Metrics and Capital Formation*" [2013 - Taylor & Francis]; and, his most recent book, "*The Adviser's Guide to Healthcare – 2nd Edition*" [2015 - AICPA].

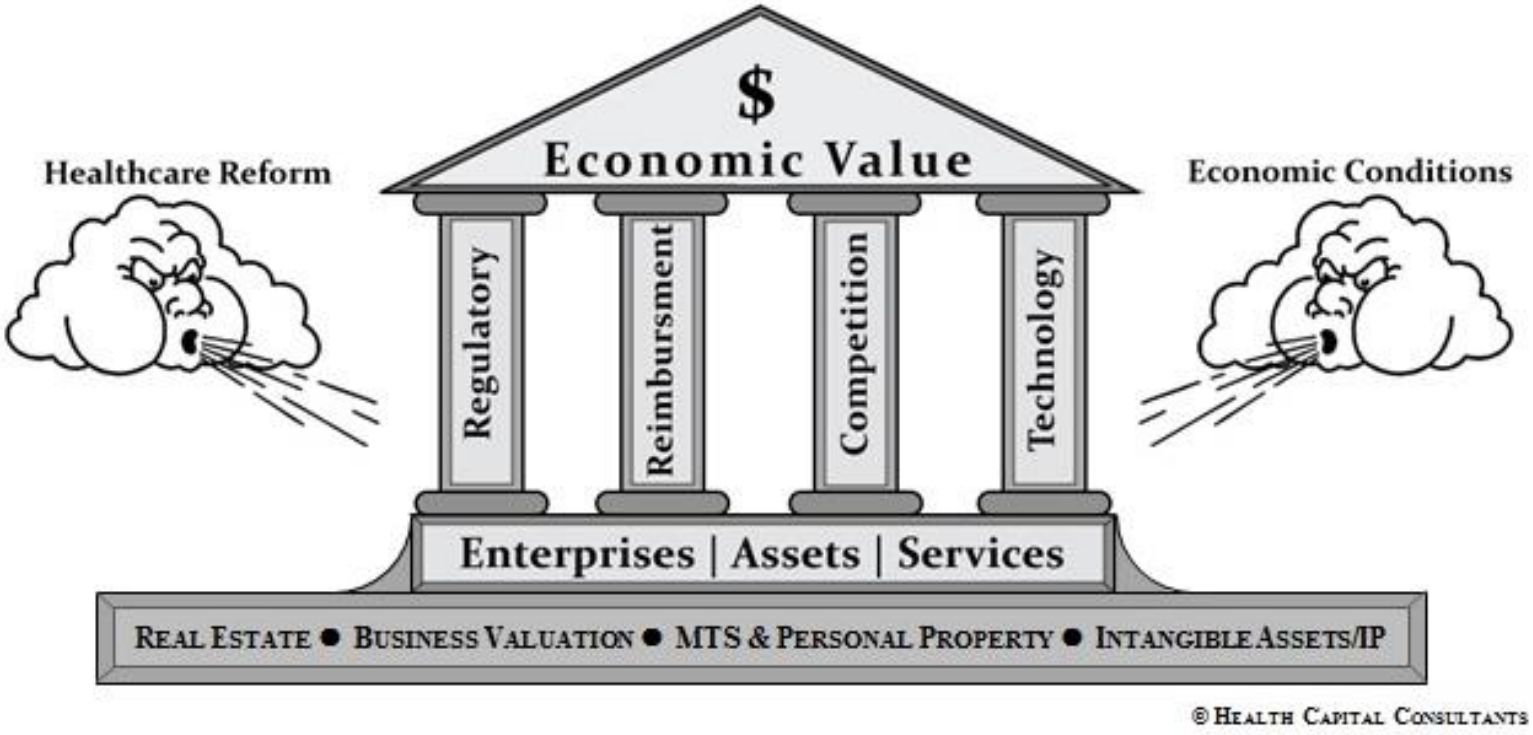
In 2006, Mr. Cimasi was honored with the prestigious "*Shannon Pratt Award in Business Valuation*" conferred by the Institute of Business Appraisers (IBA). He serves on the Editorial Board of the Business Appraisals Practice of the IBA, of which he is a member of the College of Fellows; and, as *Chair Emeritus* of the American Society of Appraisers Healthcare Special Interest Group (ASA HSIG). In 2011, he was named a Fellow of the Royal Institution of Chartered Surveyors (RICS). In 2016, Mr. Cimasi was named a "*Pioneer of the Profession*" as part of the recognition of the National Association of Certified Valuators and Analysts (NACVA) "*Industry Titans*" awards, which distinguishes those whom have had the greatest impact on the profession. You can see his full CV at

https://www.healthcapital.com/hcc/html2pdf30/RCimasi_CV.pdf.

Overview of Presentation

- Regulatory Environment for Healthcare Providers
- Description of the *Practice Loss Postulate* (PLP)
- Description of Vertical Integration
- Arguments Against the PLP
  - Economic Arguments against the PLP
  - Failure of the PLP's Commercial Reasonableness Argument
- Conclusion: PLP is Misguided and Imprudent

Healthcare Trends: *The Four Pillars*



Regulatory Environment for Healthcare Providers

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

Differences between Stark Law and Anti-kickback Statute

	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).

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. § 1320a-7b(b) (2014); "Hanlester Network v. Shalala" 51 F.3d 1390 (9th Cir. 1995); "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 10606, 124 Stat. 119, 689 (March 23, 2010).

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

"Special Fraud Alerts" Office of Inspector General, U.S. Department of Health & Human Services, http://oig.hhs.gov/compliance/alerts/index.asp (Accessed 9/6/2016); "Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability" Office of Inspector General, U.S. Department of Health & Human Services, June 9, 2015, https://oig.hhs.gov/compliance/alerts/guidance/Fraud_Alert_Physician_Compensation_06092015.pdf (Accessed 1/19/2016).

The Anti-Kickback Statute
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.

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).

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" Federal Register, Vol. 54, No. 13 (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.

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

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)

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

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).; "Prohibition on Certain Referrals by Physicians and Limitations on Billing" 42 C.F.R. § 411.353 (2015).

Stark Law
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

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

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 Law

- 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).

Differences between Stark Law and Anti-kickback Statute (continued)

	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).

Differences between Stark Law 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. § 1320a-7b(b) (2014); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn (2014).

Differences Between Stark Law and Anti-Kickback Statute (continued)

Anti-Kickback

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

Stark

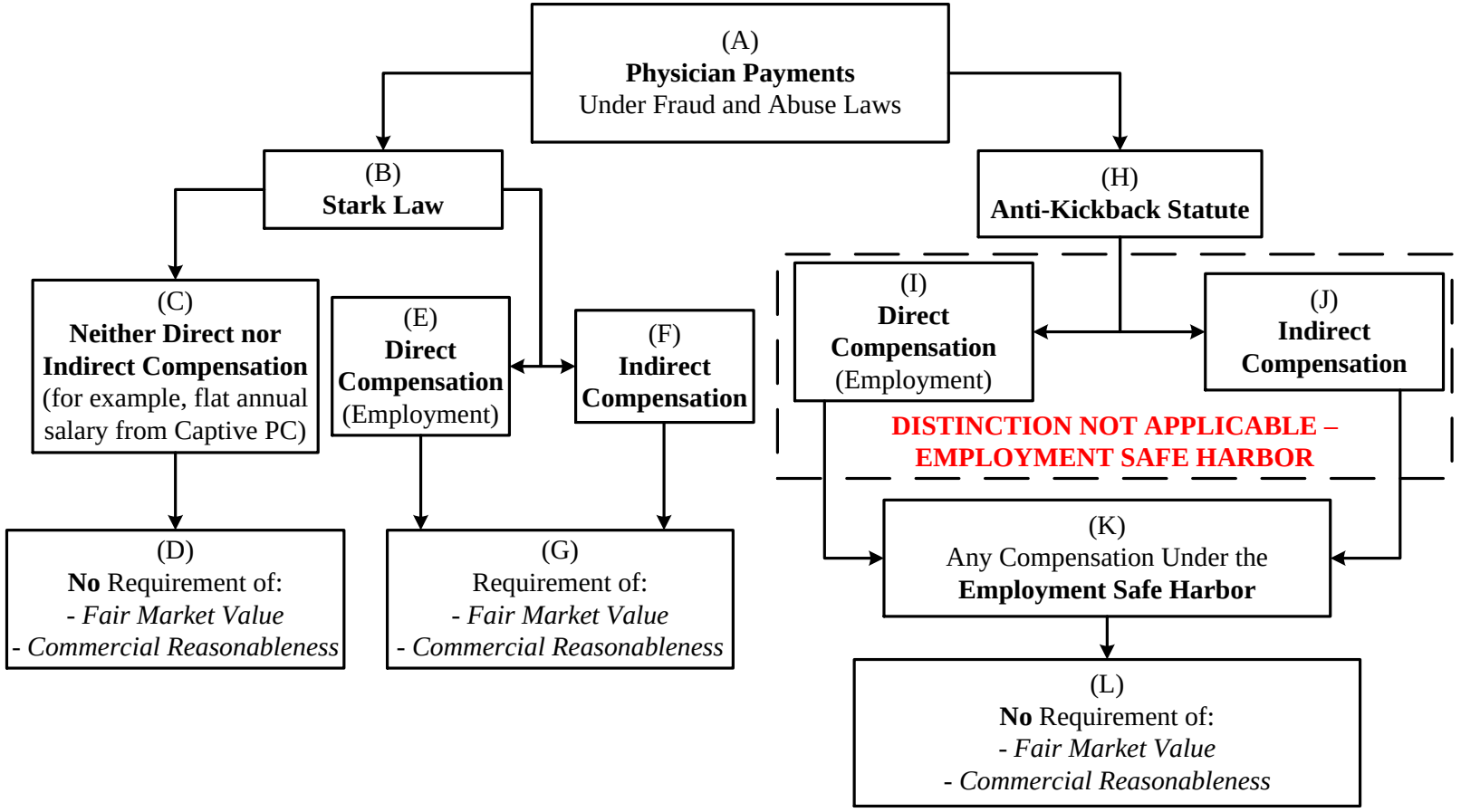
- Strict liability
- Civil liability
- Applies only to financial relationships with "physicians" or immediate family members
- Exceptions- "Must"

Determining Regulatory Compliance

- Thresholds for satisfying Fraud and Abuse laws
- Vary by:
  - Type of integration in question
    - Horizontal Consolidation
    - Vertical Integration
  - Regulatory scheme
    - Stark Law
    - *Anti-Kickback Statute* (AKS)

Determining Regulatory Compliance

- Employment Arrangement – Case Study



Determining Regulatory Compliance

- Compensation details under the **Stark Law**
  - Vary based on whether compensation arrangement is ***Direct*** or ***Indirect***
  - Direct Compensation Arrangement – "*if remuneration passes between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS without any intervening persons or entities*"

    – 42 C.F.R. § 411.354(c)(1)(i)

"Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357(c), (p) (2015).

Determining Regulatory Compliance

- Compensation details under the **Stark Law**
  - Vary based on whether compensation arrangement is ***Direct*** or ***Indirect***
  - Indirect Compensation Arrangement – Must Satisfy Three Parts - 42 C.F.R. §411.354(c)(2)
    - "*Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one) of persons or entities that have financial relationships…between them*"
    - "*The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation*"
    - "*The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS*"

"Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357(c), (p) (2015).

Determining Regulatory Compliance

- Employment and Indirect Compensation Exceptions BOTH Require:
  - *Fair Market Value* (FMV)
  - *Commercially Reasonable*

"Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357(c), (p) (2015).

Determining Regulatory Compliance

- Compensation details under the **Anti-Kickback Statute**
  - Employment Safe Harbor – "*'remuneration' does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.*" – 42 CFR § 1001.952 (2015)
  - No consideration of ***direct*** or ***indirect*** compensation arrangement
  - Safe Harbor does ***not*** require arrangement to be:
    - *Fair Market Value* (FMV)
    - *Commercially Reasonable*

"Exceptions" 42 C.F.R. § 1001.952(i) (2015).

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).

Fair Market Value and 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

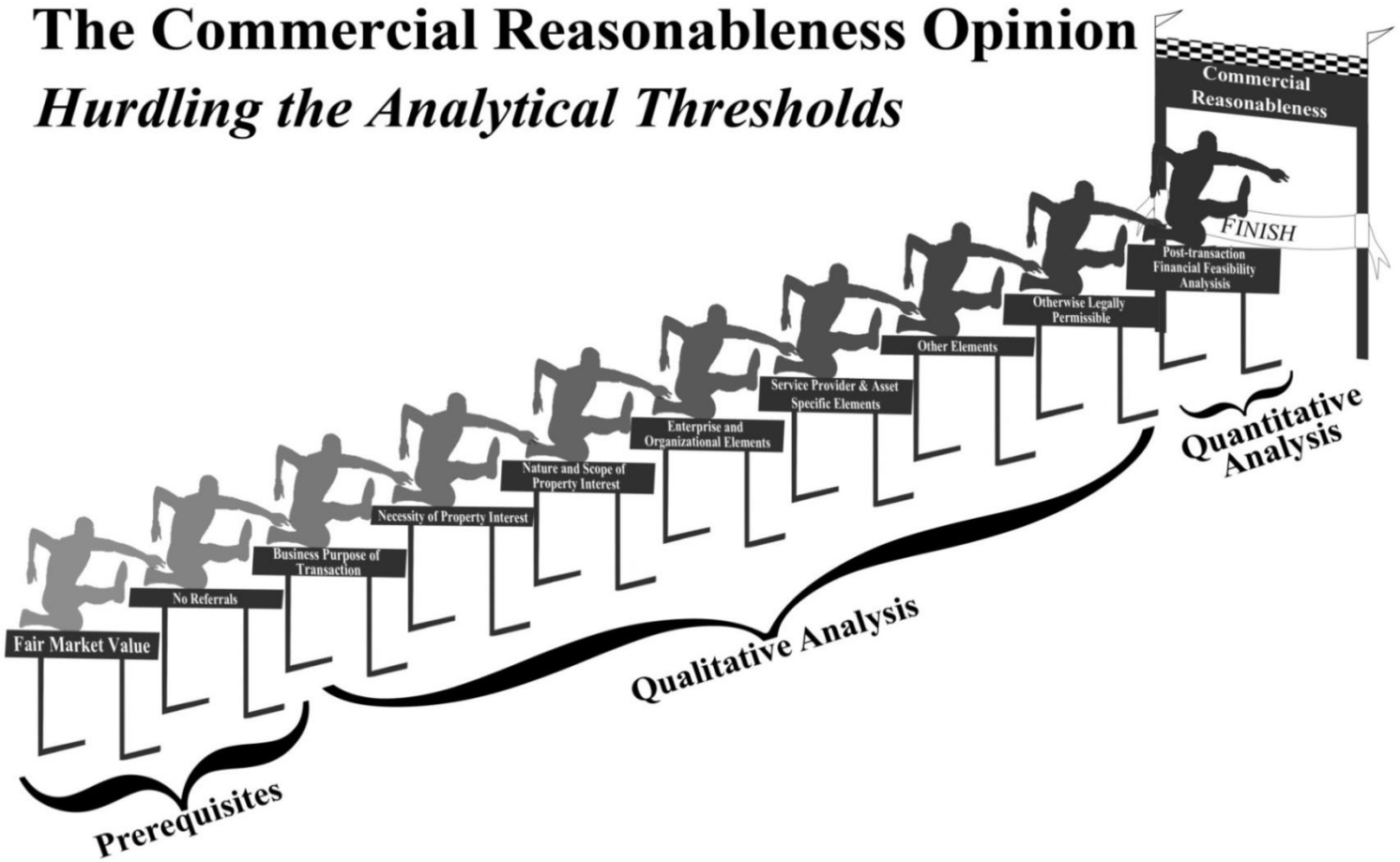
"Tread Carefully When Setting Fair Market Value: Stark Law Must Be Considered" Joyce Frieden, November 1, 2003, http://findarticles.com/p/articles/mi_m0CYD/is_/ai_110804605 (Accessed 9/26/08).

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.

Determining Commercial Reasonableness



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

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.

Antitrust Regulations

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 (2014). "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).

Antitrust Regulations

- Antitrust Scrutiny – *St. Luke's (2015)*
  - 9th Circuit Court of Appeals Opinion which confirmed trial court's ruling ordering the divestiture of the acquisition of Saltzer medical practice, located in Nampa, ID, by St. Luke's Hospital, approximately 20 miles east in Boise, ID
  - 9th Circuit Analysis Relevant to Vertically Integrated Healthcare Systems
    - Relevant Market
    - Market Share
    - Potential Benefits of Vertical Integration in Healthcare

"*Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System, Ltd.*" 778 F.3d 775 (9th Cir. 2015).

Antitrust Regulations

- Antitrust Scrutiny – *St. Luke's (2015)*
  - Relevant Market
    - Product: Adult Primary Care Services Sold to Commercially Insured Patients
    - Geographic Market: Nampa, ID
      - Court considered either Boise, ID, or Nampa, ID
      - Dependent on Ability of Health Insurers to Develop Adequate Network of Primary Care Physicians
      - Court noted 68% of Nampa residents obtain primary care services from local physicians, with only 15% of residents obtaining the same from nearby Boise

"*Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System, Ltd.*" 778 F.3d 775 (9th Cir. 2015) p. 15.

Antitrust Regulations

- Antitrust Scrutiny – *St. Luke's (2015)*
  - Market Share
    - Combined market share of St. Luke's and Saltzer primary care physicians accounted for almost 80% of adult primary care services in Nampa
    - St. Luke's and Saltzer documents indicated that both parties viewed the consolidation important because of increase in leverage to obtain higher payment rates

"*Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System, Ltd.*" 778 F.3d 775 (9th Cir. 2015) p. 15; "Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System, Ltd." Case No. 1:12-CV-00560-BLW (Dist. Ct. Idaho 2014), p. 3.

Antitrust Regulations

- Antitrust Scrutiny – *St. Luke's (2015)*
  - Discussion of Potential Benefits of Vertical Integration
    - Court noted that St. Luke's provided little to no evidence to support St. Luke's theory that it needed Saltzer primary care physicians to successfully transition to integrated care
    - Court also noted that St. Luke's did not prove that practice acquisition is required to implement electronic medical records
    - Court noted that, although vertical integration is a worthy goal, providers still need to obey antitrust regulations

"*Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System, Ltd.*" 778 F.3d 775 (9th Cir. 2015) p. 15; "Saint Alphonsus Medical Center-Nampa, Inc. v. St. Luke's Health System, Ltd." Case No. 1:12-CV-00560-BLW (Dist. Ct. Idaho 2014), p. 3.

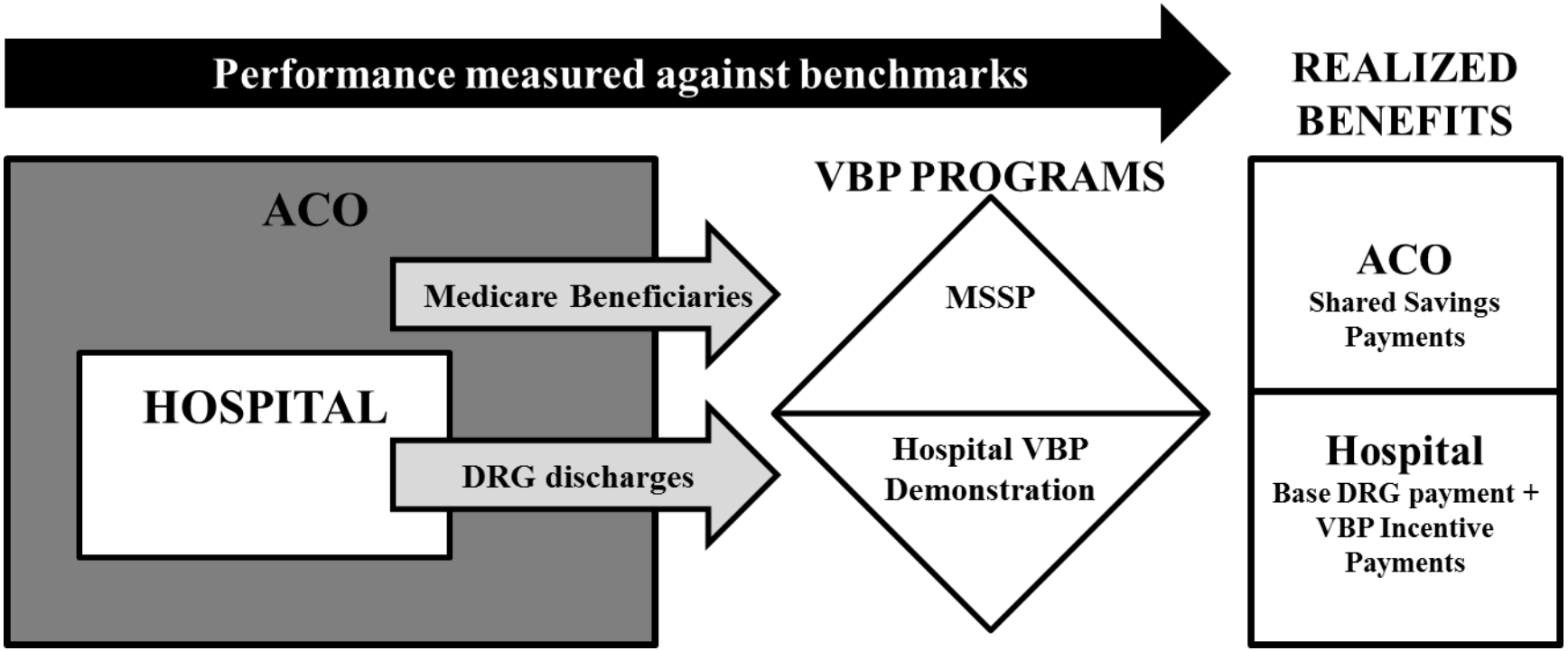
Reimbursement/Regulatory Trends

Value-Based Purchasing (VBP)

- Any model of provider payments that links reimbursement or incentive bonus payments to the quality and the cost of care which a provider can achieve for a defined patient population
- Rewards are offered to providers who meet:
  - Established standards for patient health outcomes; and,
  - Set percentage reductions in actual patient expenditures
- Example: Medicare Shared Savings Program (MSSP)
  - Links shared savings incentive payments to ACO participants that achieve established quality metrics and expenditure reductions for Medicare beneficiaries

"Lessons from Medicare's Demonstration Projects on Disease Management, Care Coordination and Value-based Payment", By Lyle Nelson, Congressional Budget Office, January 2012, p. 1; "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations," Federal Register Vol. 76 No. 212, (November 2, 2011); "Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons Inc., 2014, p. 242.

Illustration of Value-Based Purchasing Models



"Accountable Care Organizations: A Roadmap for Success: Guidance on First Steps" By Bruce Flareau and Joe Bohn, 1st ed., Virginia Beach, VA: Convergent Publishing, LLC, 2911, p. 22.

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- Repealed the SGR and replaced it with a series of pre-determined updates
  - Vary based on payment model used by provider
- Annual conversion factor updates
  - July 2015 to December 2019 – 0.5%
  - 2020 to 2025 – 0.0%
  - 2026 forward – 0.25%
    - 0.75% for a*lternative payment model* (APM) participants

"Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. No. 114-10, § 101, 129 Stat. 87, 89-90, 91 et seq. (2015).

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- April 27, 2016, CMS issued a notice of proposed rulemaking related to implementation of MACRA
- Created the "Quality Payment Program" (QPP) framework, which has two tracks
  - *Merit-Based Incentive Payment System* (MIPS) – Scores providers based on metrics in four categories: Cost, Quality, Clinical Practice Improvement, and Advancing Care Information
  - *Advanced Alternative Payment Models* (APMs) – Based on participation in programs in which *"clinicians accept both risk and reward for providing coordinated, high-quality, and efficient care."*

"Quality Payment Program" Centers for Medicare & Medicaid Services, 2016, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/NPRM-QPP-Fact-Sheet.pdf (Accessed 5/3/16), p. 1-4.

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- *Merit-Based Incentive Payment System* (MIPS)
  - Consolidation of various quality programs undertaken by the *Centers for Medicare and Medicaid Services* (CMS) into one value-based reimbursement model
    - *Physician Value-Based Payment Modifier* (PVBM)
    - *Physician Quality Reporting System* (PQRS)
    - *Meaningful use electronic health record* (EHR) incentive program

"Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician Focused Payment Models" Federal Register Vol. 81, No. 89 (May 9, 2016), p. 28168.

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- *Merit-Based Incentive Payment System* (MIPS)
  - MIPS will increase or decrease payments to providers based on certain performance metrics in the fields of:
    - Quality
    - Efficiency
    - Meaningful use of EHR
    - Clinical practice improvement activities

"May the Era Of Medicare's Doc Fix (1997-2015) Rest In Peace. Now What?" By Billy Wynne, Health Affairs Blog, April 14, 2015, http://healthaffairs.org/blog/2015/04/14/may-the-era-of-medicares-doc-fix-1997-2015-rest-in-peace-now-what/ (Accessed 4/22/2015); "Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. 114-10, § 101, 129 Stat. 96 (April 16, 2015).

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- *Advanced Alternative Payment Models* (APMs)
  - Includes ACOs, Patient-Centered Medical Homes, and other provider models created by CMS
  - To qualify as an APM participant, a provider must meet certain thresholds
    - 2019-2020: Receive at least 25 percent of payments through an eligible alternative payment entity
    - 2021-2022: Receive at least 50 percent of payments through an eligible alternative payment entity
    - 2023 forward: Receive at least 75 percent of payments through an eligible alternative payment entity

"Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. 114-10, § 101, 129 Stat. 118-121 (April 16, 2015). See the text of the statute for specific requirements for each period.

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- *Advanced Alternative Payment Models* (APMs)
  - An *alternative payment entity* is defined as an entity that:
    - Participates in an APM and meets the following requirements:
      - Requires participants in the model to use certified EHR technology
      - Provides for payment based on certain quality measures
    - Bears financial risk for material monetary losses under the APM
    - Is a medical home

"Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. 114-10, § 101, 129 Stat. 121-122 (April 16, 2015).

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

- *Advanced Alternative Payment Models* (APMs)
  - Providers that qualify as APM participants between 2019 and 2024 receive a five (5) percent bonus payment for services furnished to Medicare beneficiaries, paid in an annual lump sum
  - Beginning in 2026, the annual update to Medicare payments to providers who *do not* qualify as APM participants is 0.25 percent, while the annual update to Medicare payments for qualifying APM participants is 0.75 percent

"Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. 114-10, § 101, 129 Stat. 90, 117-118 (April 16, 2015).

15 Minute Break

Description of the Practice Loss Postulate

"Plentie is no deintie,

ye see not your owne ease.

I see, ye can not see

the wood for trees."

- John Heywood, 1546

"The Proverbs of John Heywood: Being the 'Proverbes' of That Author Printed 1546. Ed., with Notes and Introduction" By Julian Sharman, London, England: George Bell and Sons, 1874, p. 107.
Per Oxford English Dictionary: (1) "*Plentie*," or "*Plenty*" is defined as "*a full or ample amount, a sufficiency, more than enough*"; (2) "*Deintie*," or "*Dainty*" is defined as "*Estimation, honour, favour (in which anything is held)*"; (3) "*Ease*" is defined as "*Absence of painful effort; freedom from the burden of toil; leisure; in bad sense, idleness, sloth*"; and, (4) "*Wood*" is defined as "*A collection of trees growing more or less thickly together…*"; in modern meaning, i.e., "*The assumption of being wholly sufficient is not worthy, you see not your own indolence. I see, you cannot see the forest for the trees.*"

The Practice Loss Postulate

- Regulators have increasingly challenged healthcare vertical integration transactions pursuant to the *Anti-Kickback Statute* (AKS), Stark Law, and *False Claims Act* (FCA)
- An increasing volume of cases are based, in part, on the *Practice Loss Postulate* (PLP)
  - The acquisition of a physician practice, which then operates at a "*book financial loss*", is dispositive evidence of the hospital's payment of consideration based on the volume and/or value of referrals

"Whistle-blower Worries: Hospitals Likely to See More False Claims Suits Tied to Doctor Compensation" By Lisa Schencker, Modern Healthcare, November 21, 2015, http://www.modernhealthcare.com/article/20151121/MAGAZINE/311219980 (Accessed 5/10/16).

The Practice Loss Postulate

- Employment Arrangements are merely one potential integration strategy available, as there are other integration strategies (e.g., professional services arrangements, clinically integrated networks, clinical co-management arrangements, or joint ventures) which may also implicate separate regulatory exceptions and safe harbors
- In particular, the Stark Law has evolved into a web of rules that may complicate providers' efforts toward regulatory compliance

"*It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the False Claims Act*."

– Judge James A. Wynn, Jr., Concurring Opinion, *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d. 364, 395 (4th Cir. 2015).

"U.S. ex rel. Drakeford v. Tuomey" 792 F.3d 364, 395 (4th Cir. 2015); "Whistle-blower Worries: Hospitals Likely to See More False Claims Suits Tied to Doctor Compensation" By Lisa Schencker, Modern Healthcare, November 21, 2015, http://www.modernhealthcare.com/article/20151121/MAGAZINE/311219980 (Accessed 5/10/16).

The Practice Loss Postulate

- Case Law Implicating Practice Loss Postulate

	A	B	C	D	
	Case Name	Alleged Violation		Relationship Between Hospital and Physicians	
		Stark Law	Anti-Kickback Statute		
1	U.S. ex rel. Drakeford v. Tuomey Healthcare System	X		Part-Time Employee	1
2	U.S. ex rel. Parikh v. Citizens Medical Center	X	X	Full-Time Employee	2
3	U.S. ex rel. Reilly v. North Broward Hospital District	X	X	Full-Time Employee	3
4	U.S. ex rel. Payne v. Adventist Health System	X	X	Full-Time Employee; Independent Contractor	4

The Practice Loss Postulate

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System (2012)*
  - Relator alleged that Tuomey 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 below the 75th percentile, but compensation was over the 90th percentile

"United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." 675 F.3d 394, 399 (4th Cir. 2012).

The Practice Loss Postulate

- *U.S. ex rel. Drakeford v. Tuomey Healthcare System (2012)*
  - In considering the allegations, the U.S. District Court for the District of South Carolina received expert testimony from the relator and the DOJ's expert witness Kathleen McNamara, who utilized the PLP as follows:

"*Case documents I examined and the testimony I reviewed shows that Tuomey took into account the value and volume of anticipated physician referrals by…Acknowledging that the hospital's technical and facility fees earned each time the physicians performed an outpatient surgery are reasonable "off-sets" for its $1.5 [million] annual operating losses. Notably because Tuomey's technical and facilities earned [sic] are deemed to be the physicians' patient referrals.*" [Emphasis Added]

"United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." 675 F.3d 394, 399 (4th Cir. 2012); "United States ex rel. Drakeford v. Tuomey Healthcare System, Inc." Case No. 3:05-CV-2858 (D.S.C. October 15, 2012), Supplement to Expert and Rebuttal Reports, By Kathleen McNamara, p. 15.

The Practice Loss Postulate

- *U.S. ex rel. Parikh v. Citizens Medical Center (2013)*
  - *Citizens Medical Center* (CMC) allegedly paid bonuses and financial incentives to physicians who referred patients for treatment
  - Physicians' income more than doubled when they became employed by CMC

"U.S. ex rel. Parikh v. Citizens Medical Center" Case No. 6:10-cv-00064, (S.D. TX. September 20, 2013), Memorandum and Order, p. 25.

The Practice Loss Postulate

- *U.S. ex rel. Parikh v. Citizens Medical Center (2013)*
  - In a 2013 order denying CMC's motion to dismiss the relator's claims that CMC violated the AKS and Stark Law, Judge Gregg Costa of the U.S. District Court for the Southern District of Texas stated:

"[*I*]*t would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it was doing so for some ulterior motive—a motive Relators identify as a desire to induce referrals.*"

"U.S. ex rel. Parikh v. Citizens Medical Center" Case No. 6:10-cv-00064, (S.D. TX. September 20, 2013), Memorandum and Order, p. 27-28.

The Practice Loss Postulate

- *U.S. ex rel. Reilly v. North Broward Hospital District (2015)*
  - Relator alleged that Broward Health purposely tracked referrals from physicians to the hospital for *ancillary services and technical component* (ASTC) in "*Contributive Margin Reports,*" which were then used to cover the "*massive direct losses*" from excessively compensating physicians in violation of the AKS and Stark Law
  - The complaint alleged that these reports track "*the revenue from every admission, every ancillary, anything that's done to patients of employed physicians*"

"U.S. ex rel. Reilly v. North Broward Hospital District" Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relators Third Complaint under Federal False Claims Act, p. 28-31.

The Practice Loss Postulate

- *U.S. ex rel. Reilly v. North Broward Hospital District (2015)*
  - The complaint against Broward Health relies heavily on the PLP and Broward Health's alleged utilization of the "*Contributive Margin Reports*" in developing the claims of Stark Law and AKS violations, noting:

"*Broward Health's strategic scheme of paying employed physicians more than fair market value and more than they can ever hope to collect for their personal services is not a commercially sustainable business model. This practice is only sustainable by anticipating and allocating hospital referral profits to cover the massive direct losses from excessive physician compensation*." [Emphasis Added]

"U.S. ex rel. Reilly v. North Broward Hospital District" Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relators Third Complaint under Federal False Claims Act, p. 31.

The Practice Loss Postulate

- *U.S. ex rel. Payne v. Adventist Health System (2015)*
  - Relators alleged that Adventist repeatedly authorized *non-commercially reasonable* compensation arrangements that exceeded FMV with employed physicians such that the hospitals would have been forced to operate at a "*book financial loss*"
  - Relators alleged multiple Adventist hospitals overcame these book financial losses through the referrals generated by the employed physicians and by tracking these referrals
  - Alleged that Adventist considered these referrals when entering into the arrangements

"U.S. ex rel. Payne v. Adventist Health System et al." Case no. 3:12cv856-W (W.D.N.C. February 13, 2013), Relators Amended Complaint p. 4-6.

The Practice Loss Postulate

- *U.S. ex rel. Payne v. Adventist Health System (2015)*
  - The allegations against Adventist assume that hospitals and physician practices operate as stand-alone economic enterprises that, individually, must be able to survive independent of the other affiliated service lines in the vertically integrated health system:

"*[Adventist] Hospitals are thus 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*." [Emphasis Added]

"U.S. ex rel. Payne v. Adventist Health System et al." Case no. 3:12cv856-W (W.D.N.C. February 13, 2013), Relators Amended Complaint p. 56.

The Practice Loss Postulate

- Together, these four cases reflect increasing utilization of the PLP in the regulatory scrutiny of vertically integrated health systems
- Under federal *fraud and abuse* laws, healthcare transactions involving *direct* or *indirect* compensation must be demonstrated to both: (a) not exceed FMV; and, (b) be *commercially reasonable*, in order to be deemed legally permissible

"Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a), (e) (2012); "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b) (2012); "Exceptions" 42 C.F.R. § 1001.952(e) (2015).

The Practice Loss Postulate

- A failure to meet these two thresholds may result in Stark Law or AKS violations, in particular, with regard to FMV under these statutory edicts
- The judicial leap, e.g., assuming that *"[p]ayments exceeding FMV are in effect deemed 'payment for referrals'*," irregardless of the totality of the facts and circumstances regarding the total economic benefits of the vertical integration transaction under which these payments were made, illustrates a regulatory propensity to "deem" isolated payment transactions exclusive of their synergistic role with the whole of the enterprise

"Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a), (e) (2012); "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b) (2012); "Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357(h)(5-6) (2015); "Exceptions" 42 C.F.R. § 1001.952(e) (2015); "American Lithotripsy Society v. Thompson, 215 F.Supp. 2d 23, 27 (D.D.C. July 12, 2002), p. 4.

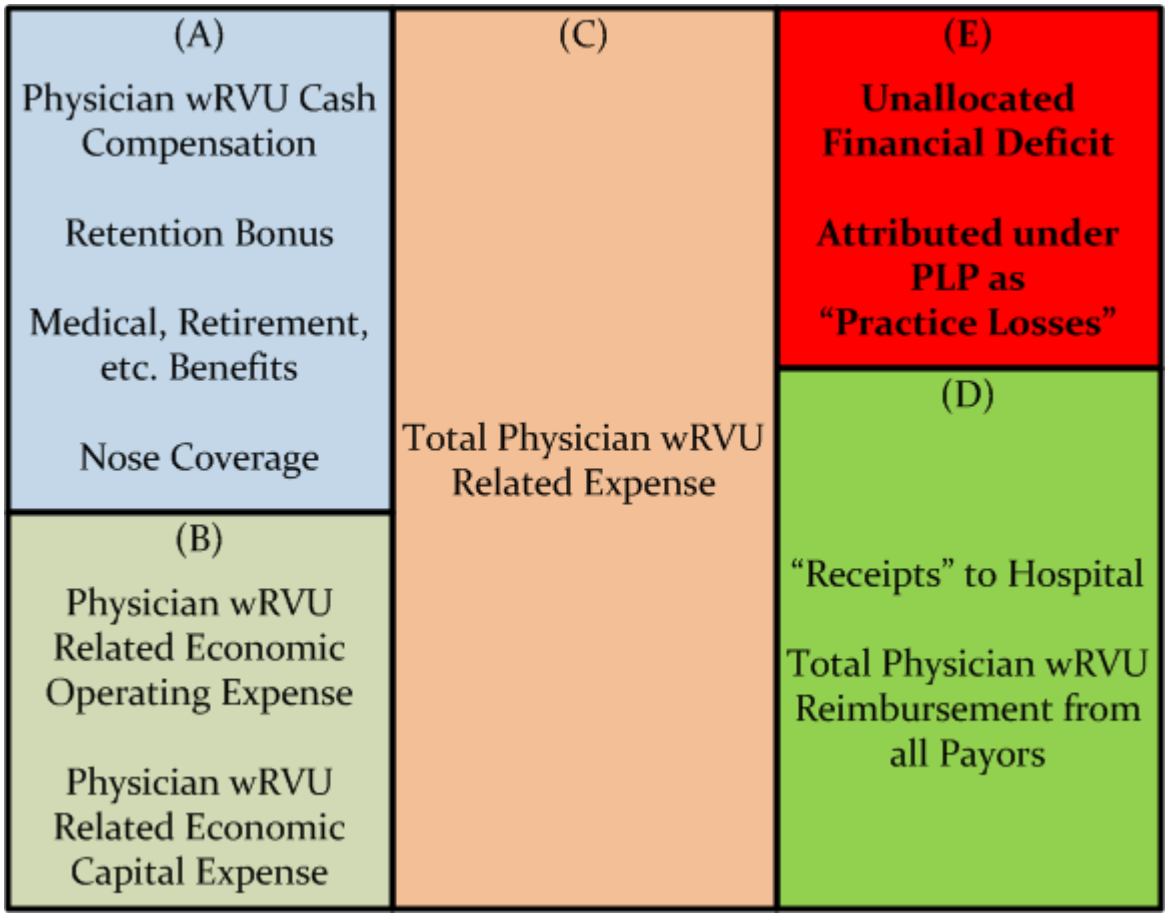
Summary of the Practice Loss Postulate

- The PLP treats vertically integrated physician practices as stand-alone economic enterprises, which, when stripped of their ASTC revenue, and relying solely on professional services, i.e., *work relative value unit* [wRVU] related revenue, and paying physicians at FMV, are almost certain to generate "*book financial losses*"
- The PLP then asserts that the hospital's subsequent losses derived from the operation of the professional practice of the employed physicians is not a subsidy supporting vertical integration
  - Instead , the hospital's sufferance of "*book financial losses*" are viewed as compensation, remuneration, or consideration being paid to the hospital's employed physicians for the referrals of ASTC services to the hospital
  - Such referrals require a physician's authority (i.e., the "*power of prescription*") to order admission, diagnostic tests, drugs, *durable medical equipment*, and other services for their patients

Summary of the Practice Loss Postulate

- In maintaining the economic delineation between physicians and hospitals, the PLP focuses *exclusively* on *immediate* and *direct* **financial (cash)** returns on, and returns of, investments by healthcare organizations related to ***vertical integration*** transactions
- The PLP ignores other economic benefits associated vertical integration in healthcare
  - Social benefit and qualitative gains
  - Avoidance of cost and efficiency gains

Summary of the Practice Loss Postulate



Summary of the Practice Loss Postulate

(E)	(F)	(G)	(H)
Unallocated Financial Deficit **Attributed under PLP as "Practice Losses"**	Non-Monetary Benefits	Avoidance of Cost	Create Operational Efficiencies
		Economies of Scope	
		Economies of Scale	Diversify Supply Chain
		Organization as a Factor of Production	
		Social Benefits	Provide Continuum of Care
			Achieve Care Coordination
			Satisfy the *Triple Aim*
			Improve Population Health
			Complimentary and Requisite Care Mapping of Services

Summary of the Practice Loss Postulate

- Consequently, under the PLP, a "*book financial loss*" on a physician practice borne by a vertically integrated health system, when viewing that practice as a stand-alone economic enterprise, is viewed as evidence of legally impermissible referrals under the Stark Law
- This regulatory conjecture hinders the ability of a vertically integrated health system to withstand fraud and abuse scrutiny, and erects a barrier to satisfying the threshold of *commercial reasonableness*

Description of Vertical Integration

Description of Vertical Integration

- Across all industries, vertical integration may be defined as *"[t]he combination in one firm of two or more stages of production normally operated by separate firms"*
- In healthcare, *vertical integration* describes the "*integration of providers at different points along the continuum of care, such as a hospital partnering with a skilled nursing facility (SNF) or a physician group*"

"Oxford Dictionary of Economics" By John Black, Oxford University Press: New York, NY, 2002, p. 495; "The Value of Provider Integration" American Hospital Association, March 2014, http://www.aha.org/content/14/14mar-provintegration.pdf (Accessed 1/14/16) p. 2.

Potential Benefits of Vertical Integration

- In most industries, vertical integration may provide certain benefits to an organization, including:
  - Economies of Scale
  - Economies of Scope
  - "*Organization*" as a factor of production, which, if considered properly, can lead to production efficiencies

"Principles of Economics" By Alfred Marshall, Eighth Edition, London, England: Macmillan and Co., 1890, Book IV, Chapter XI, p. 232-233; "The Nature of the Firm" By R. H. Coase, Economica, New Series, Vol. 4, No. 16 (November 1937), p. 402.

Potential Benefits of Vertical Integration

- In healthcare, the potential benefits of vertical integration may include, but are not limited to:
  - Satisfaction of the *charitable mission* of the enterprise
  - Achievement of higher levels of *care coordination*

"St. Elizabeth's Hospital – Project Description Review" Health Facilities and Services Review Board, State of Illinois, December 16, 2014, http://www.hfsrb.illinois.gov/Dec14sbr/11.%2014-043%20St%20%20Elizabeth's%20Hospital%20Belleville_2_.pdf (Accessed 3/15/16); "The Triple Aim: Care, Health, and Cost" By Donald M. Berwick, et al., Health Affairs, Vol. 27, No. 3 (2008) p. 760.

Potential Benefits of Vertical Integration

- In healthcare, the potential benefits of vertical integration may include, but are not limited to (continued):
  - Utilization of complimentary and requisite care mapping of services, which can:
    - Provide organizations with the size necessary to justify certain services and employ certain physicians in the instance where, separately, they would not have the patient volume or financial resources to employ a specialist or service; and,
    - Allow for the management of an enterprise to exert a span of control across the *continuum of patient care* and implement those strategies which are more likely to result in the most beneficial patient outcomes

"Integration and coordination in healthcare: An operations management view" by Paul Lillrank, Journal of Integrated Care, February 2012, https://www.researchgate.net/publication/235297735_Integration_and_coordination_in_healthcare_An_operations_management_view (Accessed 4/28/2016) p. 11.

Potential Benefits of Vertical Integration

- In healthcare, the potential benefits of vertical integration may include, but are not limited to (continued):
  - Creation of operational efficiencies
    - Reduction of duplicative treatments
    - Capitalizing on firm synergies to create more efficient provider/patient contact
    - Reduction in transportation costs for patients and their medical service providers
    - The integration of the *healthcare information technology* (HIT) across multiple sites of service

Potential Benefits of Vertical Integration

- In healthcare, the potential benefits of vertical integration may include, but are not limited to (continued):
  - Achievement of *Pay for Performance* (P4P) goals
  - Satisfaction of the "*Triple Aim*"
    - Improving patient experience of healthcare
    - Improving population health
    - Reducing health expenditures per capita

"The Triple Aim: Care, Health, and Cost" By Donald M. Berwick, et al., Health Affairs, Vol. 27, No. 3 (2008) p. 760.

Potential Benefits of Vertical Integration

- In healthcare, the potential benefits of vertical integration may include, but are not limited to (continued):
  - Mitigating providers' risk by:
    - Allowing health systems to diversify their supply chain
    - Allowing health systems to spread the risk of participation in global payment mechanisms over a larger population
  - Satisfaction of *continuum of care* requirements under state licensing regulations and *Certificate of Need* (CON) laws

"St. Elizabeth's Hospital – Project Description Review" Health Facilities and Services Review Board, State of Illinois, December 16, 2014, http://www.hfsrb.illinois.gov/Dec14sbr/11.%2014-043%20St%20%20Elizabeth's%20Hospital%20Belleville_2_.pdf (Accessed 3/15/16)

Potential Benefits of Vertical Integration

- Many of the economic benefits of vertical integration in healthcare are ***non-monetary (non-cash)*** benefits that can provide ***utility*** to the enterprise, in contrast to ***monetary (cash)*** benefits
- Although these benefits may not provide *immediate* ***monetary (cash)*** returns on and of the investment, they may still provide ***utility***, i.e., "*the ability of a product to satisfy a human want, need, or desire*"
- This distinction is essential to understand, as it highlights a primary difference between ***financial economics***, which focuses on a broader sense of ***utility***; and, ***accounting conventions***, which only focus on ***financial (cash)*** considerations

"The Appraisal of Real Estate" Appraisal Institute, 10th Edition: Chicago, IL, 1992 (originally published in 1951), p. 24.

Potential Drawbacks of Vertical Integration

- In most industries, vertical integration may have certain drawbacks
  - Antitrust implications due to non-competitive concerns
  - Increasing the capital requirements associated with market entry
  - Potential fraud and abuse violations, if the consideration provided is based on the volume or value of referrals

Potential Drawbacks of Vertical Integration in Healthcare

Vertical integration in healthcare does not always result in improved costs, care coordination, and quality:

"*The key feature of integrated delivery systems is that, to be successful, the primary focus must be the clinical effectiveness and profitability of the system as a whole, as opposed to each individual element. This emphasis requires a much higher level of administrative and clinical integration than is seen in most organizations; more important, it requires that managers of the system's individual elements place their own interests second to that of the overall system*." [Emphasis Added]

"Understanding Health Care Financial Management: Text, Cases, and Models" By Louis C. Gapenski, 7th Edition, Chicago, IL: Health Administration Press, 2015, p. 45-46.

Transactional Initiative Types

- A FMV analysis assumes a hypothetical transaction involving a universe of typical buyers, sellers, owners, and investors
- Similarly, the application of the PLP to a particular integration transaction may call into question the validity of the *commercial reasonableness* analysis of the transaction
- These analyses would necessarily include consideration of whether the hypothetical (or in the case of a *commercial reasonableness* analysis, prospective) buyers, sellers, owners, and investors are pursuing the transaction based on the objective of *horizontal consolidation* or *vertical integration*

Transactional Initiative Types

- *"**Vertical integration*** [in healthcare] *refers to integration of providers at different points along the continuum of care, such as a hospital partnering with a skilled nursing facility (SNF) or a physician group"* [Emphasis added]
- **Horizontal consolidation** may be defined as *"combining two or more enterprises at the same stage of production"*

"Oxford Dictionary of Economics" By John Black, Oxford University Press: New York, NY, 2002, p. 212, 495; "The Value of Provider Integration" American Hospital Association, March 2014, http://www.aha.org/content/14/14mar-provintegration.pdf (Accessed 1/14/16) p. 2; "Integrated Health Care: Literature Review" Essential Hospitals Institute, May 2013, http://essentialhospitals.org/wp-content/uploads/2013/12/Integrated-Health-Care-Literature-Review-Webpost-8-22-13-CB.pdf (Accessed 3/14/16), p. 4.

Transactional Initiative Types

- In healthcare, a contrast is drawn between horizontal consolidation, *"which integrates organizations providing similar levels of care under one management umbrella,* [and] *vertical integration*[, which] *involves grouping organizations that provide different levels of care under one management umbrella"*

"Oxford Dictionary of Economics" By John Black, Oxford University Press: New York, NY, 2002, p. 212, 495; "The Value of Provider Integration" American Hospital Association, March 2014, http://www.aha.org/content/14/14mar-provintegration.pdf (Accessed 1/14/16) p. 2; "Integrated Health Care: Literature Review" Essential Hospitals Institute, May 2013, http://essentialhospitals.org/wp-content/uploads/2013/12/Integrated-Health-Care-Literature-Review-Webpost-8-22-13-CB.pdf (Accessed 3/14/16), p. 4.

Government Initiatives Regarding Vertical Integration in Healthcare

- Due, in part, to the potential benefits of vertical integration, certain governmental agencies, such as the *Centers for Medicare and Medicaid Services* (CMS) and *Office of Inspector General* (OIG), have undertaken initiatives promoting or requiring vertical integration in healthcare

Government Initiatives Regarding Vertical Integration in Healthcare

- *Comprehensive Care for Joint Replacement*
  - Mandatory CMS bundled payment model that holds hospitals accountable for all of the care associated with hip and knee replacement surgeries
  - Includes tools for hospitals to integrate with other providers along the *continuum of care*
    - SNFs
    - Physician and Non-Practitioners
    - Long-Term Care Hospitals

Government Initiatives Regarding Vertical Integration in Healthcare

- *Accountable Care Organizations (ACO)*
  - ACOs integrate multiple providers along the continuum of care, and hold integrated providers accountable for defined populations, as an incentive to improve population health
  - Instituted as part of the *Patient Protection and Affordable Care Act* (ACA)

Government Initiatives Regarding Vertical Integration in Healthcare

- OIG Guidance on Physician Executive Arrangements
  - Physician Executive Arrangements often hold physician executives accountable for quality
  - Types of physician executives
    - Medical Directors
    - Service Line Co-Managers
      - Can help to achieve goals of ***vertical integration*** (e.g., improvements in quality and efficiency)
      - Note: Documentation of gains is important

Government Initiatives Regarding Vertical Integration in Healthcare

- The OIG has favorably opined on physician executive arrangements, so long as the compensation:
  - Is provided for services actually rendered
  - Does not exceed FMV
  - Does not vary with the volume of services rendered by the physician executive

Government Initiatives Regarding Vertical Integration in Healthcare

- Continuum of Care Requirements Under State Licensing and CON Laws
  - Many state CON programs require hospital enterprises to provide a full range of services along the *continuum of care*, as a condition of facility licensure
  - Influences hospitals to increase the scope of services offered to the community at different points along the *continuum of care*

Implementation of Vertical Integration

- As a result of government initiatives promoting, and sometimes requiring, **vertical integration** in healthcare, providers have engaged, or are currently engaging, in **vertical integration** transactions in the marketplace

"*The driving force behind these systems is the motivation to offer a full line of coordinated services, and hence to increase the overall effectiveness and lower the overall cost of the services provided*."

"Understanding Health Care Financial Management: Text, Cases, and Models" By Louis C. Gapenski, 7th Edition, Chicago, IL: Health Administration Press, 2015, p. 45.

Implementation of Vertical Integration

"*The goals of new payment models emanating from the ACA and [Medicare Access & CHIP Reauthorization Act of 2015] are diametrically opposed to the requirements of the Stark Law. New health care payment models are designed to integrate providers clinically and financially and compensate physicians on value and quality care, while the Stark Law is intended to keep parties financially separated*." [Emphasis Added]

"Examining the Stark Law: Current Issues and Opportunities" By Troy A. Barsky, Esq., United States Senate Committee on Finance, July 12, 2016, https://www.crowell.com/files/20160712-Senate-Finance-Committee-Testimony-Examining-Stark-Law-Barsky.pdf (Accessed 7/27/2016).

Implementation of Vertical Integration

Vertical Integration as Indicated by Physician Employment

- A 2005 survey by *Medical Group Management Association* (MGMA), entitled "*Physician Compensation and Production Survey: 2005 Report Based on 2004 Data*," reported that over half of physicians were working in entities owned by physicians
- The 2015 version of the same survey (based on 2014 data) reported that less than one third of physicians were working in entities owned by physicians
- Over the same time period (i.e., 2004-2014), share of physicians working in hospitals and health systems more than doubled

"Physician Compensation and Production Survey: 2005 Report Based on 2004 Data" Medical Group Management Association, 2005, p. 25; "2015 Physician Compensation and Production Report: Based on 2014 Data" Medical Group Management Association, 2015, p. 202.

Arguments Against the Practice Loss Postulate

Economic Arguments Against the PLP

- The PLP contraindicates established and accepted economic thought on several points, most notably in that:
  - The PLP does not satisfy the basic requirements for ***economic assumptions***
  - The PLP reflects a misapplication of fundamental ***economic principles***
  - The PLP runs contrary to established and accepted ***economic theories***

The PLP Does Not Satisfy the Basic Requirements for Economic Assumptions

- The PLP does not meet the fundamental requirements of an ***economic assumption***, as stated by Joan Robinson in 1932
  - The assumption must be "*tractable*" (i.e., it is "*manageable*" by economic analytical techniques)
  - The assumption must "*correspond to the real world*"

"Economics is a Serious Subject: The Apologia of an Economist to the Mathematician, the Scientist and the Plain Man" By Joan Robinson, W. Heffer & Sons Ltd.: Cambridge, England, 1932, p. 6.

The PLP Does Not Satisfy the Basic Requirements for Economic Assumptions

- First requirement of ***economic assumptions*** – is the PLP "*tractable*" (i.e., it is "manageable" by economic analytical techniques)
- PLP may have arisen so aggressively, and typically uncontested, on the false premise that it is *tractable*, without due consideration as to whether it is *realistic*, i.e., whether the ***economic assumption*** "*correspond[s] to the real world.*"
- PLP has dramatically **oversimplified** the nature of vertically integrated physician practices

"Economics is a Serious Subject: The Apologia of an Economist to the Mathematician, the Scientist and the Plain Man" By Joan Robinson, W. Heffer & Sons Ltd.: Cambridge, England, 1932, p. 6.

The PLP Does Not Satisfy the Basic Requirements for Economic Assumptions

- Second requirement of ***economic assumptions*** – does the PLP "*correspond to the real world*"
  - The PLP treats **vertically integrated** practices as independent enterprises
  - However, benchmarking data indicates that **vertically integrated** physician practices do not operate in the same way as **independent** physician practices
    - **Vertically integrated** hospital owned practices do not retain ASTC revenue
    - **Vertically integrated** hospital owned practices lack immediate control over their economic expenses

The PLP Does Not Satisfy the Basic Requirements for Economic Assumptions

- Second requirement of ***economic assumptions*** – does the PLP "*correspond to the real world*" (continued):
  - Typical operational differences between **vertically integrated** practices and **independent** practices:
    - **Vertically integrated** physician practices provide significantly more charity care than independent practices
    - **Vertically integrated** physician practices provide more services to Medicaid beneficiaries, and relatively fewer services to patients covered by commercial insurance, than independent practices
    - **Vertically integrated** physician practices operate with relatively fewer non-physician practitioners per physician than independent practices

"Why Hospital-Owned Medical Groups Lose Money" By David N. Gans, MSHA, FACMPE, MGMA Connexion, April 2012, http://www.mgma.com/Libraries/Assets/Practice%20Resources/Publications/MGMA%20Connexion/2012/Data-Mine-Why-hospital-owned-medical-groups-lose-money---MGMA-Connexion-magazine-April-2012.pdf (Accessed 3/29/2016), p. 20.

The PLP Does Not Satisfy the Basic Requirements for Economic Assumptions

- Second requirement of ***economic assumptions*** – does the PLP "*correspond to the real world*" (continued):
  - Together, these characteristics of **vertically integrated** physician practices may lead to reduced revenues for these hospital-acquired practices relative to the revenues generated by **independent** physician practices
  - Note that different **vertically integrated** systems may distribute revenues or operational control differently, depending on the dominant party in the system

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Scarcity**
  - *Scarcity* and *utility* underlie the entire valuation endeavor
    - *"No object, including real property, can have **value** unless **scarcity** is coupled with **utility**"* [Emphasis Added]
  - Principle of Scarcity
    - The first principle of economics
    - The inability to satisfy all of our wants
  - Economic actors must choose what they *consume* and what they will *forego*
  - As a property interest becomes more scarce, the value of the subject property interest increases

"The Appraisal of Real Estate" Appraisal Institute, 10th Edition: Chicago, IL, 1992 (originally published in 1951), p. 25, 34; "Healthcare Valuation: Volume 2 - The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, Hoboken, NJ: John Wiley & Sons, 2014, p. 5-6.

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Scarcity**

  *"What each one of us can get is limited by time, by the incomes we earn, and by the prices we must pay. Everyone ends up with some unsatisfied wants. What we can get as a society is limited by our productive resources. These resources include the gifts of nature, human labor and ingenuity, and tools and equipment that we have produced. . . . Our inability to satisfy all our wants is called **scarcity**."* [Emphasis Added]

  -Michael Parkin

"Economics" By Michael Parkin, Boston Pearson Addison Wesley, 2008, p. 2.

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Scarcity**
  - Due to the fact that physicians are becoming increasingly scarce, providers seeking to integrate with physicians must incur increasing expenses in order to retain a physician's services, which may result in a "*book financial loss*"
  - **The PLP fails to recognize this reality, and therefore ignores the *Principle of Scarcity***

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Utility**
  - The economic foundation for analyzing an individual's anticipated ***utility*** pay-off from consumption patterns of different bundles of goods
  - Defines the criteria by which individuals choose preferences
  - Model for utility maximization allows economists to identify a consumer's preferred consumption bundle

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Utility**
  - Utility is defined as *"the ability of a product to satisfy a human want, need, or desire"*
  - Rational economic actors will attempt to maximize their expected ***utility***
  - Types of ***utility*** accruing to healthcare organizations
    - ***Social Benefit***
    - ***Avoidance of Cost***
    - ***Monetary (cash)*** Benefits

"Health Care Economics" By Paul J. Feldstein, 6th Edition, Clifton Park, NY: Thomson Delmar Learning, 2005 (originally published in 1986), p. 116; "The Appraisal of Real Estate" Appraisal Institute, 10th Edition: Chicago, IL, 1992 (originally published in 1951), p. 24.

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Utility**
  - For example, if an individual is relieved of an expense, than this would increase his or her stock of ***utility***
  - An individual's stock of utility is offset by their sources of ***disutility***
  - Pain and pleasure are experienced uniquely by each individual

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Utility**
  - The PLP asserts that vertically integrated systems offset the financial losses associated with integration support payments related to physician labor through the revenues associated with legally impermissible referrals
  - However, this assigns no utility to the potential benefits of vertical integration, and indicates that the PLP conflates *"**utility**"* with *direct* and *immediate* ***financial (cash)*** return
  - **The PLP misapplies the *Principle of Utility* by construing utility as equivalent to monetary, or *financial (cash)* gain, in contrast to *"the ability of a product to satisfy a human want, need, or desire"***

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Substitution**
  - Defined as: *"The price of a desired substitute, or one of equal utility, sets the ceiling of value for a particular good or service"*
  - An individual or organization seeking to maximize ***utility*** will seek to select from the universe of possible bundles of goods and services that allocation which generates the greatest possible ***utility*** for that individual or organization

"Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons: Hoboken, NJ, 2014, Volume 2, p. 10-11.

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Substitution**
  - The PLP alleges that *integration support payments* are evidence that hospitals would be irrational to prefer **vertical integration** to continued operation in the service area, *independent* of physician practices , unless the hospitals received revenues from legally impermissible referrals
  - However, the ***Principle of Substitution*** implies that an alternative route to gaining the benefits that **vertical integration** may provide (e.g., meeting *continuum of care* requirements, satisfaction of the *Triple Aim*) would be selected by market participants and policymakers, if the alternative required a lower cost than the cost of **vertical integration**

The PLP Misapplies and/or Ignores Fundamental Economic Principles

- **Substitution**
  - Based on current implementation of **vertical integration** in the healthcare industry, healthcare organizations, acting as rational economic actors, are selecting **vertical integration** as the most efficient method to achieve these benefits
  - **The PLP ignores the choices of rational actors in selecting vertical integration as the optimal alternative under the *Principle of Substitution***

The PLP Runs Contrary to Established Economic Theories

- Economists propose economic theories based on the accepted economic principles that were established by previous investigators into the discipline of economics, allowing *"…the individual student [to] speak with the authority of his science"*
- Economists have long studied the topic of organization and integration in the marketplace, and developed complex ***economic theories***, which theories have been analyzed and accepted as models that accurately describe economists' observations of the real world

"Principles of Economics" By Alfred Marshall, Eighth Edition, New York, NY: Cosimo, Inc., 2009 (originally published in 1890), p. 25, 200.

The PLP Runs Contrary to More Complex Economic Theories

- Edgeworth's 1881 *Contract Curve*
  - The use of contracts or cooperation (in favor of individual action) **maximizes the aggregate utility** of all parties involved

- Bonbright's 1937 *Avoidance of Cost*
  - The ***avoidance of cost*** is equivalent to ***utility***

"Mathematical Psychics: An Essay on the Application of Mathematics to the Moral Sciences" By F.Y. Edgeworth, MA, C. Kegan Paul & Co.: London, England, 1881, p. vi, 25; "The Valuation of Property: A Treatise on the Appraisal of Property for Different Legal Purposes" By James C. Bonbright, William s. Hein & Co., Inc.: Buffalo, NY, 1937, Volume I, p. 71-72; "Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons: Hoboken, NJ, 2014, Volume 2, p. 8.

The PLP Runs Contrary to More Complex Economic Theories

- Coase's 1937 *Nature of the Firm*
  - Individuals organize into firms because one entity coordinating scarce resources is **more efficient** than forcing all resources to be bought and sold by independent actors in an open market
  - Operation of an open market incurs **transaction costs**, which integrated firms avoid
  - If firms are *not* more efficient than the market (i.e., if the cost of the firms' operations is greater than transaction costs), then the economic actors involved may revert to using the open market

"The Nature of the Firm" By R. H. Coase, Economica, New Series, Vol. 4, No. 16 (November 1937), p. 389, 392.

The PLP Runs Contrary to More Complex Economic Theories

- Enthoven and Tollen, 2005

"*There is more to safe, appropriate, affordable health care than what is evident to a patient in an encounter with an individual provider. We need systems to ensure that health care providers are...deployed in the appropriate...numbers and specialties to meet a population's needs efficiently; current on evidence- based practice and supported by tools (such as monitoring and reminders) to overcome widespread practice variations and quality failures; ...supported by teams of colleagues sharing goals, work processes, and information and able to coordinate care across multiple settings; supported by a system that records test results, diagnoses, and treatments and transmits orders accurately; practicing in facilities with equipment selected based on evidence of safety and efficacy; and supported financially and logistically to participate in common efforts such as guideline development...which [is] important for evidence-based practice*."

"Competition in Health Care: It Takes Systems To Pursue Quality And Efficiency" By Alain C. Enthoven and Laura A. Tollen, Health Affairs, September 7, 2005, http://content.healthaffairs.org/content/early/2005/09/07/hlthaff.w5.420.short (Accessed 6/3/16).

The PLP Runs Contrary to More Complex Economic Theories

- Porter, 2008

"*It is true that economic and social objectives have long been seen as distinct and often competing. But this is a false dichotomy; it represents an increasingly obsolete perspective in a world of open, knowledge-based competition. Companies do not function in isolation from the society around them. In fact, their ability to compete depends heavily on the circumstances of the locations where they operate…The more a social improvement relates to a company's business, the more it leads to economic benefits as well*."

"On Competition: Updated and Expanded Edition" By Michael E. Porter, Boston, MA: Harvard Business Review, 2008, p. 454-455.

The PLP Runs Contrary to More Complex Economic Theories

- Together, the aforementioned ***economic theories*** demonstrate that, by organizing into coordinated firms, individual actors can maximize aggregate ***utility*** and reduce costs
- Equivalent to the creation of ***utility***
- As reflected under the ***Principle of Substitution***, rational economic actors are choosing to engage in **vertical integration** transactions in order to maximize aggregate ***utility*** related, in part, to ***non-monetary (non-cash)*** benefits

The PLP Runs Contrary to More Complex Economic Theories

- The PLP assumes that specific and immediate "*book financial losses*" on ***vertically integrated*** physician practices constitute dispositive evidence of the payment of compensation, remuneration, and consideration based on the volume and/or value of legally impermissible physician referrals
- **With this assumption, the PLP ignores the benefits of organizing into vertically integrated firms to maximize aggregate utility and reduce costs, and thereby ignores the conclusions of an established and accepted canon of economic literature**

Failure of the PLP's Commercial Reasonableness Argument

- Losses on **vertically integrated** physician practices do not contraindicate the threshold of *commercial reasonableness.*

- *Commercial reasonableness* is a specialized concept within the realm of ***financial economics*** that considers, in part, ***utility considerations***, not solely relying on ***accounting conventions***, which focus exclusively on ***financial (cash)*** considerations.

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.

Failure of the PLP's Commercial Reasonableness Argument

- Although no single, universally accepted definition of *commercial reasonableness* has been set forth in statutes, regulations, case law, and other regulatory guidance, healthcare providers are increasingly facing prosecution for violations of this threshold.
- Notwithstanding current guidance from HHS, the IRS, the OIG, and case law, *commercial reasonableness* remains an area of great uncertainty and ambiguity within the healthcare transactional community, and behooves clarification.

Failure of the PLP's Commercial Reasonableness Argument

- In that regard, in a July 2016 hearing held by the U.S. Senate Committee on Finance, Troy A. Barsky, Esq., testified that Congress should amend the Stark Law by defining *commercial reasonableness*:

"*While a number of important exceptions have a requirement that the arrangement be commercially reasonable without taking into account Medicare referrals, the term 'commercial reasonableness' is not clearly defined anywhere. Under current law, there is confusion over whether a hospital's subsidy of a physician's practice is commercially reasonable even where the physician's compensation is in the range of FMV. I recommend either that this standard be removed completely or that the statute be amended to add a definition of commercial reasonableness e.g., that the items or services are of the kind and type of items or services purchased or contracted for by similarly situated entities and are used in the purchaser's business, regardless of whether the purchased items or services are profitable on a standalone basis*." [Emphasis Added]

Mr. Barsky is a noted private healthcare attorney with Crowell & Moring LLP, and previously served as the Director of the Division of Technical Payment Policy at CMS for four of his eleven years at HHS.
"Testimony Before the Committee on Finance" Troy A. Barsky, Crowell & Moring LLP, July 12, 2016, http://www.finance.senate.gov/imo/media/doc/12jul2016Barsky.pdf (Accessed 7/20/2016).

Failure of the PLP's Commercial Reasonableness Argument

- Examples of hospital investments in initiatives, service lines, and uses of capital that do not *immediately* (or may never) yield *direct* financial returns on or of their investment include:
  - Emergency rooms, trauma services, pathology labs, and *neonatal intensive-care units* (NICU)
  - Research labs and clinical studies

Failure of the PLP's Commercial Reasonableness Argument

- Examples of hospital investments in initiatives, service lines, and uses of capital that do not *immediately* (or may never) yield *direct* financial returns on or of their investment include (continued):
  - Principal research investigators, medical directors, and other types of physician executives
  - Education of residents
  - Artwork and other aesthetics that aim to generate therapeutic benefits for the hospitals' patients

Failure of the PLP's Commercial Reasonableness Argument

- These investments may allow hospitals to reap other forms of ***utility*** aside from ***financial (cash)*** gains
  - **Avoidance of cost**
  - Generation of **social benefits**
- Despite the lack of *immediate* or *direct* ***financial (cash)*** return on, or return of, certain investments by healthcare entities, these services may nevertheless satisfy the threshold of *commercial reasonableness*

Failure of the PLP's Commercial Reasonableness Argument

- For example, the investment may be "*necessary*" for the continued operation of the healthcare entity, or may satisfy a "*business purpose*" of the healthcare enterprise apart from obtaining referrals, such as:
  - Meeting its charitable mission
  - Providing for population health
  - Satisfying regulatory requirements (e.g., licensing, CON)

"Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons: Hoboken, NJ, 2014, Volume 2, p. 321, 946; "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, Volume 20, No. 5 (June 2008), p. 9; "Helping Patients Heal Through the Arts" By Amanda Gardner, CNN, July 5, 2013, http://www.cnn.com/2013/07/05/health/arts-in-medicine/ (Accessed 8/18/14) p. 1.

Arguments in Defense of the PLP

Arguments in Defense of the PLP

- Certain arguments may be made that the current regulatory environment supports vertical integration efforts in healthcare
- These arguments center around two main points
  - The existence of Stark Law exceptions and AKS safe harbors allowing vertical integration activities
  - The passage of the ACO fraud and abuse waivers

"Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357(h)(5-6) (2015).

Arguments in Defense of the PLP

- Stark Law and AKS Safe Harbors
  - Stark Law exceptions do promote some integration efforts, such as through the group practice exception
  - However, the requirements of FMV and *commercial reasonableness* apply across many Stark Law exceptions and AKS safe harbors that allow integration activities (e.g., the "*group practice exception*" under the Stark Law)

"Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357(h)(5-6) (2015).

Arguments in Defense of the PLP

- ACO Fraud and Abuse Waivers
  - October 2015 – CMS issued its final rule implementing certain fraud and abuse waivers for ACOs
  - 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

"Medicare Program; Final Waivers in Connection with the MSSP" Federal Register Vol. 80, No. 209 (October 29, 2015) p. 66741.

Arguments in Defense of the PLP

- ACO Fraud and Abuse Waivers
  - Both CMS and OIG noted that further rules and modifications may be implemented
  - Boards should consider and document what other regulatory exceptions and safe harbors may apply in the event waiver protection disappears, many of which require compliance with the thresholds of FMV and *commercial reasonableness*

"Medicare Program; Final Waivers in Connection with the MSSP" Federal Register Vol. 80, No. 209 (October 29, 2015) p. 66741.

Conclusion

PLP is Misguided and Imprudent

- The PLP is flawed from an economic perspective for numerous reasons, specifically in that:
  - The PLP does not meet the basic requirements for an ***economic assumption***
  - The PLP is unsupported by fundamental ***economic principles***
  - The PLP runs contrary to established and accepted ***economic theory***
- Additionally, the PLP represents a less than rational interpretation and application of the *commercial reasonableness* threshold

PLP is Misguided and Imprudent

- Should the PLP continue to evolve into accepted "*legal doctrine*," and ultimately the "*law of the land*," the result may be to impede the development of innovative new structures of emerging healthcare organizations to the extent that it would cause significant harm to the healthcare economy, such as the losses of both:
  - Operating cost-related efficiencies
  - Qualitative benefits that vertical integration can provide
    - Satisfaction of charitable mission
    - Improvements in care coordination
    - Promotion of population health
    - Achievement of the *Triple Aim*

PLP is Misguided and Imprudent

- Arguments relying on the PLP are based on ***accounting conventions***, which focus only on ***monetary (cash)*** considerations
- In fact, Stark and AKS laws are based on questions of FMV and *commercial reasonableness*
  - These concepts involve ***utility***, not simply ***monetary (cash)*** considerations
  - FMV and *commercial reasonableness* are specializations within the broader discipline of ***financial economics***

PLP is Misguided and Imprudent

"[I]t does not at all follow that economists should refrain from giving governments the benefit of their advice. If there is no doctor in the neighbourhood, it is better to ask a physiologist what is wrong with the patient than to ask an engineer…

[G]overnments [have been led] to prefer the advice of bankers, industrialists, and other practical men. But it is certainly better for the patient to ask the physiologist what is wrong with him than to ask the advice of the first man he meets. For the first man that he meets may be an undertaker who has his own view of the course that the disease ought to follow."

- Joan Robinson, "Economics is a Serious Subject: The Apologia of an Economist to the Mathematician, the Scientist and the Plain Man" p. 13-14

"Economics is a Serious Subject: The Apologia of an Economist to the Mathematician, the Scientist and the Plain Man" By Joan Robinson, W. Heffer & Sons Ltd.: Cambridge, England, 1932, p. 13-14.

Questions?