CHICAGO 2017

Commercial Reasonableness of Physician Compensation

Analytical Update with MACRA

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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 35 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].

He serves on the editorial boards of NACVA’s The Value Examiner and NACVA QuickRead. In 2006, Mr. Cimasi was honored with the prestigious “Shannon Pratt Award in Business Valuation” conferred by the Institute of Business Appraisers (IBA), and, 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

Presenter Bio

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

Mr. Zigrang is the co-author of the "*Adviser's Guide to Healthcare – 2nd Edition*" (AICPA, 2015), numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies*; *Business Appraisal Practice*; and, *NACVA QuickRead*. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute. You can see his full CV at https://www.healthcapital.com/hcc/html2pdf31/TZigrang_CV.pdf

Overview of Presentation

- Review of MACRA
- Review of the *Commercial Reasonableness* Analysis
- Tension Between MACRA and Fraud & Abuse Laws
- Concluding Remarks

Overview

- In response to the advent of *value-based reimbursement* (VBR), most recently through MACRA, which concepts emerging reimbursement models rely upon to incentivize providers to achieve better outcomes at lower cost, hospitals are increasingly seeking closer relationships with physicians
  - Practice acquisitions
  - Direct employment
  - *Provider services agreements* (PSAs)
  - Co-management
  - Joint venture arrangements

"2014 Global Health Care Outlook: Shared Challenges, Shared Opportunities" By Deloitte Touche Tohmatsu Limited, New York City, NY, 2014, p. 13; "The 5 C's of 2013 Health Care" Deloitte Touche Tohmatsu Limited, 2012, http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_MondayMemo_2013Healthcare_%205Cs_021313.pdf (Accessed 6/4/14); "Co-Management Arrangements: Common Issues with Development, Implementation and Valuation" By Ann S. Brandy, et. al., American Health Lawyers Association, May 2011, http://www.healthlawyers.org/Events/Programs/Materials/Documents/AM11/hutzler.pdf (Accessed 6/5/14); "Top 10 Factors to Consider When Exploring Joint Ventures as an Affiliation Strategy" By Jonathan Spees, The Camden Group, June 2013, http://www.thecamdengroup.com/thought-leadership/top-ten/top-10-factors-to-consider-when-exploring-joint-ventures-as-an-affiliation-strategy/ (Accessed 6/5/14).

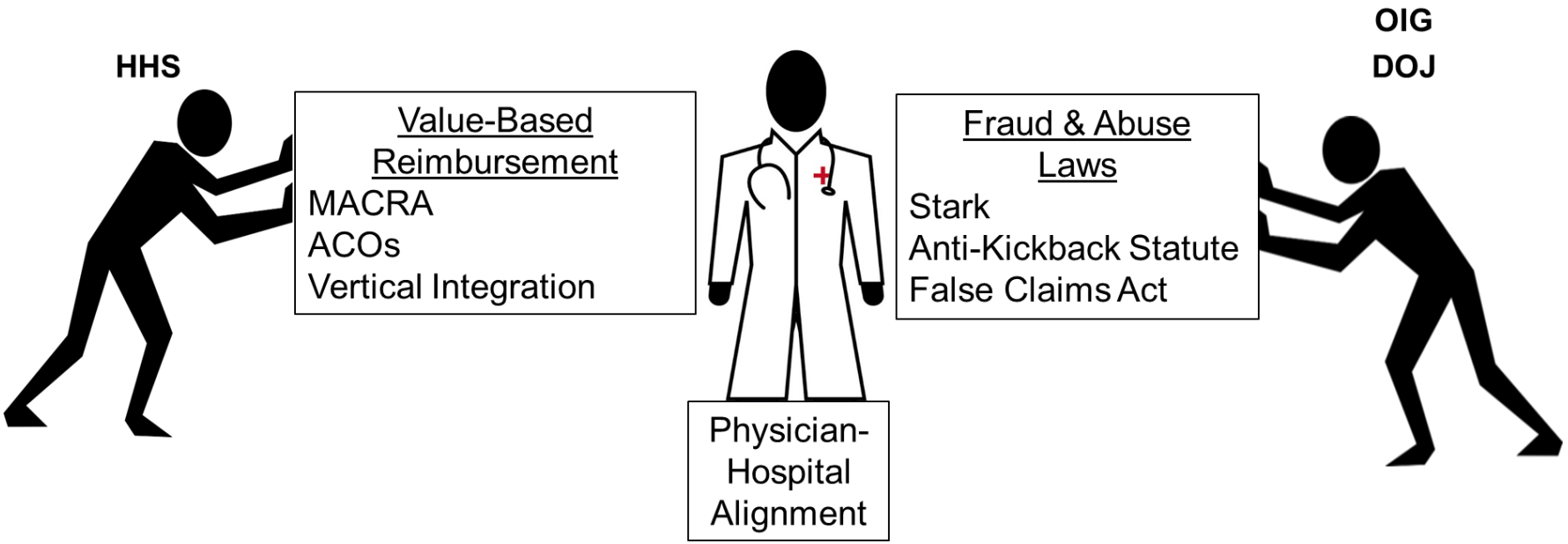
Overview

- Corresponding with this growing trend toward hospital-physician alignment, and specifically toward *vertical integration*, i.e., 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*," there has been increased federal, state, and local regulatory oversight regarding the legal permissibility of these arrangements
- More intense regulatory scrutiny related to the *Anti-Kickback Statute* (AKS) and the *Stark Law*, especially as these *fraud and abuse laws* relate to potential liability under the *False Claims Act* (FCA)
- Many of the exceptions and safe harbors in both the *Stark Law* and AKS require that any consideration paid to physicians not exceed the range of *Fair Market Value* (FMV) and be deemed *commercially reasonable*

"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. See "Health Care Fraud and Abuse Control Program Report" U.S. Department of Health and Human Services and U.S. Department of Justice, https://oig.hhs.gov/reports-and-publications/hcfac/ (Accessed 5/18/17). "Health Care Fraud and Abuse Control Program: Annual Report for FY 1997" By The Department of Health and Human Services & The Department of Justice, Report for the United States Congress, Washington, DC, 1998; "Health Care Fraud and Abuse Control Program: Annual Report for FY 2007" By The Department of Health and Human Services & The Department of Justice, Report for the United States Congress, Washington, DC, 2008; "Health Care Fraud and Abuse Control Program: Annual Report for FY 2013" By The Department of Health and Human Services & The Department of Justice, Report for the United States Congress, Washington, DC, 2014. "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(3)(B) (2012); "Limitations on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1) (2012); "Personal Services and Management Contracts" 42 C.F.R. § 1001.952(d) (2007); "Bona Fide Employment Relationships" 42 U.S.C. § 1395nn(e)(2) (2010); "General Exceptions to the Referral Prohibition Related to Both Ownership/Investment and Compensation" 42 C.F.R. § 411.355(e)(ii)(B) (2014); "Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357 (2010); "FMV: Analysis and Tools to Comply With Stark and Anti-kickback Rules," By: Robert A. Wade, Esq. and Marcie Rose Levine, Esq., Audio Conference, HCPro, Inc.: Marblehead, MA, March 19, 2008, http://content.hcpro.com/pdf/content/207583.pdf (Accessed 10/29/15), p. 6, 48.

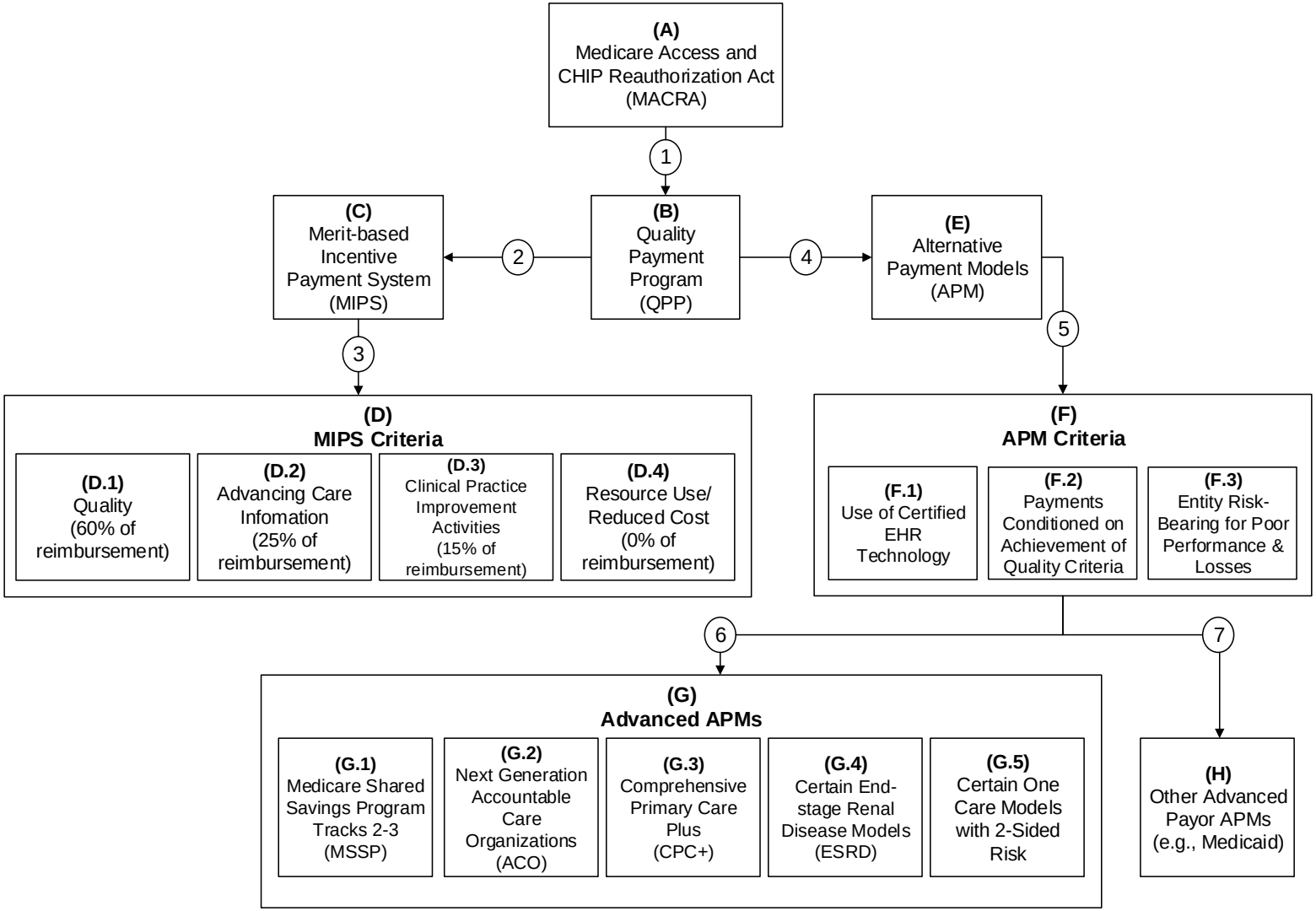
Overview

"*The Left Hand Doesn't Know What the Right Hand is Doing*"



Medicare Access & CHIP Reauthorization Act of 2015 (MACRA)

MACRA Overview



MACRA Overview

- The *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) in part shifts physician reimbursement from a *volume-based* approach to a *value-based* approach
  - Replaced failed *sustainable growth rate* (SGR) formula with the Quality Payment Program (QPP)
- "*Paying providers based on the quality, value, and results of the care they deliver and not piecemeal for individual services regardless of the clinical need for or appropriateness of those services*"

"Implementing MACRA" Health Affairs (March 27, 2017), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf (Accessed 4/3/17), p. 7. "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. 214 (Nov. 4, 2016) p. 77010.

MACRA Required Participants

- Already participating in an Advanced APM -OR-
- Meet the Minimum Billing/Patient Population Requirements
  - Annually billing Medicare > $30,000 in Part B allowed charges -AND-
  - Annually care for >100 Medicare patients
- To participate in MIPS, providers must:
  - Be a Medicare provider prior to 2017
  - Be a:
    - Physician
    - Physician assistant (PA)
    - Nurse practitioner (NP)
    - Clinical nurse specialist
    - Certified registered nurse anesthetist (CRNA)

"Quality Payment Program" CMS, Quality Payment Program, https://qpp.cms.gov/ (Accessed 4/3/17).

MACRA's QPP Timeline

- **November 4, 2016**: Final Rule Issued by the *Centers for Medicare & Medicaid Services* (CMS)
- **January 1, 2017**: Start of First Performance Period
  - CMS projects up to 90-95% of Medicare Part B billings and 500,000 physicians will be affected by MIPS starting in 2017
- **March 31, 2018**: Performance Data Due to CMS
- **January 1, 2019**: Providers Begin Receiving "*Payment Adjustments*" (based on data that was submitted in March 2018)

"Quality Payment Program" CMS, Quality Payment Program, https://qpp.cms.gov/ (Accessed 4/3/17). "Implementing MACRA" Health Affairs, (March 27, 2017), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf (Accessed 4/3/17), p. 7.

MACRA Participation Structure

- Clinicians can choose between two paths:
  - Participation in *Merit-Based Payment System* (MIPS)
    - Clinicians can choose to *not participate*, *participate partially*, or *participate fully*
      - *No participation: 4% downward payment adjustment in 2019*
      - *Partial participation: Positive or neutral payment adjustment*
      - *Full participation: Up to 4% payment adjustment in 2019*

"Quality Payment Program" CMS, Quality Payment Program, https://qpp.cms.gov/ (Accessed April 3, 2017).

MACRA MIPS Reimbursement

- Those who participate fully will earn a positive payment adjustment
- MIPS reimbursement is based on 4 criteria:
  - Quality: Currently determines 60% of Medicare reimbursement, but is decreasing to 30% in 2018
  - Advancing Care Information: Currently determines 25% of Medicare reimbursement
  - Clinical Practice Improvement Activities: Currently determines 15% of Medicare reimbursement
  - Cost: Currently determines 0% of Medicare reimbursement but will increase to 30% in 2018

"What's the Merit-based Incentive Payment System (MIPS)?" Quality Payment Program, Centers for Medicare & Medicaid Services, https://qpp.cms.gov/learn/qpp (Accessed 5/16/17). "Quality Payment Program" CMS, Quality Payment Program, https://qpp.cms.gov/ (Accessed 4/3/17).

Participation in Alternative Practice Models (APMs)

- CMS partners with clinician community to provide added incentives for higher quality and cost-efficient care
- Three main requirements:
  - Certified EHR technology (CEHRT)
  - Reimbursement of payments on measures comparable to MIPS
  - Agreement to take on financial burden or meet specifications of Medical Home

"Implementing MACRA" Health Affairs, (March 27, 2017), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf (Accessed 4/3/17), p. 5.

Participation in Alternative Practice Models (APMs)

- Examples of advanced APM models include:
  - *Medicare Shared Savings Program Tracks* (MSSP) *Next Generation ACOs*
  - *Comprehensive Primary Care Plus* (CPC+)
  - *End-Stage Renal Disease Model* (ESRD)
  - *One Care Models with 2-Sided Risk*

"Quality Payment Program" Centers for Medicare and Medicaid Services, Quality Payment Program, https://qpp.cms.gov/learn/apms (Accessed 4/3/17).

Participation in Alternative Practice Models (APMs)

- APMs have increased rapidly
  - From their inception as part of the ACA, the four APMs offered by CMS in 2017 now have:
    - 359,000 participating clinicians
    - 12.3 million participating Medicare and Medicaid beneficiaries
- Whereas participation in MIPS incentivizes high quality yet efficient care through a performance-based payment adjustment, APM participants will earn incentive payments for participating in an innovative payment model

"Quality Payment Program" CMS, Quality Payment Program, https://qpp.cms.gov/ (Accessed 4/3/17). "Changing How Doctors Get Paid" By Dave Barkholz, March 11, 2017, Modern Healthcare, http://www.modernhealthcare.com/article/20170311/MAGAZINE/303119983 (Accessed 5/26/17).

MACRA Payment Structure & Timeline

	A	B	C	D	E
1	Performance Year	2017	2018	2019	2020
2	Payment Adjustment Year	2019	2020	2021	2022
	MIPS				
3	Maximum Positive Payment Adjustment	4%	5%	7%	9%
4	Maximum Negative Payment Adjustment	-4%	-5%	-7%	-9%
5	MIPS Performance Category Weights				
6	Quality	60%	50%	30%	30%
7	Cost	0%	10%	30%	30%
8	Improvement Activities	15%	15%	15%	15%
9	Advancing Care Information	25%	25%	25%	25%
	Advanced APMs				
10	Bonus Quality Payment	5%	5%	5%	5%

"Quality Payment Program" CMS, Quality Payment Program, https://qpp.cms.gov/ (Accessed 4/3/17).

MACRA Ramifications

- Much debate still surrounding MACRA and the QPP – whether its stated goals will, in fact, be accomplished through its provisions
- MACRA sought to "*fix*" Medicare Part B SGR, under which payment policy, hospitals were able to "…*mark up their employed physicians' services as 'provider based' and charge technical fees for their services.*"
- MACRA ostensibly rectified this underlying "*payment anomaly*," i.e., "*physician services are worth more to Medicare in hospital employment than in private practice.*"
- However, in reality, MACRA actually served to "*grandfather in most of the existing payment differentials while reducing some payments for hospital ambulatory services provided more than 200 yards from the main hospital campus*."

"The Tangled Hospital-Physician Relationship" By Jeff Goldsmith, Nathan Kaufman, and Lawton Burns, Health Affairs Blog (May 9, 2016), http://healthaffairs.org/blog/2016/05/09/the-tangled-hospital-physician-relationship/ (Accessed 5/16/17).

The Threshold of Commercial Reasonableness

Definition of Commercial Reasonableness

- Internal Revenue Service
  - The 1993 Exempt Organizations IRS text "*Reasonable Compensation*"
    - "*Reasonable compensation is…the amount that would ordinarily be paid for like services by like organizations in like circumstances*"
  - Chapter 2 of Publication 535 "*Business Exp*enses"
    - "…*reasonable pay is the amount that a similar business would pay for the same or similar services*" [emphasis added]

"Reasonable Compensation" By Jean Wright and Jay H. Rotz, Exempt Organizations Continuing Professional Education (1993), http://www.irs.gov/pub/irs-tege/eotopici93.pdf (Accessed 9/4/2012), p. 3. "Publication 535 - Business Expenses" Internal Revenue Service, 3/4/13, http://www.irs.gov/pub/irs-pdf/p535.pdf (Accessed 4/1/13), p. 6.

Definition of Commercial Reasonableness

- Internal Revenue Service
  - Federal Regulations on "*Excess Benefit Transactions*"
    - "*reasonable compensation [is]…the amount that would ordinarily be paid for like services by like enterprises (whether taxable or tax-exempt) under like circumstances*" [emphasis added]

"Excess Benefit Transaction" 26 CFR Section 53.4958-4(ii) (2012).

Definition of Commercial Reasonableness

- Department of Health and Human Services (HHS)
  - An arrangement which appears to be "…*a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals*" is *commercially reasonable*

"Medicare and Medicaid Programs: Physicians Referrals to Health Care Entities with which They Have Financial Relationships" 63 Federal Register 1700 (1/9/98).

Definition of Commercial Reasonableness

- Stark Law
  - *"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 DHS [designated health services] referrals*."

"Medicare Program: Physicians Referrals to Healthcare Entities with which They Have Financial Relationships (Phase II)" 69 Federal Register 16093 (3/26/04).

Definition of Commercial Reasonableness

- Office of the Inspector General (OIG)
  - A *commercially reasonable* transaction is a transaction in which "…*the aggregate services contracted do not exceed those which are reasonably* necessary to accomplish the commercially reasonable business purpose of the service."

"Subpart C: Permissive Exclusions - Exceptions" 42 CFR Section 1001.952 (2012).

Relationship to & Distinguished from Fair Market Value (FMV)

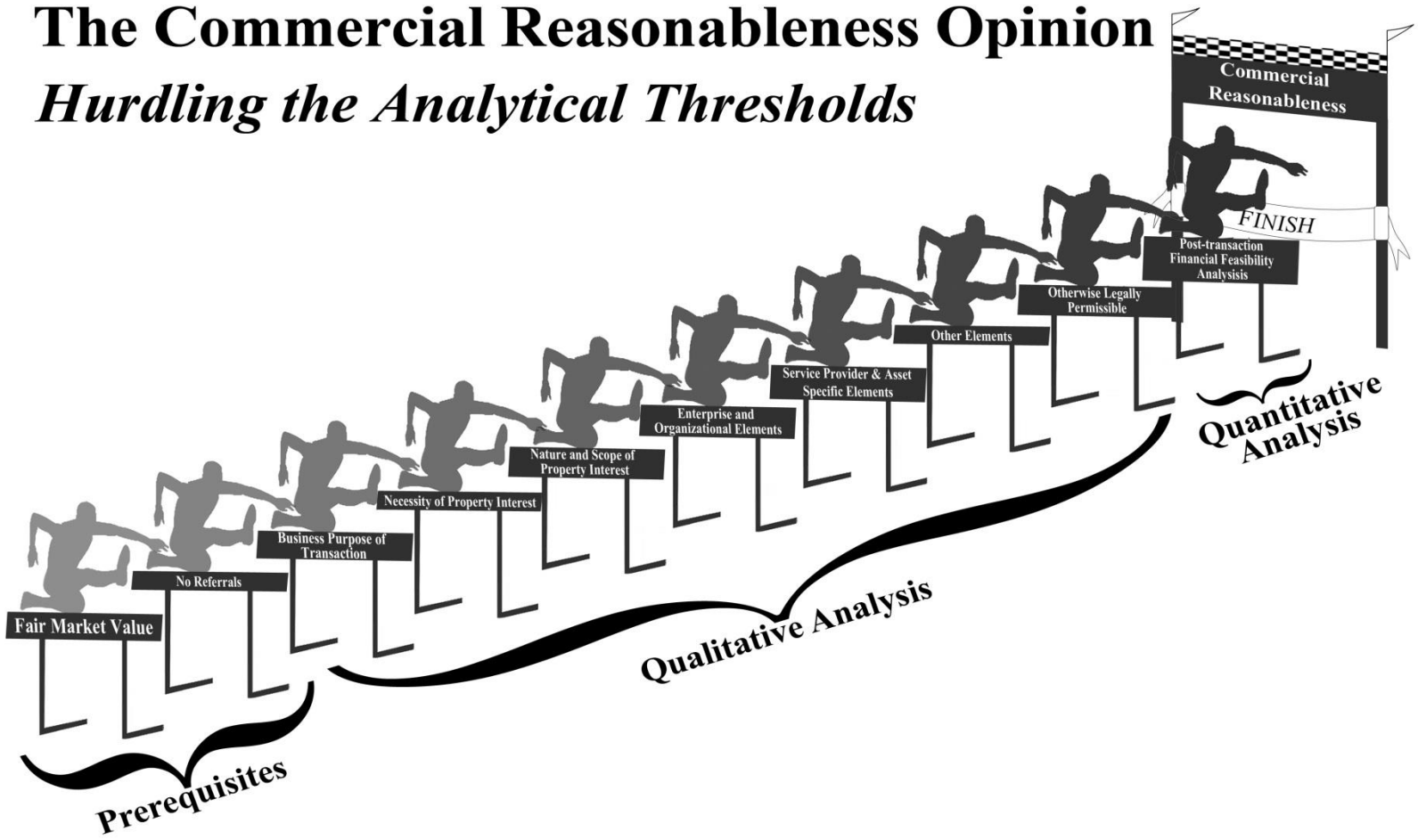
- While FMV looks to the "*range of dollars*" paid for a product or service, the threshold of commercial reasonableness looks to the reasonableness of the business transaction generally
- *Commercial Reasonableness* is a separate and distinct, but related, threshold to a FMV analysis
- Furthermore, the consideration and analysis of one threshold *does not preclude* the analysis of the other threshold

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

The Commercial Reasonableness Analysis

- Comprised of three component phases:
  - Ensuring that certain *prerequisites* for the transaction are satisfied
  - Developing a *qualitative analysis* of the transaction focusing on furthering the business's interest(s)
  - Developing a *quantitative analysis* focusing on the transaction's financial feasibility

The Commercial Reasonableness Analysis



The Commercial Reasonableness Analysis

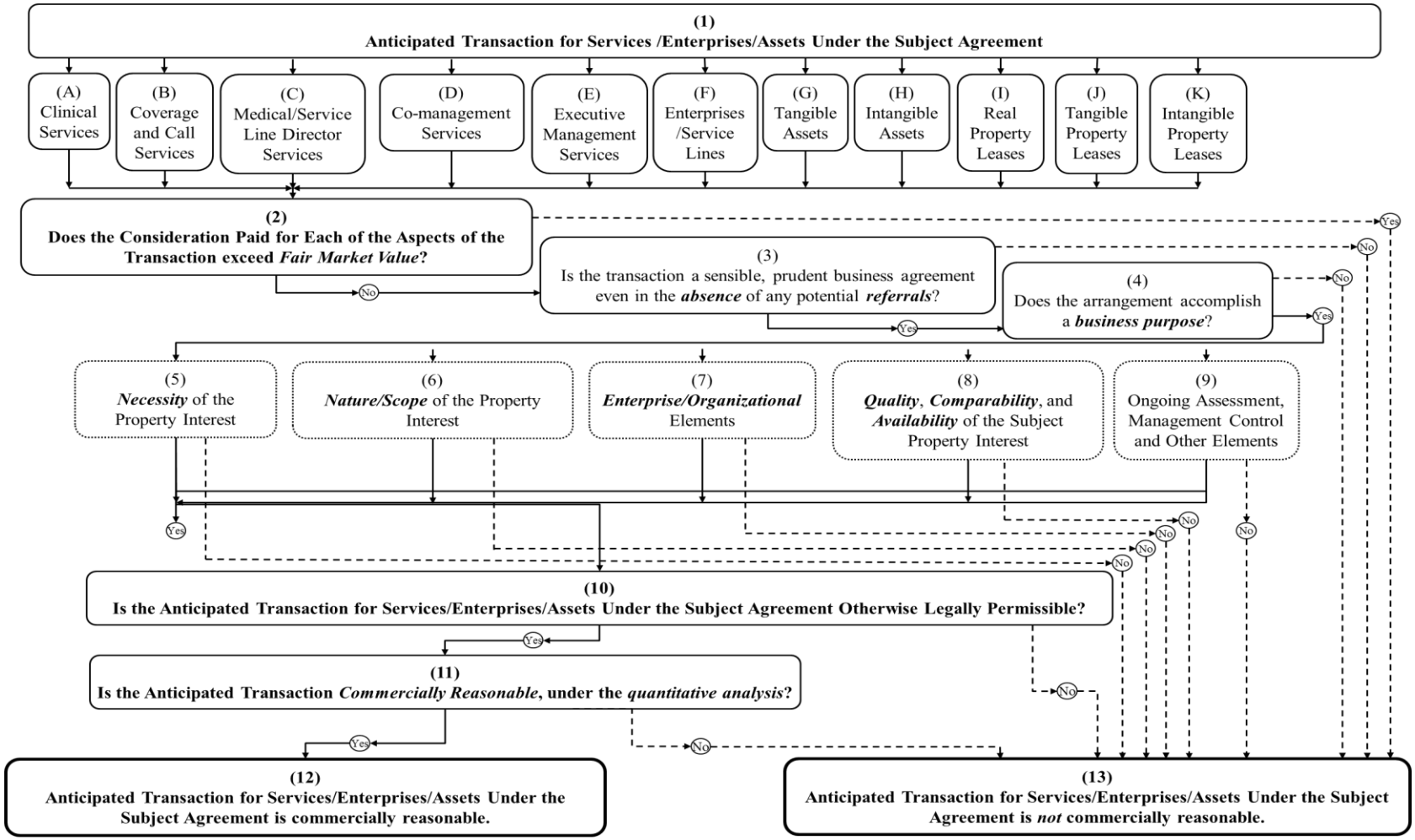
- Transactional Prerequisites
  - FMV
    - Consideration paid for all aspects of the transaction must be at fair market value. FMV is implicated by three distinct bodies of law that fall under the federal Fraud & Abuse laws:
      - *The Internal Revenue Code*
      - *The Stark Law*
      - *The Anti-Kickback Statute*
    - An FMV analysis will need to be completed by the appraiser to support the Commercial Reasonableness opinion

The Commercial Reasonableness Analysis

- Transactional Prerequisites
  - "*Sensible, Prudent Business Agreement in the Absence of Referrals*"
    - Applies in the areas of:
      - *"rental of office space"*
      - *"rental of equipment"*
      - *"bona fide employment relationships"*
      - *"personal service arrangements"*
      - *"physician incentive plans"*
      - *"physician recruitment"*
      - *"isolated transactions, such as a one-time sale of property"*
      - *"certain group practice arrangements"*

"Limitation on Certain Physician Referrals" 42 USC Section 1395nn (1/3/12).

Steps in Determining Commercial Reasonableness



"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. 941.

Qualitative Analysis

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

Commercial Reasonableness Qualitative Analysis

- Business Purpose
  - Transactions have a *business purpose* if they can be "*reasonably calculated to further the business of the lessee or acquirer*"
  - Additional business purposes beyond net economic benefit
    - The net economic benefits generated from the invested capital may not be the sole business purpose of the anticipated transaction
    - Includes focus on:
      - Expansion into new geographic areas
      - Expansion into new business lines
      - Diversification benefits (e.g., diversifying payor mix, geographically, etc.)
      - Increased asset utilization
      - Improved research and development

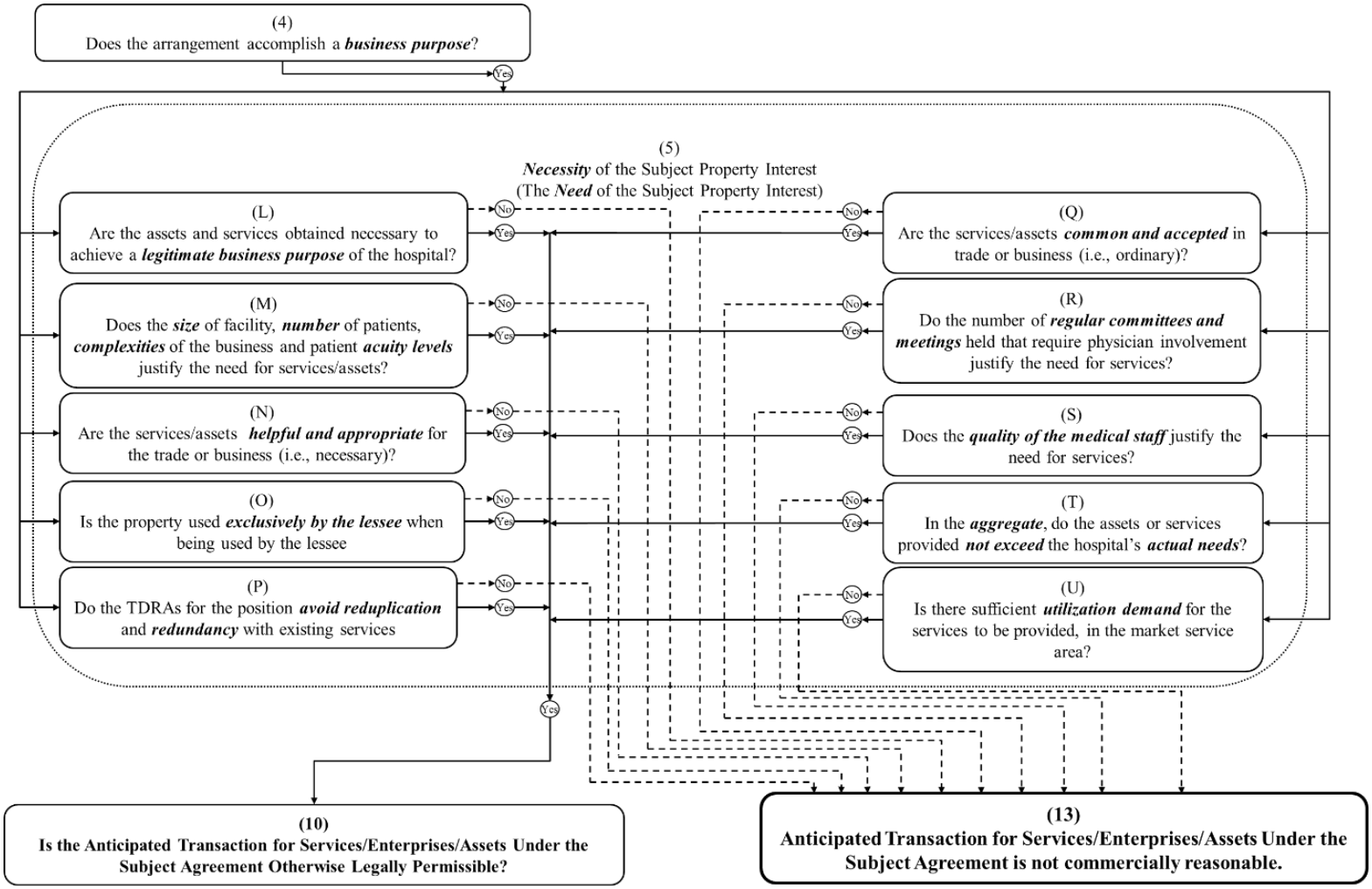
"Medicare and State Health Care Programs: Fraud and Abuse: Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute," 64 Federal Register 63525 (11/19/99).
"Hospital Mergers: Why They Work, Why They Don't," By Larry Scanlan, Chicago, IL: Health Forum, 2010, p. 27.
"Mergers, Acquisitions, and Corporate Restructurings," By Patrick Gaughan, Hoboken, NJ: John Wiley & Sons, 2011, p. 14-15.
"Joint Ventures for Hospitals and Physicians: Legal Considerations," By Ross Stromberg and Carol Boman, American Hospital Publishing, 1986, p. 5." Mergers, Acquisitions, and Corporate Restructurings," By Patrick Gaughan, Hoboken, NJ: John Wiley & Sons, 2011, p. 175.

Commercial Reasonableness Qualitative Analysis

- Necessity of the Property Interest
  - The IRS requires a determination of whether the consideration paid for the property interest is
    - "*ordinary*"
      - i.e., "*common and accepted in trade or business*"
    - *"necessary*"
      - i.e., "*helpful and appropriate for the trade or business*", in light of the "*the volume of business handled*" by the acquirer, e.g., the number of "*beds, admissions, or outpatient visits*;" "*the complexities of the business*;" and/or, the "*size of the organization*"

Trade or Business Expenses for Itemized Deductions for Individuals and Corporations for the Computation of Taxable Income for Normal Taxes and Surtaxes, 26 USC Section 162 (1/3/12). "Deducting Business Expenses, Internal Revenue Service, 1/2/2013, http://www.irs.gov/Businesses/Small-Businesses-&-Self-Employed/Deducting-Business-Expenses (Accessed 2/26/13). "Publication 535 Business Expenses, Internal Revenue Service, 2011, http://www.irs.gov/publications/p535/ch02.html (Accessed 2/25/13). "IRS Exempt Organizations Hospital Compliance Project: Final Report," Internal Revenue Service, 11/7/08, p. 136. "Physician Compensation Arrangements: Management and Legal Trends," By Daniel Zismer, Gaithersburg, MD: Aspen Publishers, 1999, p. 204.

Analytical Process for Assessing the Necessity of the Subject Property Interest



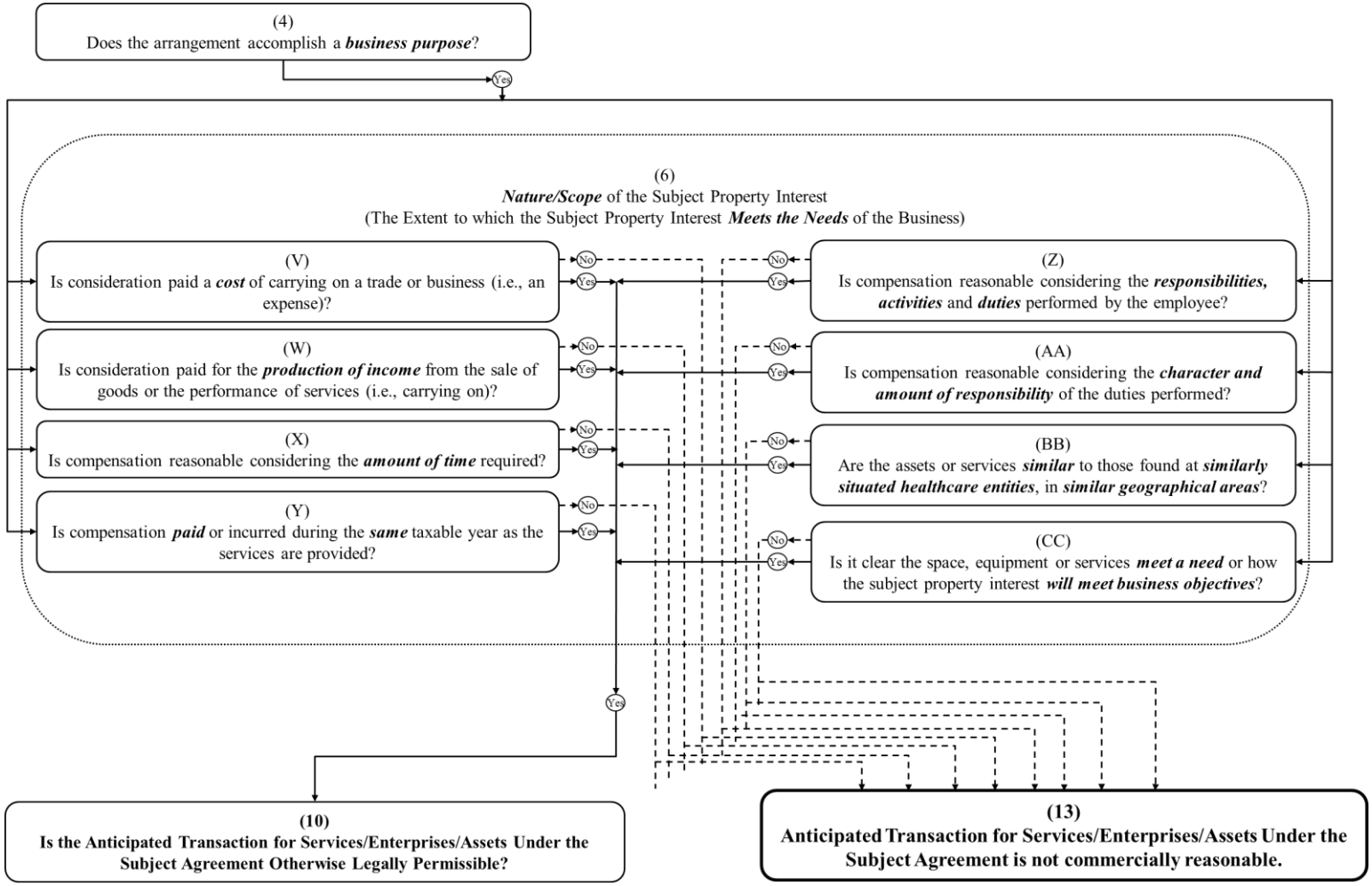
"Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services," By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons Inc., 2014, p. 949.

Commercial Reasonableness Qualitative Analysis

- Nature and Scope of the Property Interest
  - IRS - The nature and scope of services provided should be analyzed to determine as to whether their cost is:
    - A "*cost of carrying on a trade or business*"
    - Undertaken "*for the production of income from the sale of goods or the performance of services*"
    - "…*paid or incurred during the taxable year*"
    - "…*reasonable in terms of the responsibilities and activities…assumed under the contract*"
    - "…*reasonable in relation to the total services received*"

"Unrelated Trade or Business" in "Taxation of Business Income of Certain Exempt Organizations", 26 USC Section 513 (1/3/12). "Trade or Business Expenses for Itemized Deductions for Individuals and Corporations for the Computation of Taxable Income for Normal Taxes and Surtaxes", 26 USC Section 162 (1/3/12). "IRS Revenue Ruling 69-383, 1969-2 CB 113", Internal Revenue Service, 1969. "Health Care Provider Reference Guide", By Janet Gitterman and Marvin Friedlander, Internal Revenue Service, 2004, p. 19.

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



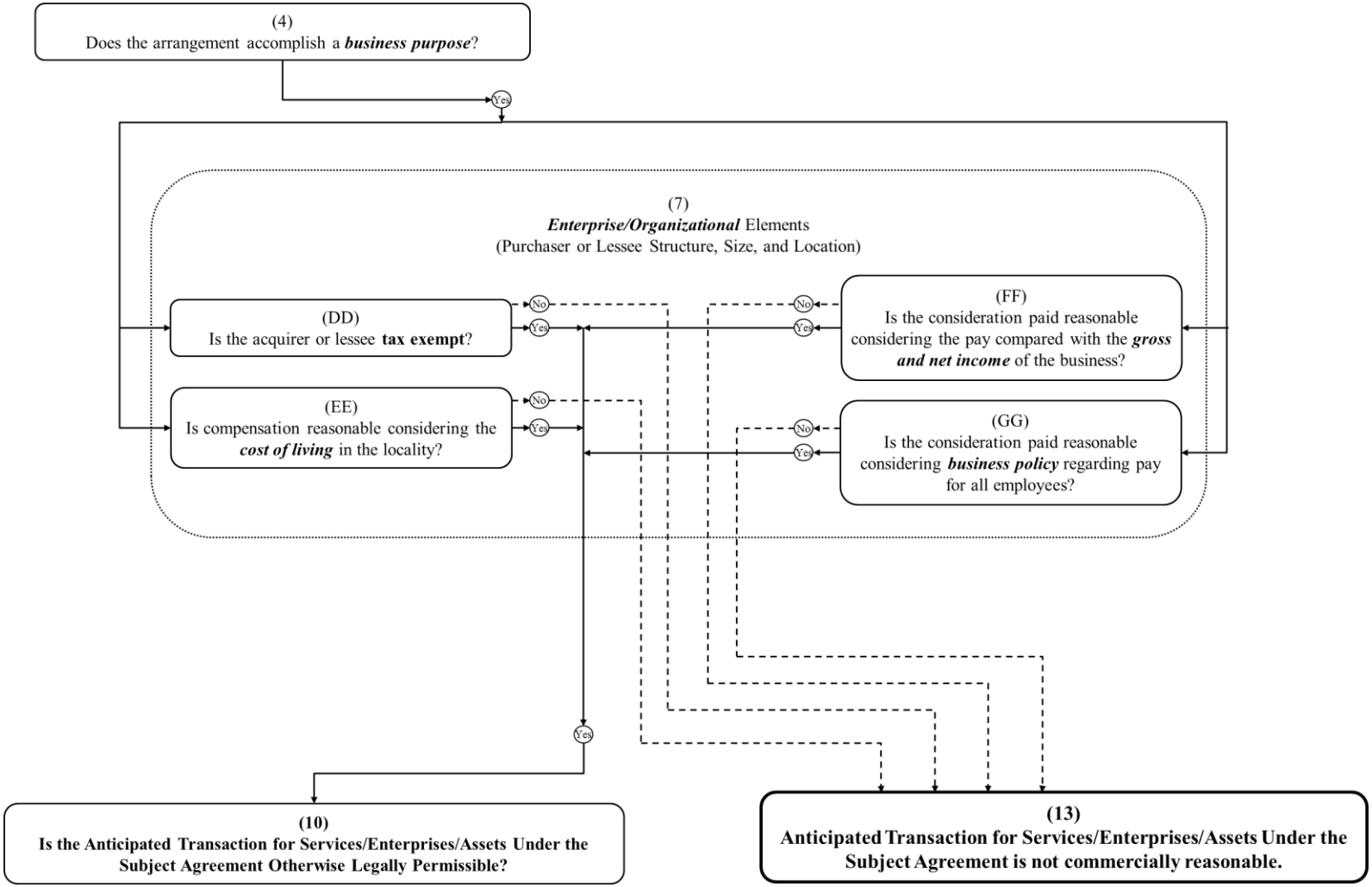
"Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services," By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons Inc., 2014, p. 953.

Commercial Reasonableness Qualitative Analysis

- Enterprise and Organizational Elements
  - The IRS pronouncements on reasonable compensation for tax purposes offer analysts guidance that a determination should be made as to whether the consideration paid for the property interest is "…*a sensible, prudent business agreement*…" within the context of:
    - "*the pay compared with the gross and net income of the business*"
    - "*business policy regarding pay for all employees*"
    - "*the cost of living in the locality*," based on an analysis of the "*national and local economic conditions*" including whether the acquirer is located in a "…*rural, urban, or suburban*" area

"Medicare and Medicaid Programs: Physicians Referrals to Health Care Entities with Which They Have Financial Relationships", 63 Federal Register 1700, (1/9/98). "Publication 535 Business Expenses", Internal Revenue Service, 2011, http://www.irs.gov/publications/p535/ch02.html (Accessed 2/25/13). "Physician Compensation Arrangements: Management and Legal Trends", By Daniel Zismer, Gaithersburg, MD: Aspen Publishers, 1999, p. 204. "IRS Exempt Organizations: Hospital Compliance Project Final Report", Internal Revenue Service, 11/7/08, p 136.

Analytical Processes for Assessing the Enterprise and Organizational Elements



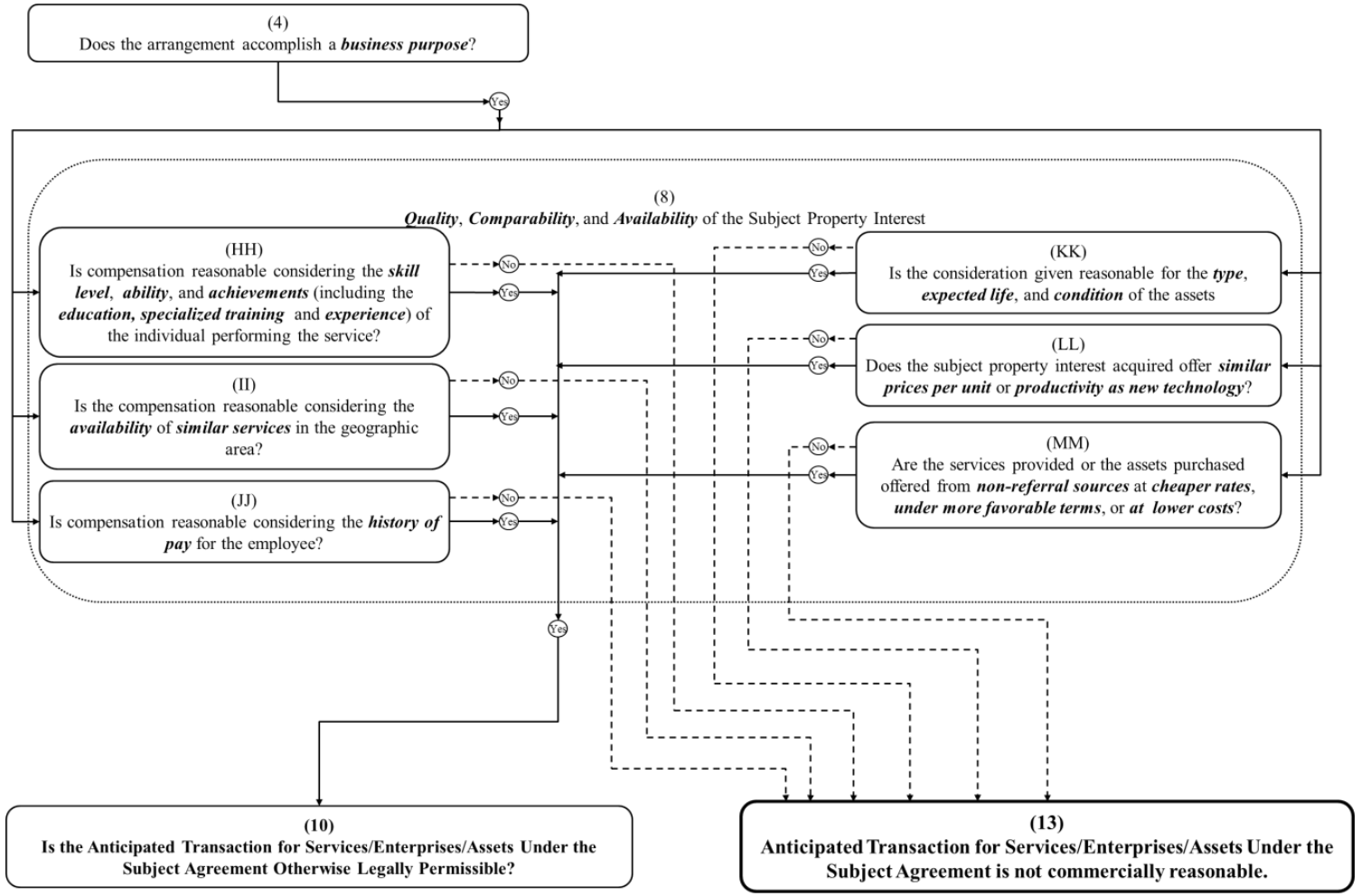
"Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services," By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons Inc., 2014, p. 955.

Commercial Reasonableness Qualitative Analysis

- Quality, Comparability, and Availability of the Subject Property Interest
  - Based on the nature and scope of the services provided, the analyst should determine:
    - Those attributes which speak to the nature and quality of the services, assets, and enterprises included in the anticipated transaction
      - Including the education and specialized training of those individuals subject to the transaction

"IRS Exempt Organizations Hospital Compliance Project: Final Report", Internal Revenue Service, 11/7/08, p. 136. "Publication 535 Business Expenses", Internal Revenue Service, 2011, http://www.irs.gov/publications/p535/ch02.html (Accessed 2/25/13). Note that the commentary below offers justification for paying physicians at higher rates per unit of productivity than they historically earned in private practice.

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



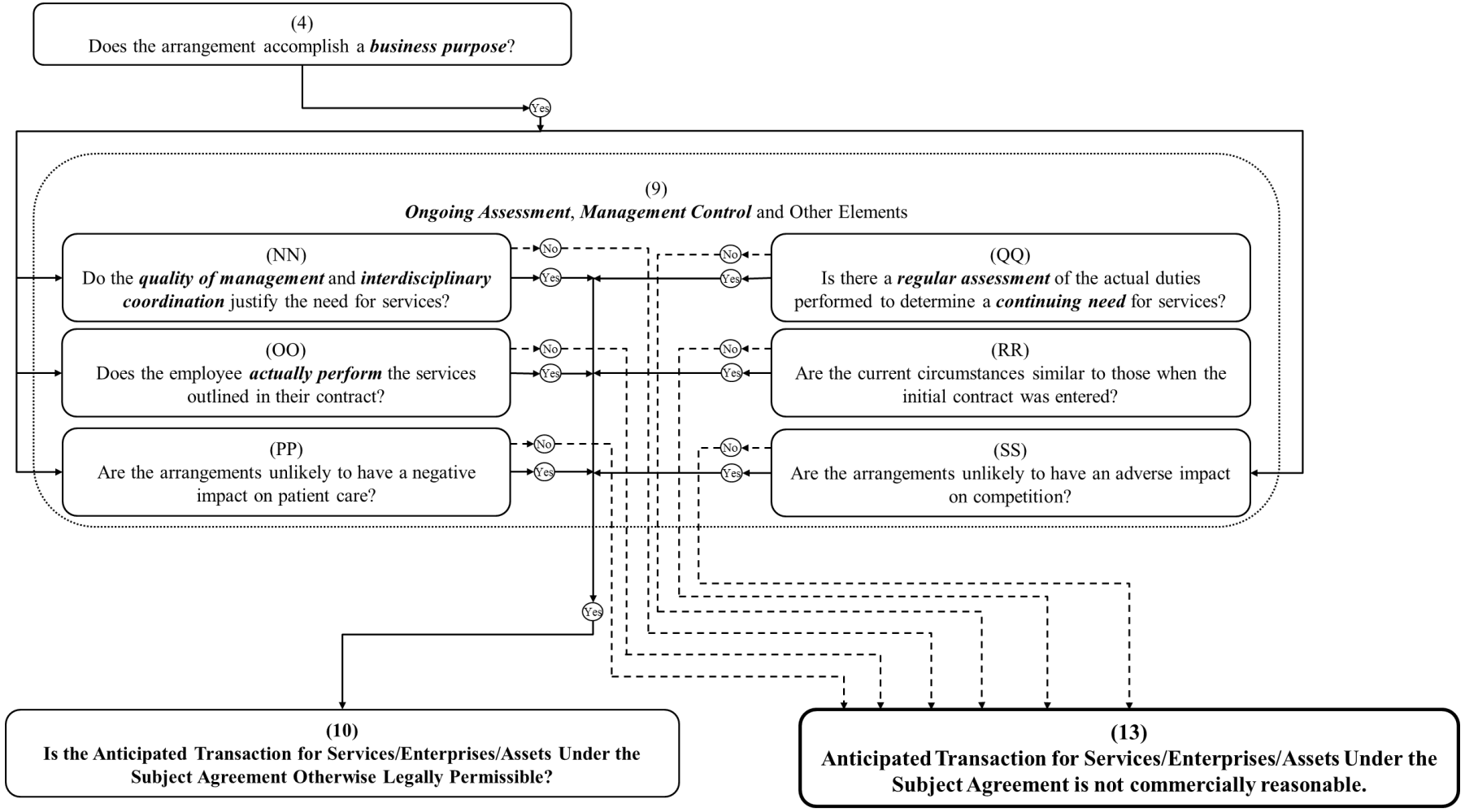
"Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services," By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, John Wiley & Sons Inc., 2014, p. 957.

Commercial Reasonableness Qualitative Analysis

- Management Control, Ongoing Assessment, & Other Elements
  - The "*quality of management and interdisciplinary coordination*"
  - "*Consideration given and received [is paid] under materially different circumstances*" than when the contract was initially entered
  - The openness of the proposal process
  - The effects of patient care and market competition
  - The hospital's current physician integration efforts

"Fair Market Valuation of Medical Director of Program Director Services", By Kathy McNamara, Mayer Hoffman McCann PC, 7/12/05, in Plaintiff United States Designation of Expert Witness, "United States ex rel. Kaczmarczyk, et. al. v. SCCI Hospital Houston Central, et. al" No. H-99-1031 (S.D.T.X. 2005). "U.S. ex rel. Ted Kosenske, MD, v Carlisle HMA, Inc., and Health Managements Associates, Inc.," 07-4616 US District Court 05-cv-02184, (1/21/09), p. 18. "OIG Advisory Opinion Number 12-09", Office of Inspector General, 7/23/12, p. 6-7.

Analytical Processes for Assessing the Ongoing Assessment, Management Control, & Other Elements



"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. 959.

Commercial Reasonableness Qualitative Analysis

- Otherwise Legally Permissible
  - Antitrust Considerations
    - Additional factors to consider may be found in Antitrust pronouncements by the *Federal Trade Commission* (FTC)
    - Example: FTC's success in blocking St. Luke's Health System's acquisition of Saltzer Medical Group in Idaho in 2014
  - IRS Considerations
    - The IRS prohibits *excess benefit transactions* between tax-exempt organizations (such as a hospital) and other parties, in which "*the value of the economic benefit provided exceeds the value of the consideration received for providing the benefit*"

"Statements of Antitrust Enforcement Policy in Health Care", US Department of Justice and the Federal Trade Commission, August 1996, p. 4. Taxes on excess benefit transactions. 26 CFR 53.4958-4(a)(1).

Commercial Reasonableness Qualitative Analysis

- Otherwise Legally Permissible
  - Stark Law Considerations
    - Prohibits physicians from referring Medicare or Medicaid patients to an entity for *designated health services* if the physician, or an immediate family member, has a financial relationship with that entity
    - However, there are numerous exceptions, notably:
      - Bona fide employment exception
      - Personal services exception

42 U.S.C. Section 1395nn(a)(1)(A). 42 CFR 1001.952 - Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors for Certain Electronic Prescribing and Electronic Health Records Arrangements Under the AntiKickback Statute.

Commercial Reasonableness Qualitative Analysis

- Otherwise Legally Permissible
  - Anti-Kickback Statute Considerations
    - Illegal to:
      - "*knowingly and willfully solicit or receive any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program*."

"Antikickback Statute", 42 USC Section 1320a-7b(b).

Commercial Reasonableness Quantitative Analysis

- Post-Transaction Financial Feasibility Analysis
  - The analyst should also undertake a *quantitative analysis* as part of the determination of the *Commercial Reasonableness* of both:
    - The discrete elements
    - The entirety of the anticipated transaction
  - Takes into account all consideration to be paid by acquirers to sellers and lessors

Quantitative Analysis

- When performing a *cost/benefit analysis* for a *particular buyer,* a valuation analyst may also wish to consider the *value metrics*, which result from the application of one or more of the following analytical methods, to serve as a basis for a *commercial reasonableness* opinion related to an anticipated transaction:

  - *Net present value (NPV) analysis*, which examines the total *expected risk-adjusted future net economic benefits* (e.g., present value of the future net cash flows) anticipated to be generated from the operation of the subject property interest net of the *initial economic expense burdens* (e.g., initial cash outlays) necessary to acquire the property interest;

  - *Internal rate of return (IRR) analysis,* which calculates the discount rate necessary to result in a **zero** *net present value*, which rate can be compared to an investors required rate of return for a specific property interest to determine the viability of the investment;

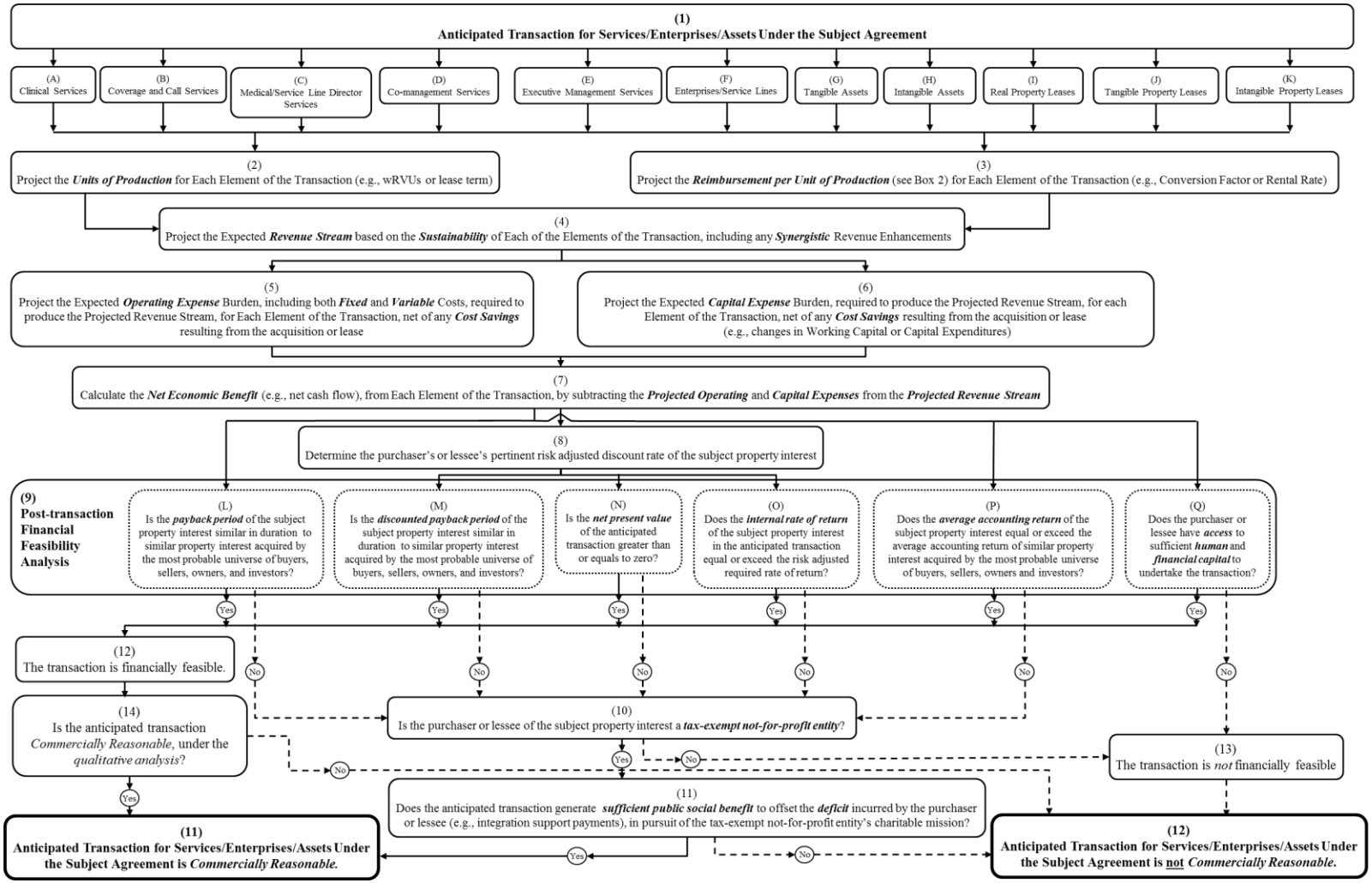
Fundamentals of Corporate Finance," By Stephen Ross, et al., Second Edition, Boston, MA: Irwin, 1993, p. 220, 231. "Principles of Corporate Finance," By Richard Brealey, et al., Ninth Edition, New York, NY: McGraw-Hill Irwin, 2008, p. 120-122, 228.

Quantitative Analysis

- When performing a *cost/benefit analysis* for a *particular buyer,* a valuation analyst may also wish to consider the *value metrics*, which result from the application of one or more of the following analytical methods, to serve as a basis for a *commercial reasonableness* opinion related to an anticipated transaction:
  - *Average accounting return (AAR) analysis*, which determines the average of the *net income* arising from the assets or services to be acquired in the anticipated transaction *for each discrete accounting period*, divided by the book value of those subject property interest(s) acquired *for each of the corresponding accounting periods*;
  - *Payback period analysis*, which calculates the number of discrete periods necessary for *"the cumulative forecasted [undiscounted] cash flow [to] equal the initial investment*;" and,
  - *Discounted payback period analysis*, which is similar to a *payback period analysis,* calculates the number of discrete periods *"…until the sum of the* ***discounted*** *cash flow is equal to the initial investment*" [emphasis added].

Fundamentals of Corporate Finance," By Stephen Ross, et al., Second Edition, Boston, MA: Irwin, 1993, p. 220, 231. "Principles of Corporate Finance," By Richard Brealey, et al., Ninth Edition, New York, NY: McGraw-Hill Irwin, 2008, p. 120-122, 228.

Analytical Process for the Quantitative Analysis



"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. 965.

Quantitative Analysis

- Each of the *value metrics* that results from the *cost/benefit analyses* described above should be considered within the context of the *qualitative factors* of the *commercial reasonableness* analysis
- This is especially true when the *cost/benefit analysis* reflects a *financial (cash) loss*, as a transaction may still be *commercially reasonable* after the *non-monetary benefits* that may arise from the anticipated transaction are taken into consideration
- For example, the benefits produced by a transaction that results in an expansion into new geographic areas and/or new service lines or an improvement in the access to technology and/or innovation may provide substantial evidence of a prudent business decision, i.e., *commercial reasonableness*

For a detailed discussion on the *qualitative factors* of the commercial reasonableness analysis, see "Threshold of Commercial Reasonableness: The Qualitative Analysis," Health Capital Topics, Vol. 7, Issue 11, December 2014, http://www.healthcapital.com/hcc/newsletter/12_14/QUALITATIVE.pdf (Accessed 1/12/15); or, "Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services," By Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, Vol. 2, Hoboken, NJ: John Wiley & Sons, Inc., 2014, p. 940-963.

Inherent Conflict between MACRA & Commercial Reasonableness

Distortion of the Commercial Reasonableness Analysis

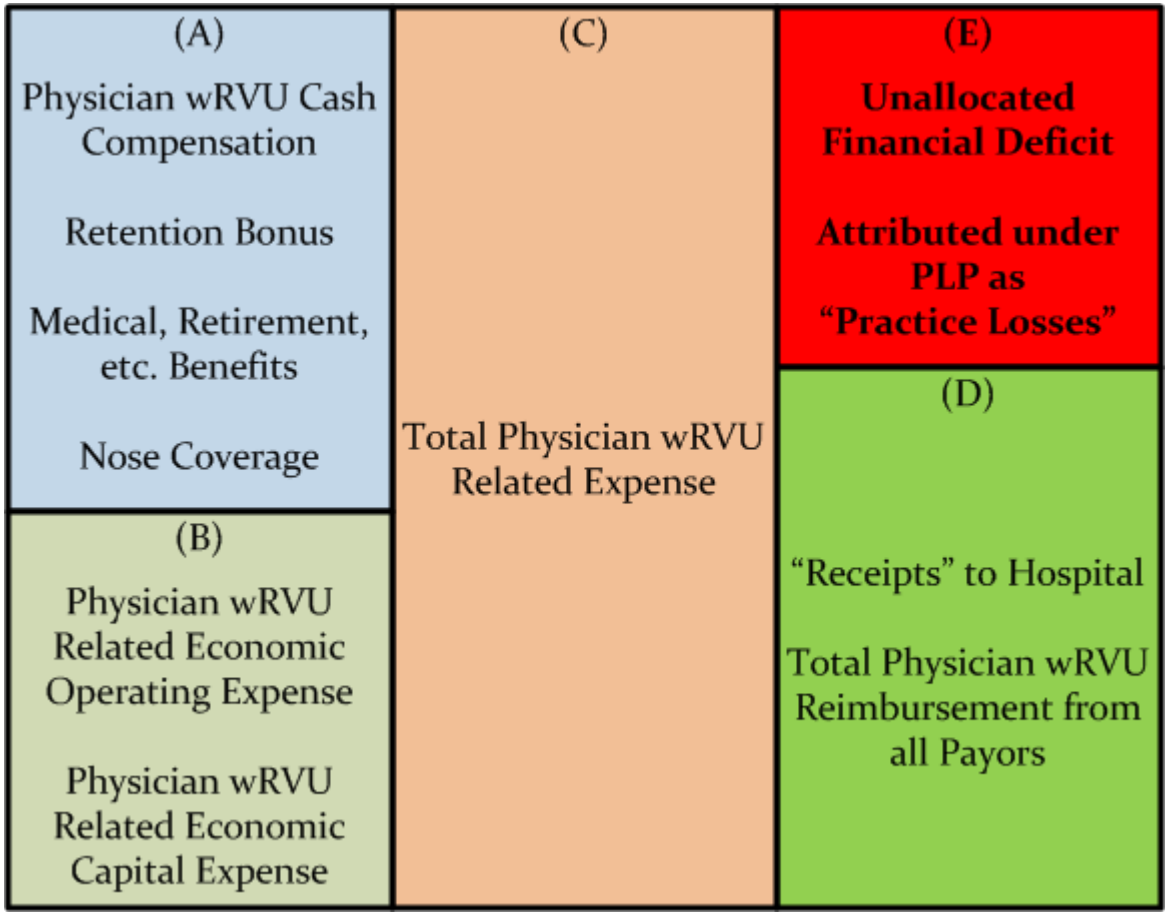
Government regulators (more specifically, the OIG and the DOJ) have, in some cases, challenged vertical integration transactions under various federal and state *fraud and abuse laws*, partly basing their arguments on the concept, termed the *Practice Loss Postulate* (PLP), that the acquisition of a 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

American Hospital Association Letter to U.S. Senate, By Thomas P. Nickels, Letter to The Honorable Orrin Hatch and The Honorable Ron Wyden, re Stark Law, January 29, 2016.

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*

Distortion of the Commercial Reasonableness Analysis

This misguided theory overly simplifies the *commercial reasonableness* analysis, such that the threshold has been "*contorted to cap a physician's compensation at levels that he or she could generate if he or she remained an independent seller of physician services, even if part of that compensation is paid for supervising non-physician members of a multidisciplinary team in the efficient delivery of quality care*."

American Hospital Association Letter to U.S. Senate, By Thomas P. Nickels, Letter to The Honorable Orrin Hatch and The Honorable Ron Wyden, re Stark Law, January 29, 2016.

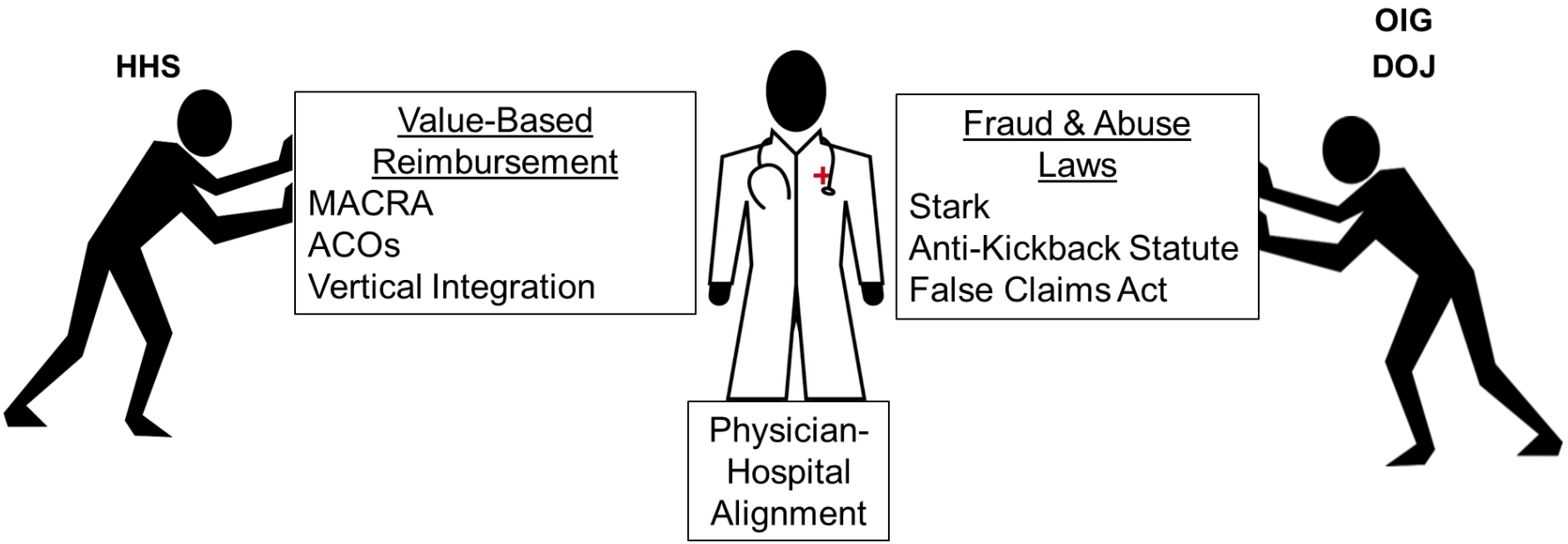
Distortion of the Commercial Reasonableness Analysis

Government regulators (more specifically, the OIG of HHS and the DOJ) have, in some cases, challenged vertical integration transactions under various federal and state fraud and abuse laws, basing their arguments, in part, on the concept, termed the *Practice Loss Postulate* (PLP) that 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

"United States ex rel. Drakeford v. Tuomey Healthcare System, Inc." 675 F.3d 394, 407 (4th Cir. 2012); "United States 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; "United States ex rel. Reilly v. North Broward Hospital District, et al." Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relators Third Amended Complaint Under Federal False Claims Act, p. 31; "United States ex rel. Payne et al. v. Adventist Health System et al." Case No. 3:12cv856-W (W.D.N.C. February 13, 2013), Relators Amended Complaint, p. 56; "Health System Practice Losses Make Headlines, Plaintiffs Make New Stark Law" By Eric B. Gordon and Daniel H. Melvin, BNAs Health Care Fraud Report, Bloomberg BNA, November 25, 2015, http://www.mwe.com/files/Publication/a1a5d17c-3c79-4380-baef-0d11822334a1/Presentation/PublicationAttachment/5bb1e6ca-6491-4907-9a57-1049c2f3eec6/Gordan-Melvin.pdf (Accessed 12/15/15).

Inherent Conflict between MACRA and Fraud & Abuse Laws

"*The Left Hand Doesn't Know What the Right Hand is Doing*"



Fraud & Abuse Laws

- Regulatory considerations related to fraud have had a significant impact on:
  - Value attributable to each property interest
  - Valuation process itself
- *"Fraud"*
  - Several distinct meanings within the context of the healthcare regulatory framework
  - Effects the property's profitability and sustainability
  - Creates significant risk and uncertainty for business entities

Anti-kickback Statute (AKS)

- Makes it 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
- Arrangements must not take into account the *"volume or value"* of referrals

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

Anti-kickback Statute (AKS)

- Violations punishable by up to five years in prison and/or criminal fines up to $25,000
- Affordable Care Act – *"With respect to violations of [the Anti-kickback Statute] a person need not have actual knowledge of this section or specific intent to commit a violation of this section"*

"Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b); "Patient Protection and Affordable Care Act, Sec. 10606" Pub. Law 111-148, 124 Stat. 119 (March 23, 2010), p. 689.

Stark Law

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

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

Designated Health Services

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

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

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.

Inherent Conflict between MACRA and Fraud & Abuse Laws

- The goals of VBR and federal *fraud and abuse laws* are fundamentally discordant
  - MACRA (as well as the ACA) has furthered the transition to VBR, which payment models seek to reduce the overutilization of services, by incentivizing the provision of efficient, *evidence-based care* (in part through the utilization of *big data*), through a "*carrot and stick*" approach, i.e., through *shared savings* and *losses*

"Remaining Stark-Compliant with Practice Losses" and Ancillary Services" By Daniel W. Kiehl, JD, LLM, Coker Group, November 2016, http://cokergroup.com/wp-content/uploads/2016/11/Remaining-Stark-Compliance-with-Practice-Losses-and-Ancillary-Services_November-2016.pdf (Accessed 5/3/17).

Inherent Conflict between MACRA and Fraud & Abuse Laws

- The goals of VBR and federal fraud and abuse laws are fundamentally discordant
  - In order to provide coordinated, efficient care to meet these VBR goals, many organizations are considering various alignment strategies that amass the needed specialties and resources to provide for the full continuum of a patient episode of care, to take advantage of the VBR reforms

"Remaining Stark-Compliant with Practice Losses" and Ancillary Services" By Daniel W. Kiehl, JD, LLM, Coker Group, November 2016, http://cokergroup.com/wp-content/uploads/2016/11/Remaining-Stark-Compliance-with-Practice-Losses-and-Ancillary-Services_November-2016.pdf (Accessed 5/3/17).

Inherent Conflict between MACRA and Fraud & Abuse Laws

- As a result of aligning, particularly when aligning through employment arrangements with hospitals and health systems, many hospitals or health systems sustain *practice losses*
  - Due to a number of reasons, including:
    - Encountering a more adverse payor mix in a hospital setting
    - Needing to pay more competitive salaries to employed providers
    - The treatment of ancillary services by the hospital or health system

"Remaining Stark-Compliant with Practice Losses" and Ancillary Services" By Daniel W. Kiehl, JD, LLM, Coker Group, November 2016, http://cokergroup.com/wp-content/uploads/2016/11/Remaining-Stark-Compliance-with-Practice-Losses-and-Ancillary-Services_November-2016.pdf (Accessed 5/3/17).

July 2016 Senate Finance Committee Hearing on Stark Law

- In addition to requesting comments on technical Stark violations and Stark integration with MACRA, the committees also welcomed input on other Stark law challenges
- However, the two committees asked that additional comments be limited to a few topics, such as problems with the Stark law, costs of Stark law compliance and disclosure and potential fee-for-service fixes (*FMV*, *takes into account*, and *commercial reasonableness* safe harbors)

"Lawmakers Consider Changes to Physician Self-Referral Law" By James Swann, Bloomberg BNA, February 1, 2016, https://www.bna.com/lawmakers-consider-changes-n57982066790/ (Accessed 5/3/17).

July 2016 Senate Finance Committee Hearing on Stark Law

Senate Finance Committee Majority Staff White Paper:

"*The Stark law has become increasingly unnecessary for, and a significant impediment to, value-based payment models that Congress, CMS, and commercial health insurers have promoted. The risk of overutilization, which drove the passage of the Stark law, is largely or entirely eliminated in alternative payment models*."

"Why Stark, Why Now?" Senate Finance Committee Majority Staff (2016), p. 2, 15-16.

July 2016 Senate Finance Committee Hearing on Stark Law

American Hospital Association Letter to US Senate:

"*As interpreted today, the two 'hallmarks' of acceptability under the Stark law – fair market value and commercial reasonableness – are not suited to the collaborative models that reward value and outcomes*."

American Hospital Association Letter to U.S. Senate, By Thomas P. Nickels, Letter to The Honorable Orrin Hatch and The Honorable Ron Wyden, re Stark Law, January 29, 2016.

July 2016 Senate Finance Committee Hearing on Stark Law

Troy A. Barsky, Esq.:

"*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]

"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). 162 Cong. Rec. S5010 (July 12, 2016); "Examining the Stark Law: Current Issues and Opportunities" U.S. Senate Committee on Finance, July 12, 2016, http://www.finance.senate.gov/hearings/examining-the-stark-law-current-issues-and-opportunities (Accessed 8/31/16).

Failure of the PLP's *Commercial Reasonableness* Argument

- Losses on vertically integrated physician practices do not contraindicate the threshold of *commercial reasonableness*
- Hospitals routinely invest in initiatives, service lines, and uses of capital that do not immediately (or may never) yield direct ***financial (cash)*** returns on, or returns of, their investment, such as:
  - Emergency rooms, trauma services, pathology labs, and neonatal intensive-care units (NICU);
  - Research labs and clinical studies;
  - Principal research investigators, medical directors, and other types of physician executives;
  - Education of Residents; and,
  - Artwork and other aesthetics with the aim for therapeutic benefits to patients

"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.

Failure of the PLP's *Commercial Reasonableness* Argument

However, these investments may allow hospitals to reap other forms of ***utility*** aside from ***financial (cash)*** gains, e.g., the ***avoidance of cost*** or the generation of ***social benefits***. Therefore, 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. 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

"OIG Supplemental Compliance Program Guidance for Hospitals" Federal Register, Vol. 70, No. 19 (January 31, 2005) p. 4866.

Other Potential Specific Regulatory Implications

- In addition to these generally discordant objectives of MACRA and fraud and abuse laws, MACRA may present additional questions through the commercial reasonableness analysis in the evaluation of certain physician compensation arrangements
  - Example: Whether or not it is *commercially reasonable* to compensate or share MACRA reimbursement increases with physicians who are *not directly responsible* for improving quality

Other Potential Specific Regulatory Implications

- In order to encourage participation, CMS and the OIG have issued certain fraud and abuse waivers for advanced APMs, but each model has a different set of waiver rules, with which rules must be strictly complied to guarantee protection from fraud and abuse violations
- Because these waivers have been largely untested, some providers may still seek to remain compliant with fraud and abuse laws as a "*fall back*" measure

Concluding Remarks

Concluding Remarks

As succinctly stated in their *Journal of the American Medical Association* (JAMA) essay almost a decade ago by Professors Timothy S. Jost and Ezekiel J. Emanuel, MD, PhD:

> "*[t]he current legal environment has created major barriers to delivery system innovation. Innovation will not occur if each novel way to organize and pay for care needs to be adjudicated case-by-case or is threatened with legal proceedings*."

"Legal Reforms Necessary to Promote Delivery System Reform Innovation" By Timothy S. Jost and Ezekiel J. Emanuel, JAMA Vol. 299, no. 2561 (2008), p. 2561.

Concluding Remarks

- In summary, the current trend in the regulatory application of the PLP to challenge healthcare VBR models that incentivize vertical integration in healthcare is misguided and imprudent
- The PLP represents a less than rational interpretation and application of the *commercial reasonableness* threshold, in that it focuses its analysis solely on the financial ***quantitative*** factors, e.g., ***monetary (cash)*** returns, and ignores the ***qualitative*** factors, e.g., the ***avoidance of cost***, and the generation of ***social benefit***

Concluding Remarks

- 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 payment models to the extent that it would cause significant harm to the healthcare economy
- This may lead regulators, legislators, legal professionals, and analysts to lose sight of the overall benefits of vertical integration
- In essence, they are misled by a myopic fixation on the immediacy of red ink derived from a compartmentalized, stand-alone segment of the overall enterprise, such that they "*cannot see the forest for the trees*"

Concluding Remarks

- This potential impediment to sound decision-making on policy and case law is particularly troubling, given the acute need to improve the quality, accessibility, and efficiency of the U.S. healthcare delivery system
- If there was ever a time for the legal and economic communities to collaborate to address these important issues impacting the U.S. economy, and more particularly the U.S. healthcare delivery system, it would be now

"Mirror, Mirror on the Wall: How the Performance of the U.S. Health Care System Compares Internationally" By Karen Davis et al., The Commonwealth Fund, June 2014, http://www.commonwealthfund.org/~/media/files/publications/fund-report/2014/jun/1755_davis_mirror_mirror_2014.pdf (Accessed 5/27/2016).