CHICAGO 2017

# Commercial Reasonableness of Physician Compensation

## *Analytical Update with MACRA*

**Todd A. Zigrang, MBA, MHA, FACHE, ASA**

**HEALTH CAPITAL CONSULTANTS**

**Wednesday, December 13, 2017**

**9:15 – 11:50 a.m.**



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# Presenter Bio

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

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


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# Overview of Presentation

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


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# 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).


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# 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.


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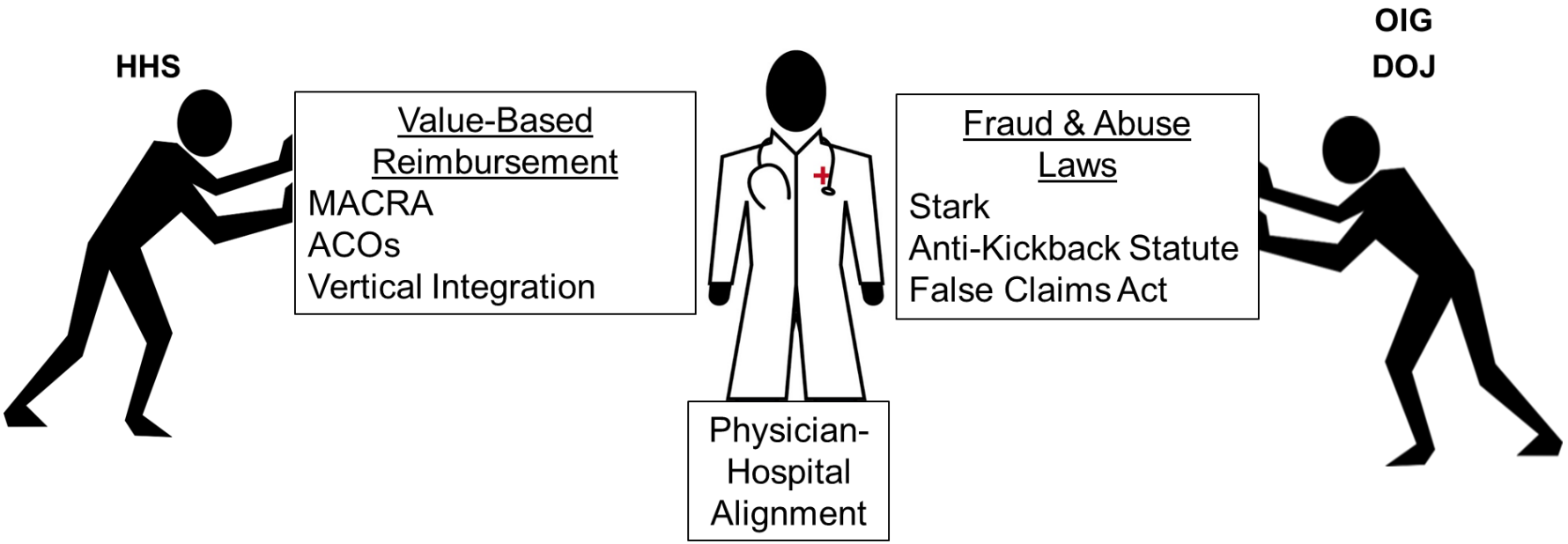
# Overview

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





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# Medicare Access & CHIP Reauthorization Act of 2015 (MACRA)


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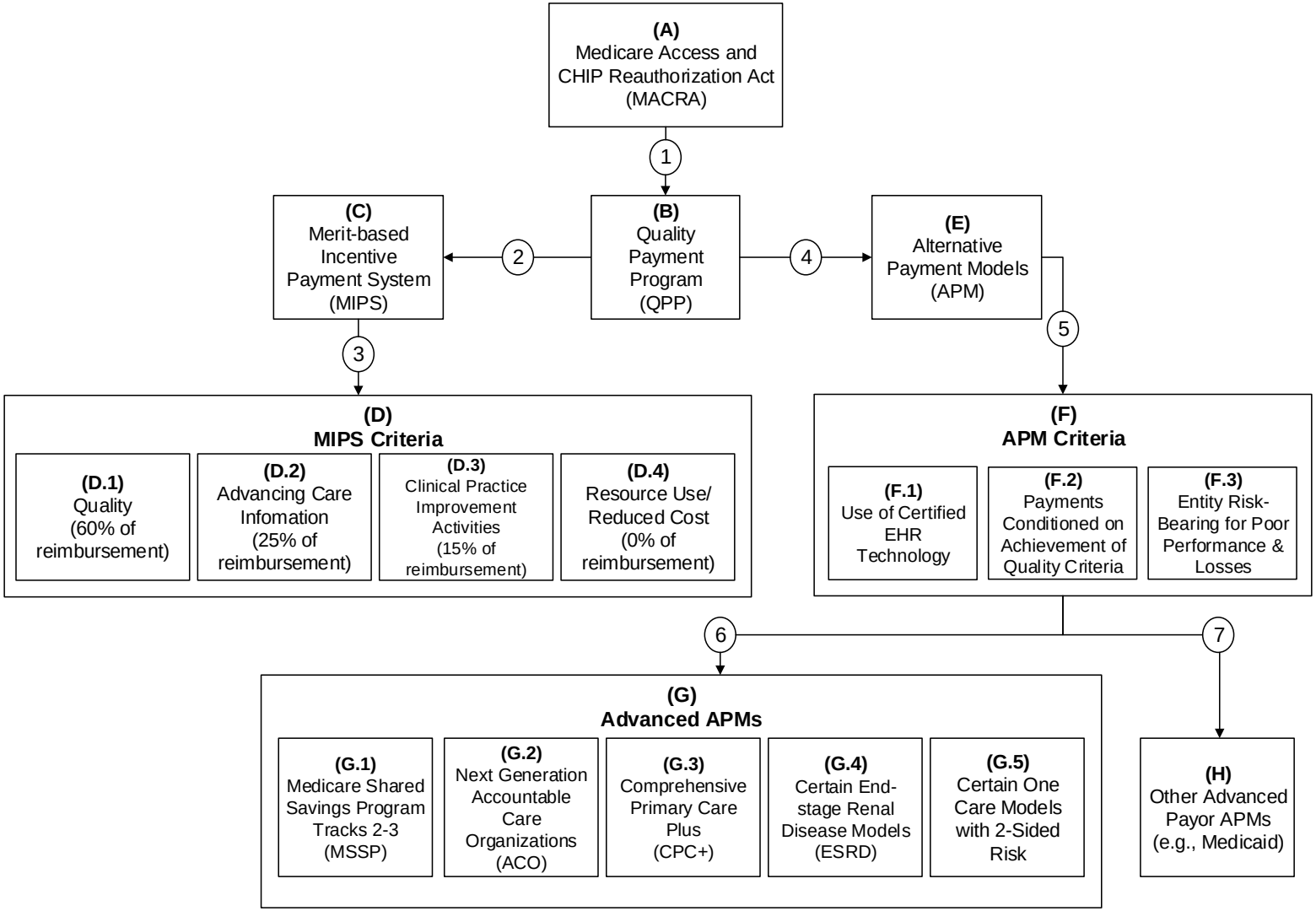
# MACRA Overview





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# 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.


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# 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).

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# 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.



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# 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).

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# 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).

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# 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.


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# 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).

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# 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).


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# 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).

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# 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).

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# The Threshold of Commercial Reasonableness


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# 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.


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# 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).

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# 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).



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# 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).



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# 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).

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# 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).

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# 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


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# Relevant Case Law Related to Commercial Reasonableness

- U.S. ex rel. Richard Raugh v. McLeod Regional Medical Center
  - *"[t]he claims for services referred, ordered or arranged by those physicians were alleged to be false in three respects:*
    - *First, Section 1877 of the Social Security Act, 42 USC 1395nn (also known as Stark II), prohibited McLeod from billing Medicare for items or services referred or ordered by physicians with whom it had such financial relationships*
    - *Second, McLeod forfeited its right to submit those claims to the federal health care programs by paying remuneration intended to induce those and other referrals in violation of the Anti-Kickback Statute, 42 USC 1320a-7(b)*
    - *And third, McLeod certified falsely on Medicare cost reports that the services identified or summarized were not provided or procured through payment directly or indirectly of a kickback or billed in violation of federal law"*



"McLeod Regional Medical Center to Pay U.S. Over $15 Million to Resolve False Claims Act Allegations," U.S. Dept. of Justice, Press Release, November 1, 2002, Accessed at http://www.justice.gov/opa/pr/2002/November/02_civ_634.htm (Accessed 3/25/2014).

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# Relevant Case Law Related to Commercial Reasonableness

- U.S. v. SCCI Hospital Houston
  - Qui tam action (eventually settled)
  - Commercial reasonableness of the compensation paid by the hospital to 3 physician medical directors challenged
  - Government's financial expert proposed:
    - Commercial reasonableness depends on agreement being *essential* to the functioning of the hospital
    - In order to be commercially reasonable, there has to be sound business reasons for paying medical director fees to refer physicians



"Fair Market Value in Health Care Transactions," By Lewis Lefko, Haynes and Boone, LLP, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

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# Relevant Case Law Related to Commercial Reasonableness

- U.S. v. SCCI Hospital Houston
  - Government's financial expert assessed commercial reasonableness through evaluating the:
    - Size of the hospital, number of patients, patient acuity levels, and patient needs
    - Quality of activities and involvement of medical staff in need of medical direction
    - Number of regular committees and meetings that required physician involvement
    - Quality of hospital management and interdisciplinary coordination of patient services



"Fair Market Value in Health Care Transactions," By Lewis Lefko, Haynes and Boone, LLP, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

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# Relevant Case Law Related to Commercial Reasonableness

- U.S. v. SCCI Hospital Houston
  - Government's financial expert concluded that Commercial Reasonableness depends on the hospital:
    - Performing a regular assessment of the actual duties performed by the medical director
    - Assessing the effectiveness of the medical director in performing his duties
    - Determining whether there is a bona fide need for continuing the medical director services



"Fair Market Value in Health Care Transactions," By Lewis Lefko, Haynes and Boone, LLP, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

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# Relevant Case Law Related to Commercial Reasonableness

- U.S. v. Covenant Medical Center
  - Five of Covenant's physicians were reportedly among highest-paid physicians in entire U.S., making as much as $2.1 million, despite Covenant's tax exempt status
    - Amounts significantly exceeded 75th percentile for physician compensation in the respective specialties
  - Significant discrepancies between the compensation paid to the 5 Covenant physicians, as compared to compensation paid to physicians in the region and around the country



"Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations," Press Release, U.S. Dept. of Justice, August 25, 2009, http://www.justice.gov/opa/pr/2009/August/09-civ-849.html (Accessed 3/25/2014).

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# Relevant Case Law Related to Commercial Reasonableness

- U.S. v. Bradford Regional Medical Center
  - Two physicians and the Medical Center had a direct financial relationship through non-compete clause of a sublease agreement for a nuclear camera
  - Court used a FMV analysis to determine legal impressibility of the sublease arrangement, applying Stark's definition of FMV and "*value or volume*" standard to determine whether lease took into account anticipated referrals
    - Significant exchange was the non-compete payments that required the physicians to *not* engage in the nuclear camera business



"Executive Summary of Report of Charles T. Day, CPA," U.S. ex rel. Singh v. Bradford Regional Medical Center, Civil No. 04-186 Erie (W.D. Pa.), November 10, 2010. "U.S. ex rel. Singh v. Bradford Regional Medical Center," Opinion, Civil No. 04-186 Erie (W.D. Pa.), November 10, 2010, p. 48-49.

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# Relevant Case Law Related to Commercial Reasonableness

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



Executive Summary of Report of Charles T. Day, CPA," U.S. ex rel. Singh v. Bradford Regional Medical Center, Civil No. 04-186 Erie (W.D. Pa.), November 10, 2010. "U.S. ex rel. Singh v. Bradford Regional Medical Center," Opinion, Civil No. 04-186 Erie (W.D. Pa.), November 10, 2010, p. 48-49.

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# Relevant Case Law Related to Commercial Reasonableness

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



"U.S. ex rel. Drakeford v. Tuomey," 2012 U.S. Ct. App. WL 1059849.

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# Relevant Case Law Related to Commercial Reasonableness

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



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

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# Relevant Case Law Related to Commercial Reasonableness

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

"U.S. ex rel. Baklid-Kunz v. Halifax Hosp. Med Ctr., et al," Civ. Act. No. 6:09-CV-1002-ORL-31 DAB, (M.D. Fla.), November 4, 2011, p. 17-18. "DOJ asks Halifax Health to pay up to $600 million in whistleblower case" The Pathology Blawg, June 6, 2013, http://pathologyblawg.com/medical-news/doj-asks-halifax-health-pay-up-600-million-whistleblower-case/ (Accessed 10/3/2013). "Damages in whistle-blower Medicare fraud case against Halifax Hospital could hit $1B" By Marni Jameson, Orlando Sentinel, July 5, 2013, http://articles.orlandosentinel.com/2013-07-05/health/os-whistleblower-medicare-fraud-halifax-20130705_1_elin-baklid-kunz-damages-marlan-wilbanks (Accessed 10/3/2013).



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# Relevant Case Law Related to Commercial Reasonableness

- U.S. ex rel. Heesch v. Diagnostic Physicians Group
  - The Clinic's compensation to the physician group allegedly included a percentage of the money collected from Medicare for tests and procedures the providers referred to the Clinic
  - The government alleges that physicians "*received a financial benefit from ordering tests at [the Clinic] that they did not receive from referring tests to other clinics and hospitals*"
    - Physicians were paid "*compensation for order tests outside their specialties*"

"The United States Complaint in Intervention" in "U.S. ex rel. Heesch v. Diagnostic Physicians Group" Civil Action No. 11-0364-KD-B, S.D. Ala., (Aug. 8, 2013), p. 29. "US Joins False Claims Act Lawsuit Alleging Illegal Physician Compensation by Mobile, Ala. Health Firm" US. Department of Justice Office of Public Affairs, http://www.justice.gov/opa/pr/2013/July/13-civ-768.html, July 8, 2013, (Accessed 3/25/2014). "The United States Complaint in Intervention" in "U.S. ex rel. Heesch v. Diagnostic Physicians Group" Civil Action No. 11-0364-KD-B, S.D. Ala., (Aug. 8, 2013), p. 29. "US Joins False Claims Act Lawsuit Alleging Illegal Physician Compensation by Mobile, Ala. Health Firm" US. Department of Justice Office of Public Affairs, http://www.justice.gov/opa/pr/2013/July/13-civ-768.html, July 8, 2013, (Accessed 3/25/2014).



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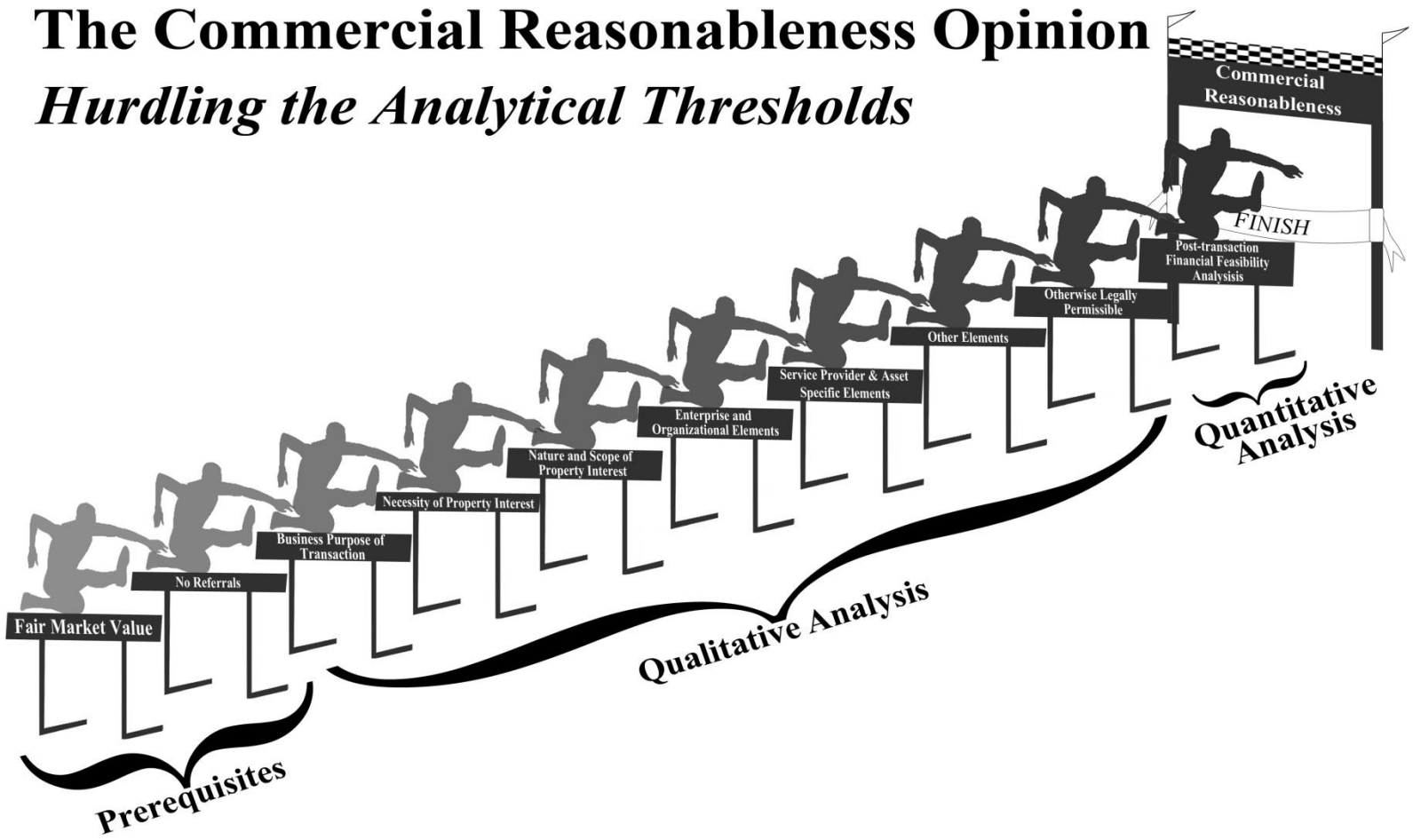
# The Commercial Reasonableness Analysis





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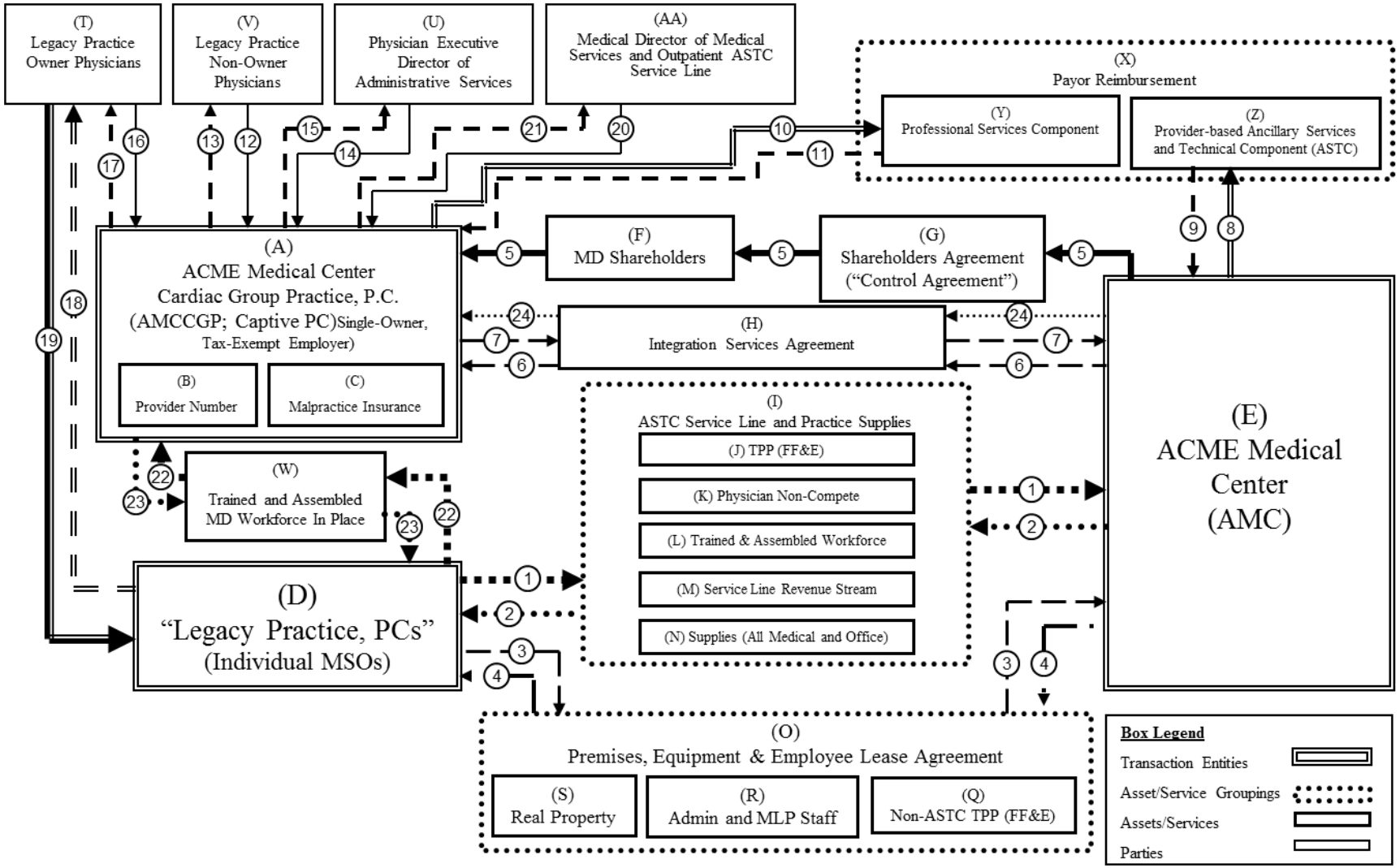
# Illustrative Summary of a Healthcare Transaction



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# 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


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# 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).



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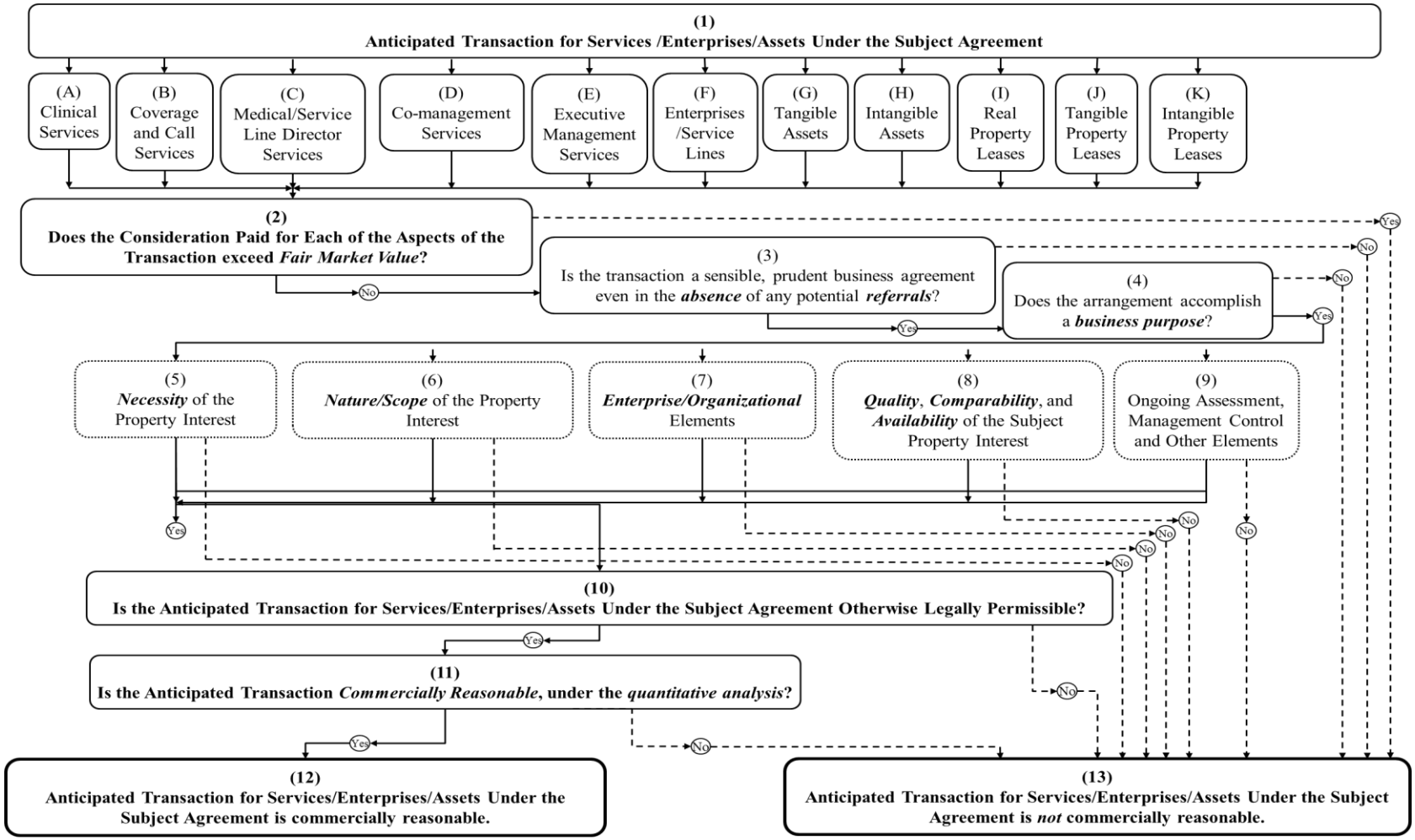
# Steps in Determining Commercial Reasonableness




"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.



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# 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?


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# 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
      - 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.


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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Business Purpose
  - Examples:
    - Prevalence, incidence, and mortality rates of cardiovascular disease in the *Market Service Area* (MSA), State, & US
    - Number of patients with cardiovascular diseases
    - Number of deaths as a result every year
    - Number of new diagnoses per year
    - Relative frequency of demographic and behavioral risk factors associated with heart disease in MSA, State, & US



Can compare the number of new diagnoses to the mortality rates to ascertain whether the prevalence is likely to grow in the area.

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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Business Purpose
  - Examples (continued):
    - Cardiovascular disease risk factors:
      - Physical activity
      - Nutrition
      - Obesity
    - Cardiovascular screening and diagnosis efforts in MSA, State, and US
    - Types of screening tests
    - Compliance with screening tests


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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Business Purpose
  - Examples (continued):
    - Cardiovascular disease treatment options in MSA, State, & US
      - Sources: American Heart Association, National Heart, Lung, & Blood Institute
    - Supply of cardiologists and cardiovascular surgeons and cardiology services in MSA, State, and US
    - Economic costs related to Cardiovascular Disease in MSA & US
      - Sources: Data.CMS.gov: Medicare Provider Utilization and Payment Data (filter for cardiology), Centers for Disease Control website


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# Commercial Reasonableness Qualitative Analysis



- Cardiology Practice Case Study – Business Purpose
  - Examples (continued):
    - The level of competition related to the service lines of the Subject Entity within the MSA
      - Potential competitors:
        - Short-term acute care hospitals
        - Cardiology practices that provide a full range of services
        - Diagnostic imaging centers
      - Sources: Data.CMS.gov: Medicare Provider Utilization and Payment Data (filter for cardiology), American Hospital Directory, American Board of Medical Specialties (ABMS), American College of Cardiology, Intersocietal Accreditation Commission



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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Business Purpose
  - Examples (continued):
    - The payor environment in the State and the US
      - Examine:
        - All private insurance
        - Commercial HMOs
        - Medicare
        - Medicaid
        - Other public payors
        - Number of uninsured
      - Determine for each, in both the State and the US:
        - Number of plans
        - Number of enrollees
        - Enrollees per plan
        - Total population
        - Enrollees as a % of the population


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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Business Purpose
  - Potential Sources:
    - American Heart Association
    - State/Local Department of Health
    - "*Physician Characteristics and Distribution in the US: 2014 Edition*" By the American Medical Association
    - Health Insurance Coverage of the Total Population per state, compiled by Kaiser Family Foundation
    - US Population Estimates from the US Census Bureau
    - State Population Estimates from the US Census Bureau
    - American College of Cardiology
    - Intersociety Accreditation Commission (Echocardiography, Nuclear/PET, Vascular Testing Facilities)


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# 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.


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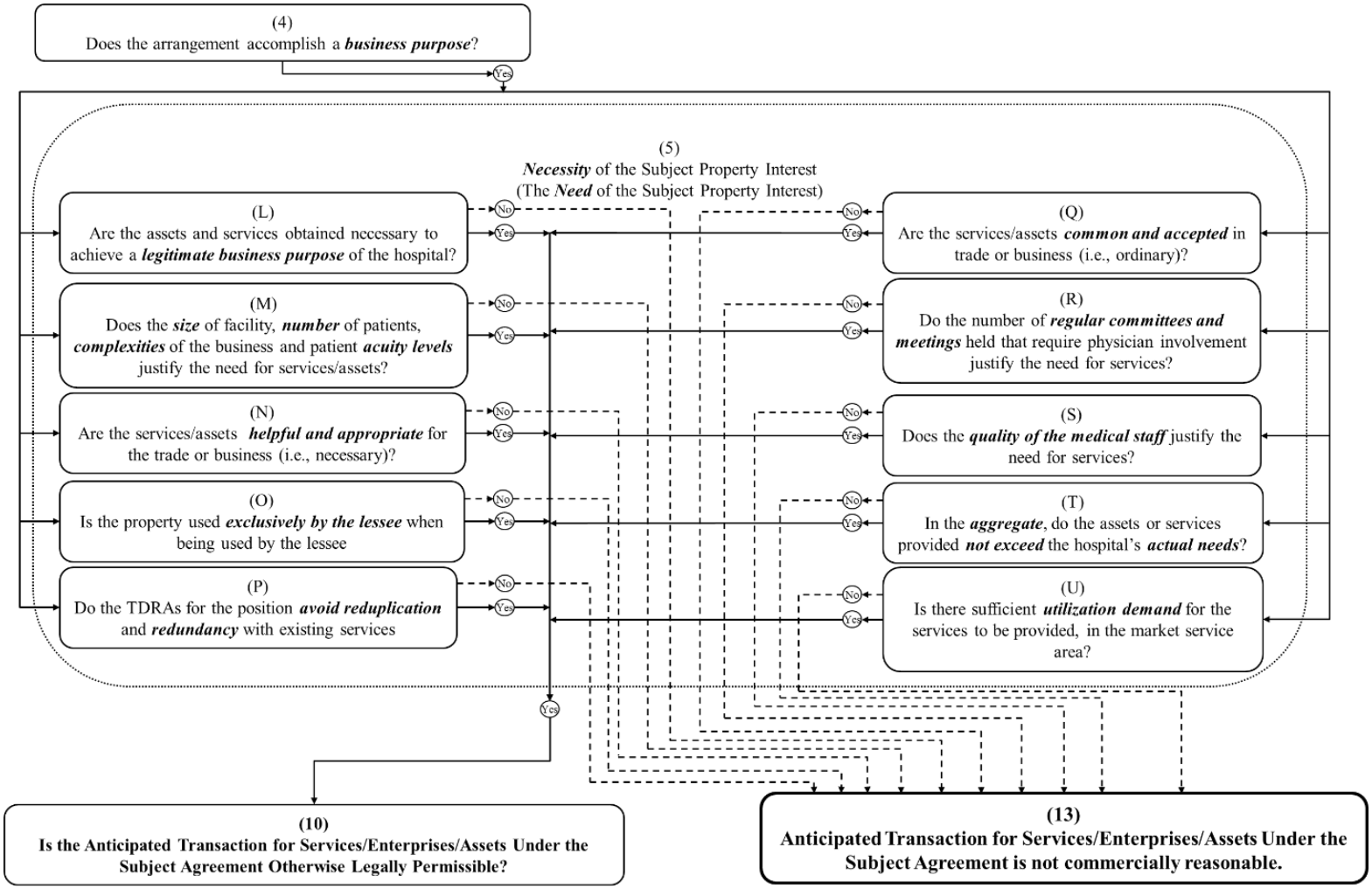
# Analytical Process for Assessing the Necessity of the Subject Property Interest






"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.

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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Necessity
  - The historical and expected volume of clinical services performed by the Subject Entity
  - The incidence and prevalence of cardiovascular disease, including future utilization demand projections based upon estimated growth and cardiovascular disease risk factors in the patient demographic in the MSA
    - e.g., that demand for cardiovascular services, including any ancillary services, will increase as the population segments most susceptible to cardiovascular disease continue to increase at a rapid rate


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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Necessity
  - Current and anticipated supply of physicians in MSA, including provider supply, as compared to state and national levels
  - Competitive and managed care environment of MSA
  - Economic and demographic trends of MSA


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# 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.


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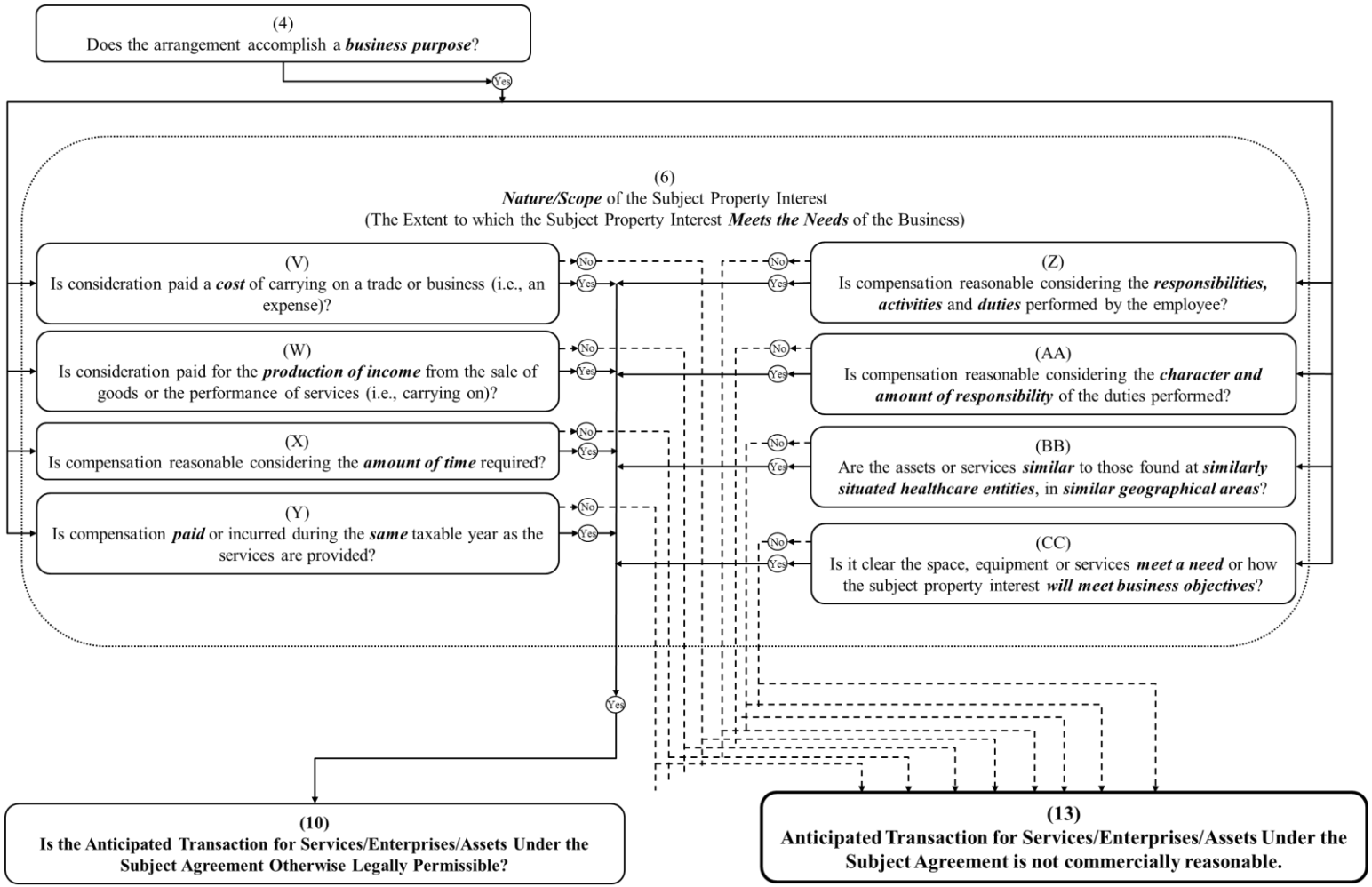
# Analytical Processes for Assessing the Nature & Scope of the Subject Property Interest



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# Commercial Reasonableness Analysis

- Cardiology Practice Case Study – Nature and Scope
  - Look to the Integration Transaction documentation to determine the enterprises, assets, and services included in the transaction
    (e.g., the agreement(s) between the Subject Entity and the Acquiring Entity (ACME Hospital))
    - Do the nature and scope of the assets and services of the Subject Entity meet the stated needs of ACME Hospital?
      - e.g., based on any anticipated changes in demand, any anticipated changes in competition the charitable mission of the hospital


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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Nature and Scope
  - Determine whether the services/assets of the Subject Entity were "*ordinary*", compare the various enterprises/assets/services with industry norms
  - FMV reports may indicate that the *consideration paid* for the elements of the Integration Transaction do not exceed the range of FMV, and therefore, the *consideration paid* for these assets and services was considered to be for "*ordinary*" assets and services


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# 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.


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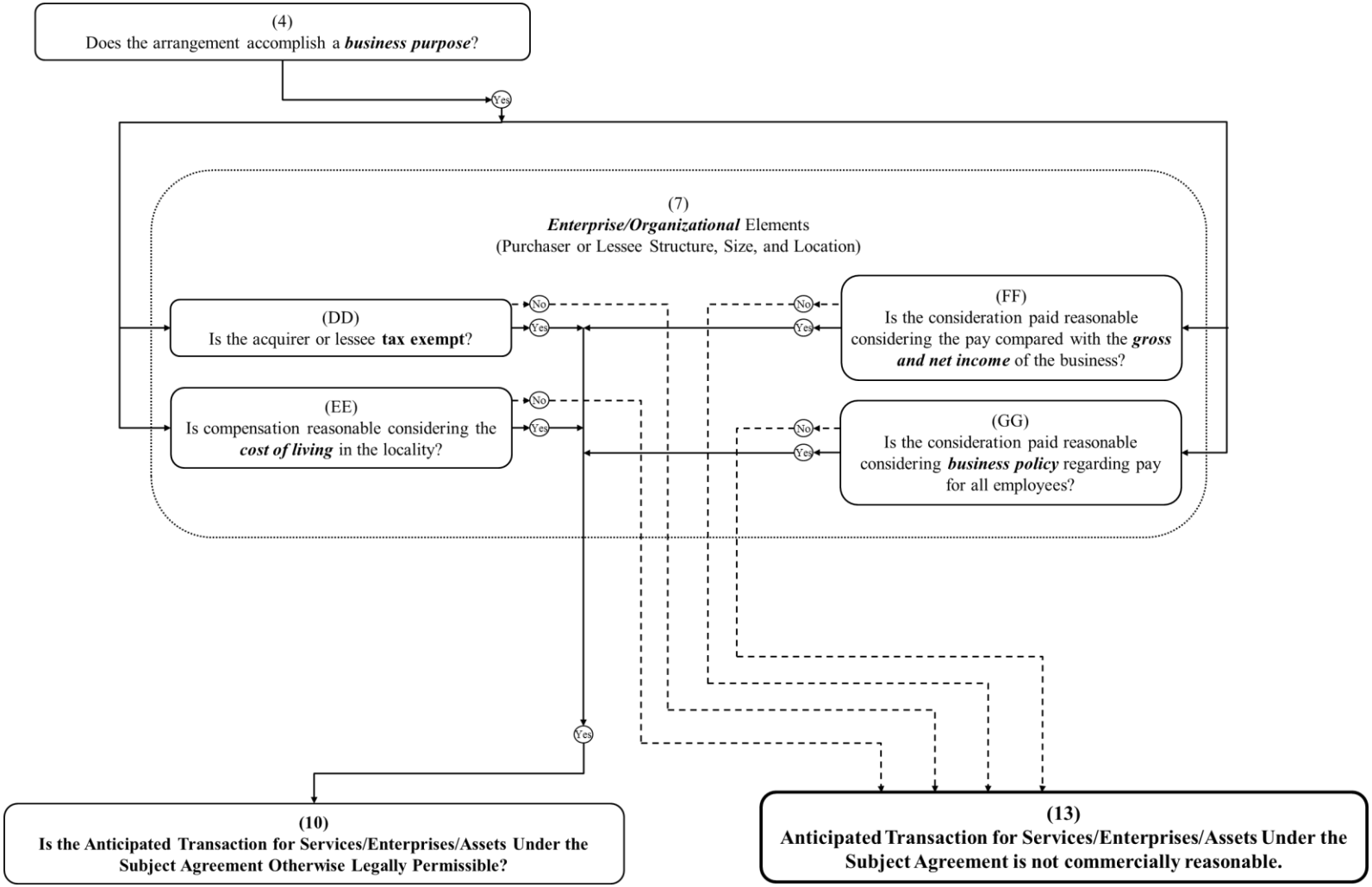
# Analytical Processes for Assessing the Enterprise and Organizational Elements



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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study – Enterprise and Organizational Elements
  - ACME Hospital's strategic goals and operational plans related to the Integration Transaction
    - Sources:
      - Hospital's website
      - Internal documents from the client
      - Analysis performed by strategic consulting firms
        - Analysis of competing hospital strategies


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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study (continued)
  - Does the Integration Transaction support ACME Hospital's charitable mission in light of the economic and demographic conditions of the MSA in which ACME Hospital serves its patients?
  - Analyze other pertinent enterprise and organizational elements of the Integration Transaction
- Potential Sources
  - Hospital's charitable mission
  - Hospital's website (description of services and indigent care policies)


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# 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.


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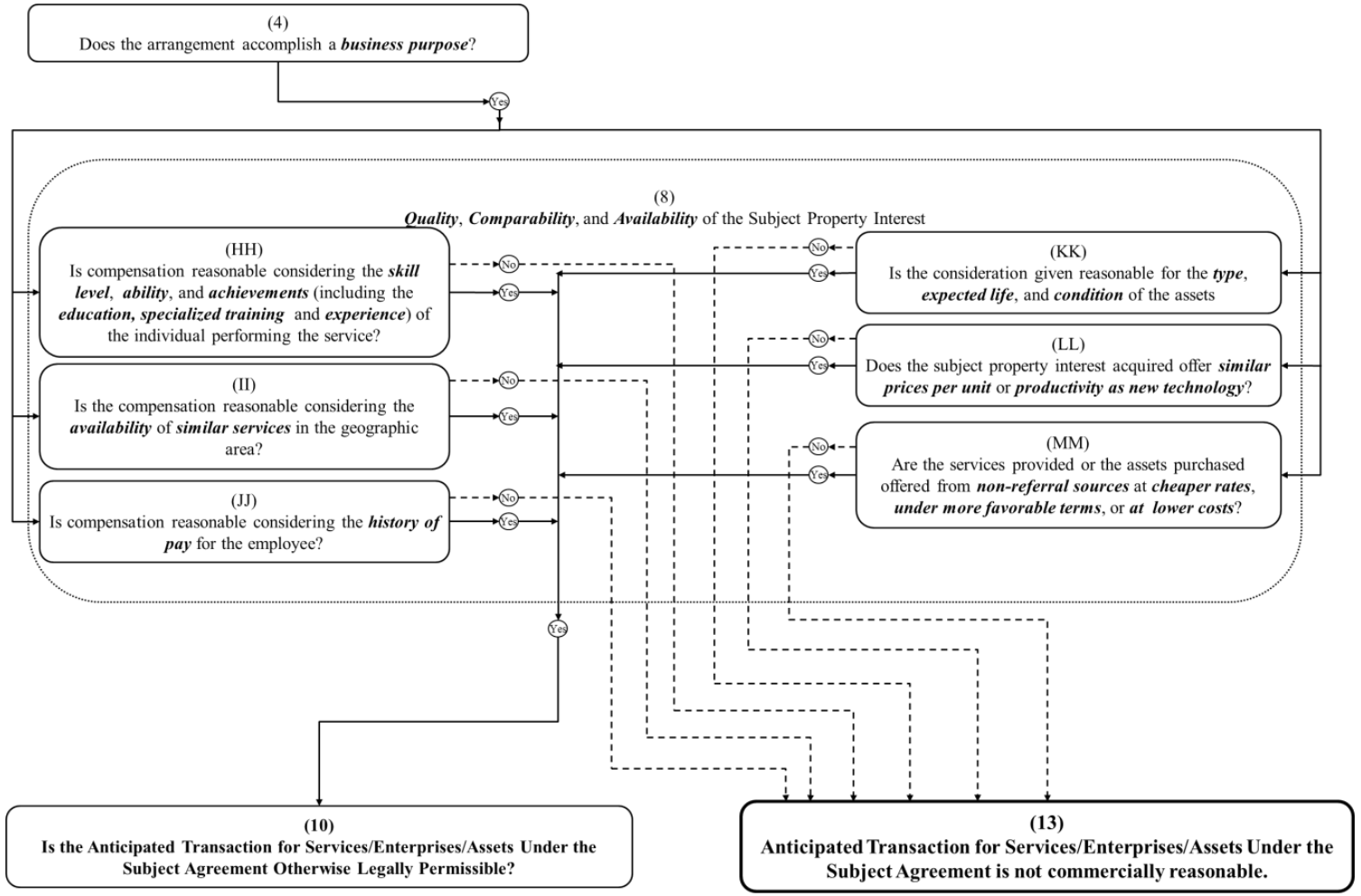
# Analytical Processes for Assessing Quality, Comparability, & Availability of Subject Property Interest



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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study
  - Quality, Comparability, and Availability of Care Provided by the Physicians Included as Part of the Integration Transaction
    - Review the Physicians in the Integration Transaction as related to:
      - "*[T]he ability and achievements of the individual performing the service*," including "*education*," "*specialized training and experience of the*" individual
        - Research
        - Publications
        - HCHAPS and PQRS scores
        - Patient Outcomes
      - "*[T]he history of pay for the employee*"
      - "…*[T]he availability of similar services in the geographic area*…"
      - "…*[T]he skill level and experience reasonably necessary to perform the contracted services*"

"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. "OIG Supplemental Compliance Program Guidance for Hospitals" 70 Fed. Reg. 4867 (1/31/05).



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# Commercial Reasonableness Qualitative Analysis

- Cardiology Practice Case Study
  - Quality, Comparability, and Availability of the Subject Property Interest - Sources
    - Physicians' CVs
    - Local, regional, & state scorecards
    - U.S. News and World Report
    - American Medical Association
    - American Board of Medical Specialties


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# 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.


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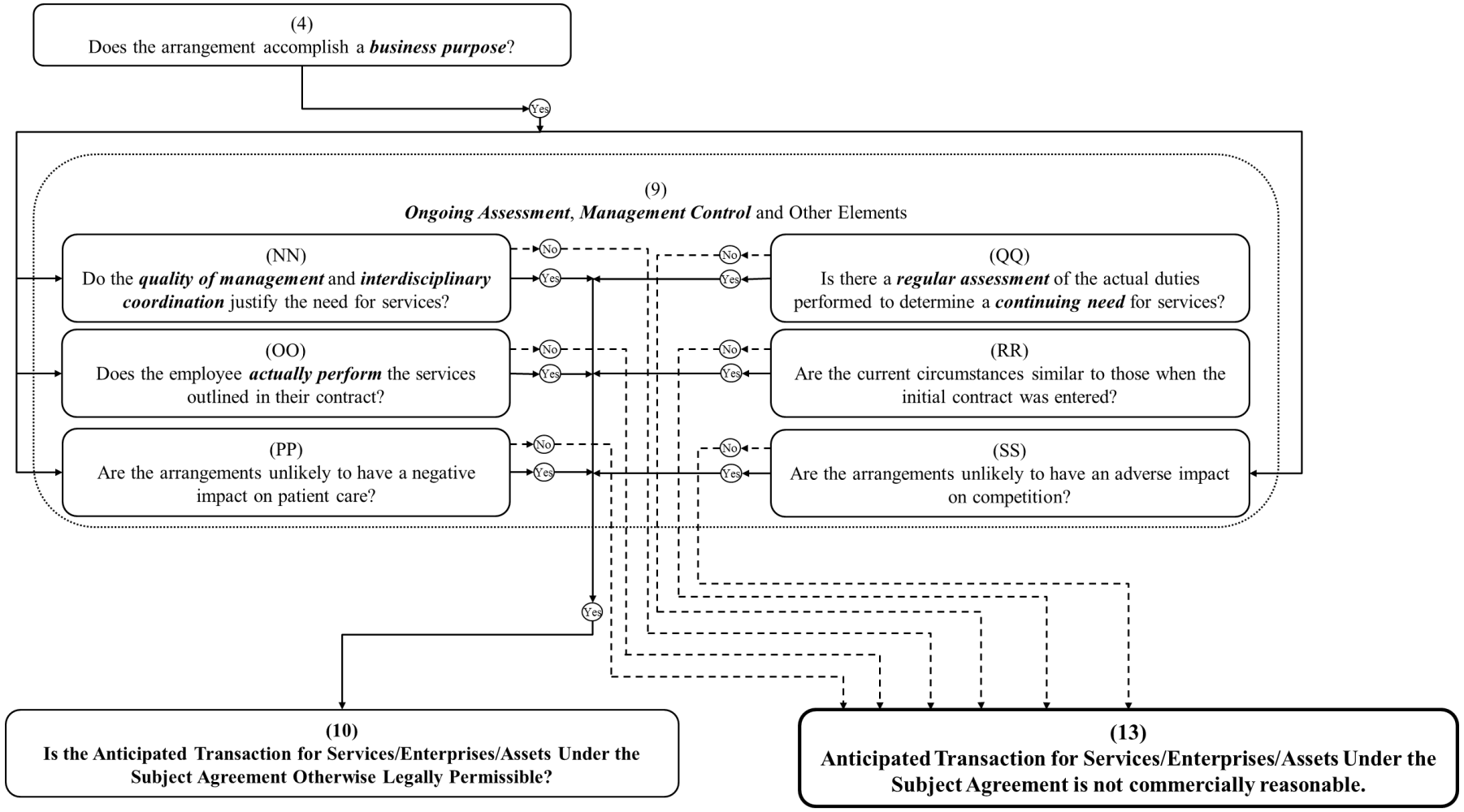
# Analytical Processes for Assessing the Ongoing Assessment, Management Control, & Other Elements



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# Commercial Reasonableness Analysis Qualitative Analysis

- Cardiology Practice Case Study
  - ACME Hospital's Ongoing Assessment, Management Control, and Other Elements relating to the Integration Transaction
    - Examine:
      - ACME Hospital's monitoring plans (e.g., timesheets)
      - ACME Hospital's organizational structure hierarchy
    - Sources:
      - Internal data provided by hospital


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# 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).


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# 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.


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# 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).

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# 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


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# 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.

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# 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.


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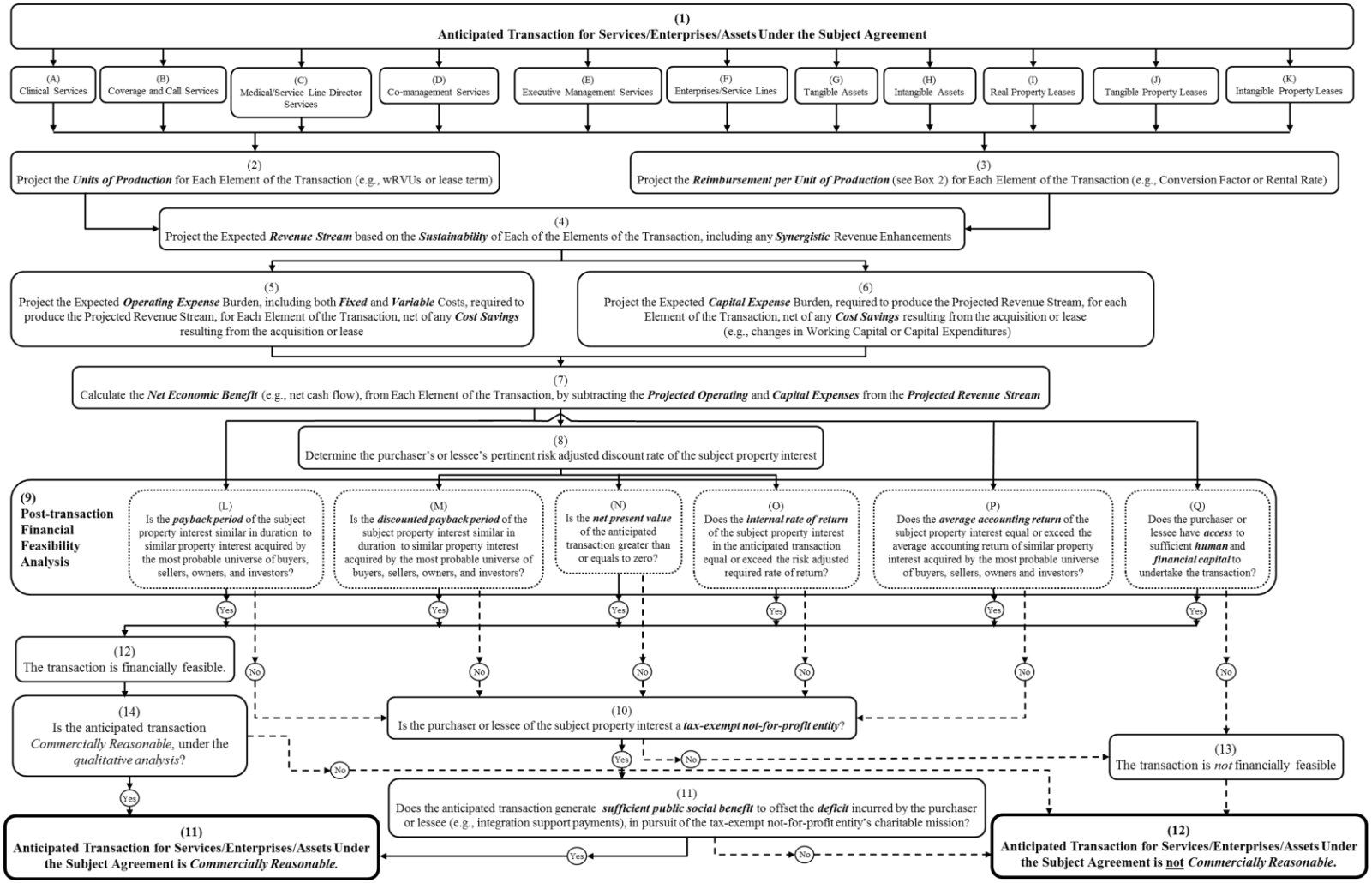
# Analytical Process for the Quantitative Analysis




"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.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# 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.


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# Commercial Reasonableness Quantitative Analysis

- Cardiology Practice Case Study
  - Analysis of the Financial Feasibility of the Integration Transaction in its Entirety
    - Examples
      - Impact of Integration Transaction on *Ancillary Services and Technical Component* (ASTC) services reimbursement
      - Cost containment efforts by ACME Hospital (e.g., reducing overhead)
      - Impact on ACME Hospital's net income and free cash flow


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# Inherent Conflict between MACRA & Commercial Reasonableness


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# 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.

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# 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


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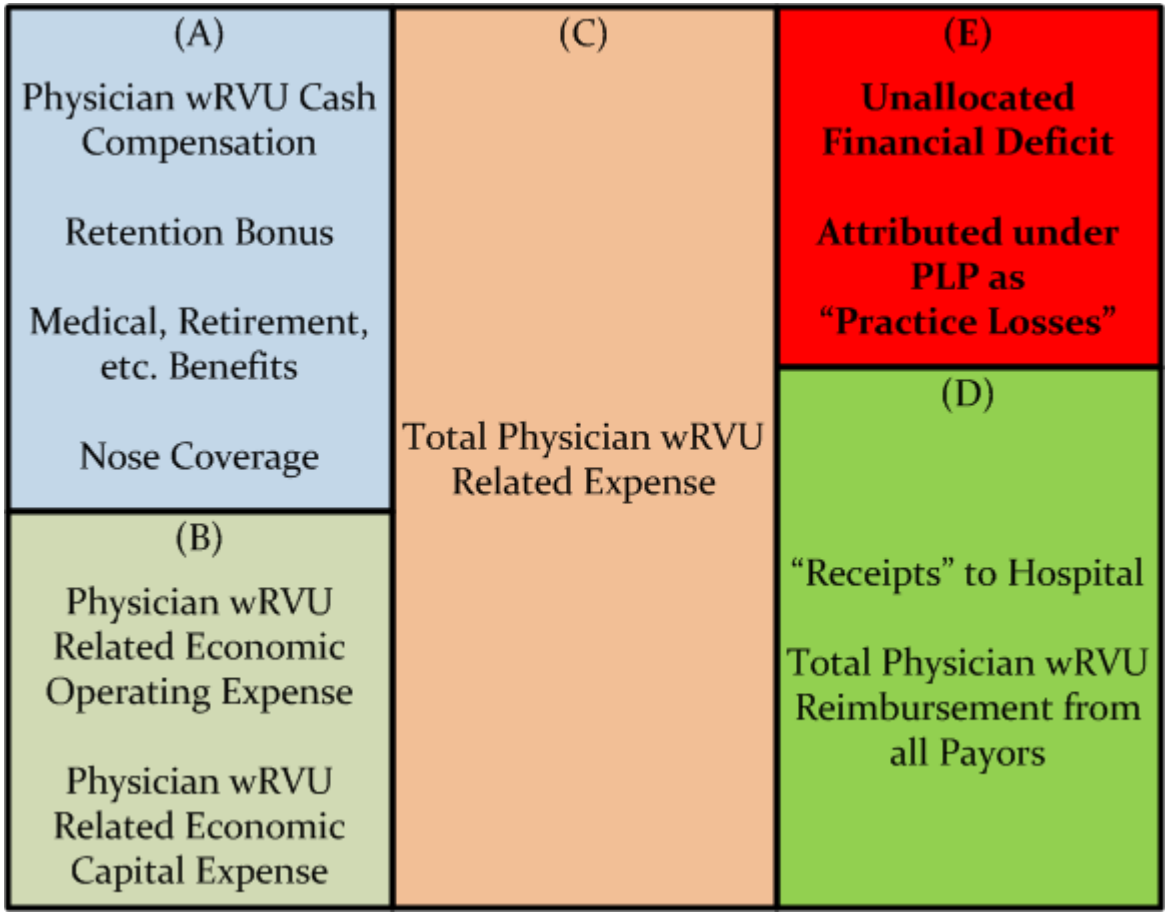
# Summary of the Practice Loss Postulate





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# Summary of the Practice Loss Postulate

| (E) | (F) | (G) | (H) |
|---|---|---|---|
| **Unallocated Financial Deficit**<br><br>**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 |


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# 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*


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# 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.

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# 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).


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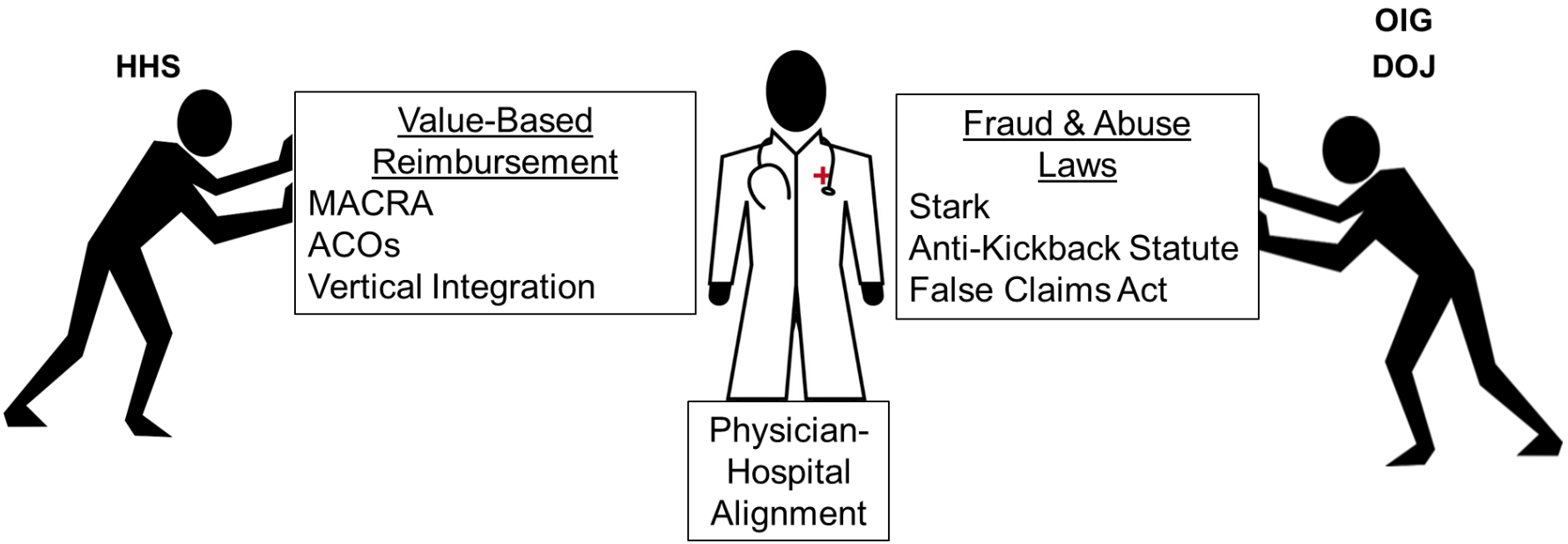
# Inherent Conflict between MACRA and Fraud & Abuse Laws

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





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# 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


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# 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).


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# 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.


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# 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).


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# 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:<br>• Magnetic resonance imaging<br>• Computerized axial tomography scans<br>• 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).

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# 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.


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# 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).


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# 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).


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# 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).


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# 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).


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# 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.

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# 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.



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# 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).



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# 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.


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# 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.



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# 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


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# 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


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# Concluding Remarks


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# 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.

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# 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***


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# 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*"


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# 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).

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