Healthcare Valuations: The New, the Old, and the Ugly

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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

Presenter Bio

Lisa M. Cribben, CPA/ABV, ASA, CMA, leads the valuation services group at Wipfli, LLP, and has worked with companies all over the United States with their valuation and business sale and purchase transaction needs. With over 10 years of operational and 15 years of valuation experience, she is able to provide expert advice with an understanding of client needs. Lisa has extensive experience in testifying in court on valuation and other financial matters. She is a frequent speaker on valuation and transition planning topics

Her areas of focus include:

- Leads Wipfli's valuation service line
- Prepares valuations of closely held businesses and provides consulting to business owners on how to maximize the value of their business
- Industry valuation experience in health care, manufacturing, construction and real estate, auto dealerships, and service companies
- Extensive specialty expertise in the valuation of health care practices including hospitals; ASCs; physician, dental, and physical therapy practices; and other health care entities
- Merger and acquisition transaction support
- Acquisition assistance including cash flow analysis, negotiations, due diligence, and other sale assistance
- Expert testimony in court relating to business valuations, damages, and lost profits

Overview of Presentation

- The New
  - Value-Based Reimbursement (VBR)
- The Old
  - Fraud and Abuse Laws
- The Ugly
  - Tension Between VBR and fraud & abuse laws

The New

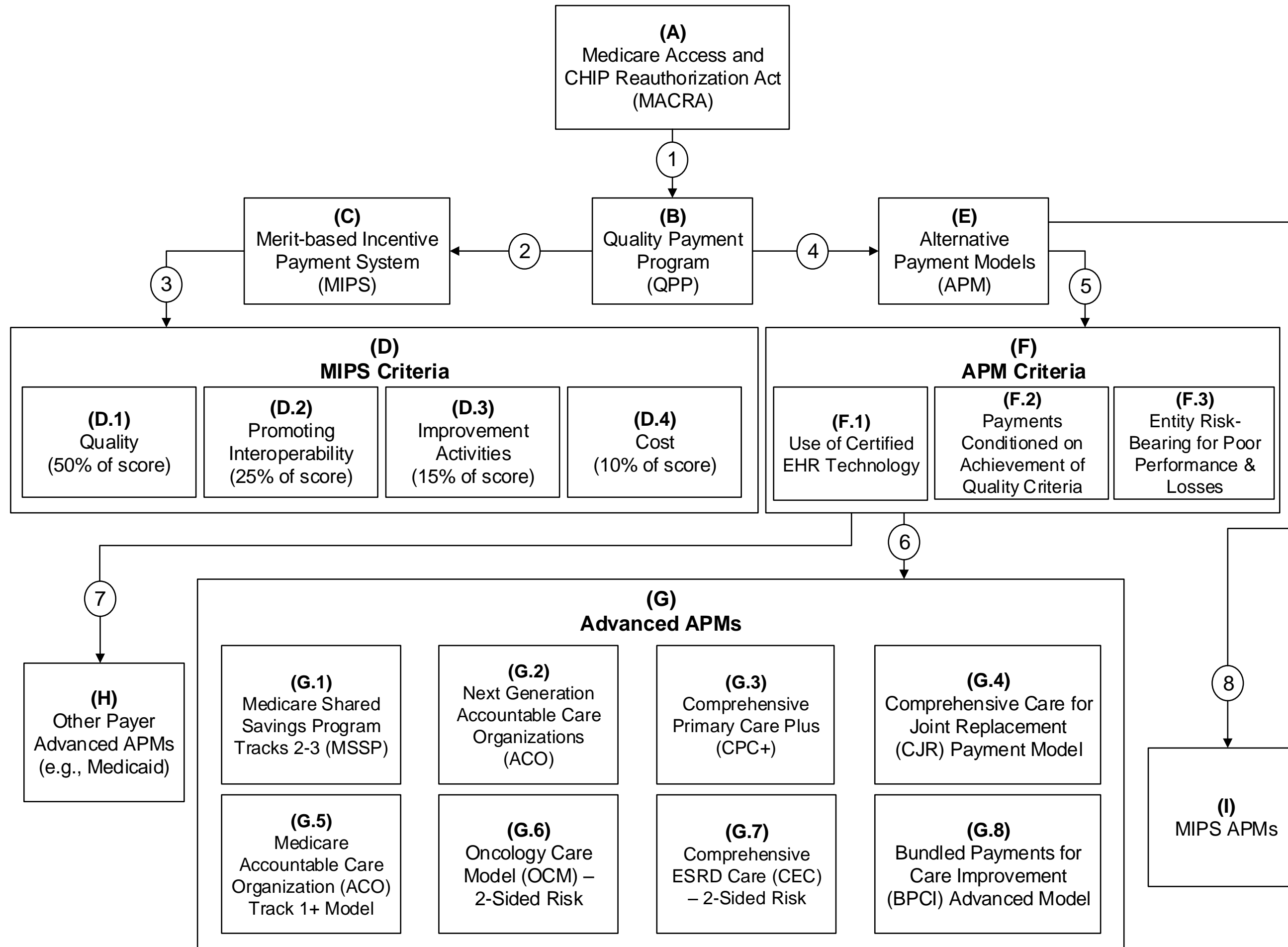
AICPA

The New (Again)

The Shift from Volume (Fee-for-Service) to Value Based Reimbursement (VBR)

- Challenges for determination of FMV
- Challenges for compliance with Anti-Kickback Statute and Stark Law

MACRA Overview



MACRA Payment Structure & Timeline

	A	B	C	D	E
1	Performance Year	2017	2018	2019	2020
2	Payment Adjustment Year	2019	2020	2021	2022 (and on)
3	Annual Fee Schedule Update	+0.5%	+0.5%	+0.5%	TBD
	MIPS				
4	Maximum Positive Payment Adjustment	4%	5%	7%	9%
5	Maximum Negative Payment Adjustment	-4%	-5%	-7%	-9%
6	MIPS Performance Category Weights				
7	Quality	60%	50%	30%	30%
8	Cost	0%	10%	30%	30%
9	Improvement Activities	15%	15%	15%	15%
10	Promoting Interoperability	25%	25%	25%	25%
	Advanced APMs				
11	Bonus Quality Payment	5%	5%	5%	5%

"How the QPP Affects Medicare Part B Payments" The Physicians Advocacy Institute's Medicare Quality Payment Program (QPP) Physician Education Initiative, http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/Background-Resources/How%20the%20QPP%20Affects%20Medicare%20Part%20B%20Payments.pdf (Accessed 8/14/18), p. 3.

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).

VBR and Valuation Implications

- Pay-for-Performance (P4P) Arrangements
- Shared Shaving Arrangements
- Episodic Payments
- Global Budgets

Pay for Performance (P4P) Arrangements

Remuneration system in which part of the payment is dependent on performance

- Measured against a defined set of criteria
- Measures & performance standards for establishing target criteria
- Rewards (typically financial incentives) that are at risk, including the amount and method for allocating the payments among those who meet or exceed the reward threshold
- Example of a P4P Arrangement: Medicare's Hospital Readmissions Reduction Program

Shared Savings Arrangements

- Incentivizes providers to reduce healthcare spending for a defined patient population by offering a percentage of net savings realized as a result of their efforts.
- Example of a Shared Savings Arrangement: Accountable Care Organizations (ACOs)

Episodic Payments

- A single price for all of the services needed by a patient for an entire episode of care (e.g., all of the inpatient and outpatient care they need after having a heart attack).
- An episode payment system reduces the incentive to overuse unnecessary services within the episode, and gives healthcare providers the flexibility to decide what services should be delivered, rather than being constrained by fee codes and amounts.
- Define what is included in an episode payment:
- The length of time that is covered
- The range of providers and services that are included
- Gives healthcare providers the flexibility to decide what services should be delivered.
- Not every type of condition or patient has to be paid on an episode basis.
- Example of a Episodic Payment Arrangement: Bundled Payments for Care Improvement (BPCI) Initiative

Global Budget

- A fixed prepayment made to a group of providers or a healthcare system (as opposed to a health care plan) that covers most or all of a patient's care during a specified time period.
- Two key elements of coverage: Who and What
- They require tradeoffs between *cost (price) of a service* and the *volumes of services delivered*
- Example of a Global Budget Arrangement: *Maryland's global budget* program

Other VBR Models

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).

VBR Ramifications

- 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.

The Old

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).

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.

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).

June 2018 CMS Request for Information regarding Stark Law

Approximately 2 years later, CMS published a Request for Information (RFI) seeking input on:

- The undue regulatory impact that Stark Law has placed on VBR and coordinated care
- Strategies to reduce this burden

"Medicare Program; Request for Information Regarding the Physician Self-Referral Law" Federal Register, Vol. 83, No. 122 (June 25, 2018), p. 29524.

June 2018 CMS Request for Information regarding Stark Law

Information sought from healthcare industry stakeholders includes:

- Requests on topics involving *alternative payment models* (APMs)
- Additional exceptions to the Stark Law to facilitate innovation
- Changes to the current provisions of Stark Law
- Changes to existing compensation formulas
- Exceptions necessary to protect *accountable care organizations* (ACOs) and bundled payment models

"Medicare Program; Request for Information Regarding the Physician Self-Referral Law" Federal Register, Vol. 83, No. 122 (June 25, 2018), p. 29525-6.

June 2018 CMS Request for Information regarding Stark Law

- July 17, 2018 – House Committee on Ways and Means hosted a hearing on modernizing the Stark Law to ensure a successful transition from volume to value-based Medicare reimbursement
- HHS plans to make modifications to Stark Law administratively (i.e., not through Congress), which it will seek to accomplish by creating a proposal to address the comments that CMS receives and other efforts to streamline coordination of care
- HHS Deputy Secretary, Eric Hagan, emphasized the agency's interest in regulatory reforms for both Stark Law and AKS
- Hagan stated both laws could be stifling innovative arrangements, and thus, hindering better patient outcomes.
- HHS plans to issue a separate RFI on AKS reform

"Hearing on Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program" Committee on Ways and Means, U.S. House of Representatives, July 17, 2018, https://waysandmeans.house.gov/event/hearing-on-modernizing-stark-law-to-ensure-the-successful-transition-from-volume-to-value-in-the-medicare-program/ (Accessed 7/16/18).

June 2018 CMS Request for Information regarding Stark Law

July 17, 2018 – House Committee on Ways and Means hearing

- Panelist Michael Lappin, Chief Integration Officer, Advocate Aurora Health: Congress should be involved in any reforms, specifically to define key terms such as FMV and other terms that would offer physicians bright-line guidance to ensure proper compliance
- Panelist Claire Sylvia, healthcare attorney: Lawmakers should proceed with caution, because paying for value and/or coordinated care does not completely eliminate the financial motive for physicians to "*overlook*" a patient's best interests

  View in line with that of Representative Sander Levin (D-MI9), who argued that this move to VBR may potentially weaken "important tools for protecting Medicare beneficiaries from inappropriate referrals and overutilization of care."

"HHS Eying Stark and Anti-Kickback Reform" American Health Lawyers Association, July 20, 2018, https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/2018/July%202018/July%2020%202018/HHS-Eying-Stark-and-Anti-Kickback-Statute-Reforms.aspx (Accessed 7/23/18).

June 2018 CMS Request for Information regarding AKS

August 24, 2018 – HHS Office of Inspector General (OIG) published another RFI seeking public input on changes to the Anti-Kickback Statute (AKS)

Seeking comments on ways that AKS safe harbors could be improved, specific to 4 categories:

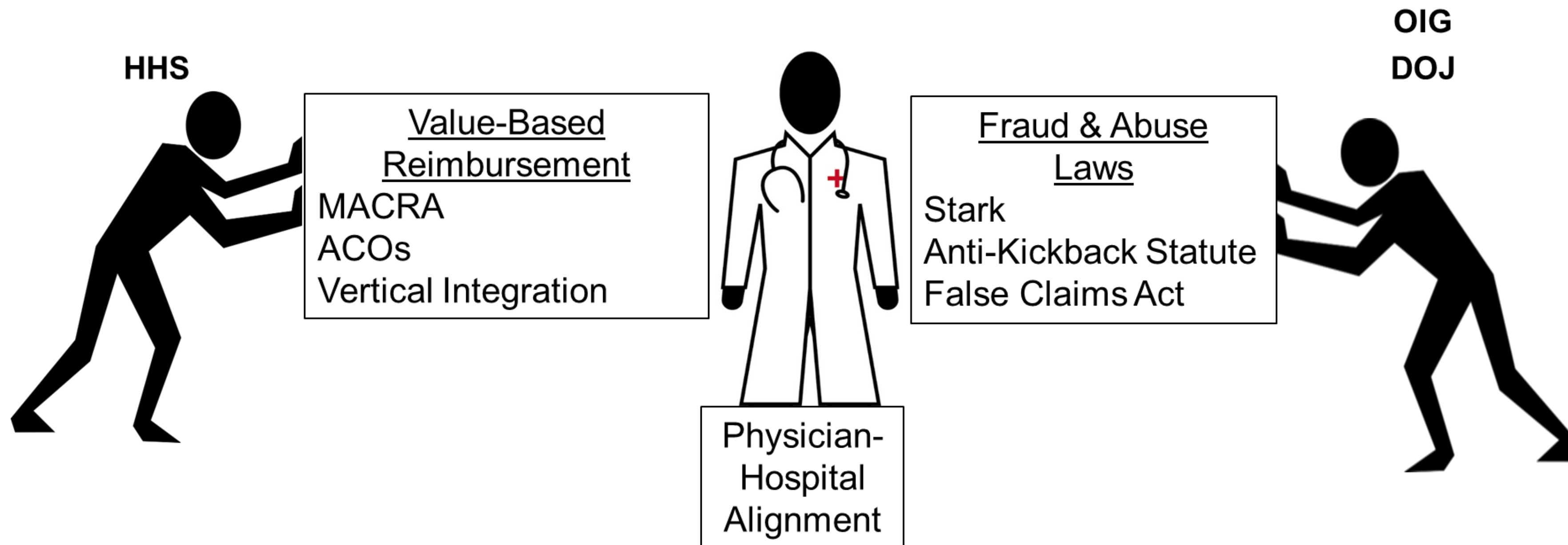
- Promotion of care coordination and value-based care
- Beneficiary engagement, including beneficiary incentives and cost-sharing obligations
- Other regulatory topics, including feedback on current fraud and abuse waivers, cybersecurity-related items and services, and new exceptions required by the Bipartisan Budget Act of 2018
- The intersection of the Stark Law and AKS

"HHS Eying Stark and Anti-Kickback Reform" American Health Lawyers Association, July 20, 2018, https://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/2018/July%202018/July%2020%202018/HHS-Eying-Stark-and-Anti-Kickback-Statute-Reforms.aspx (Accessed 7/23/18).

The Ugly

Overview

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



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 Expenses*"
    - *"…reasonable pay is the amount that a similar business would pay for the same or similar services"* [emphasis added]
  - 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]

"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

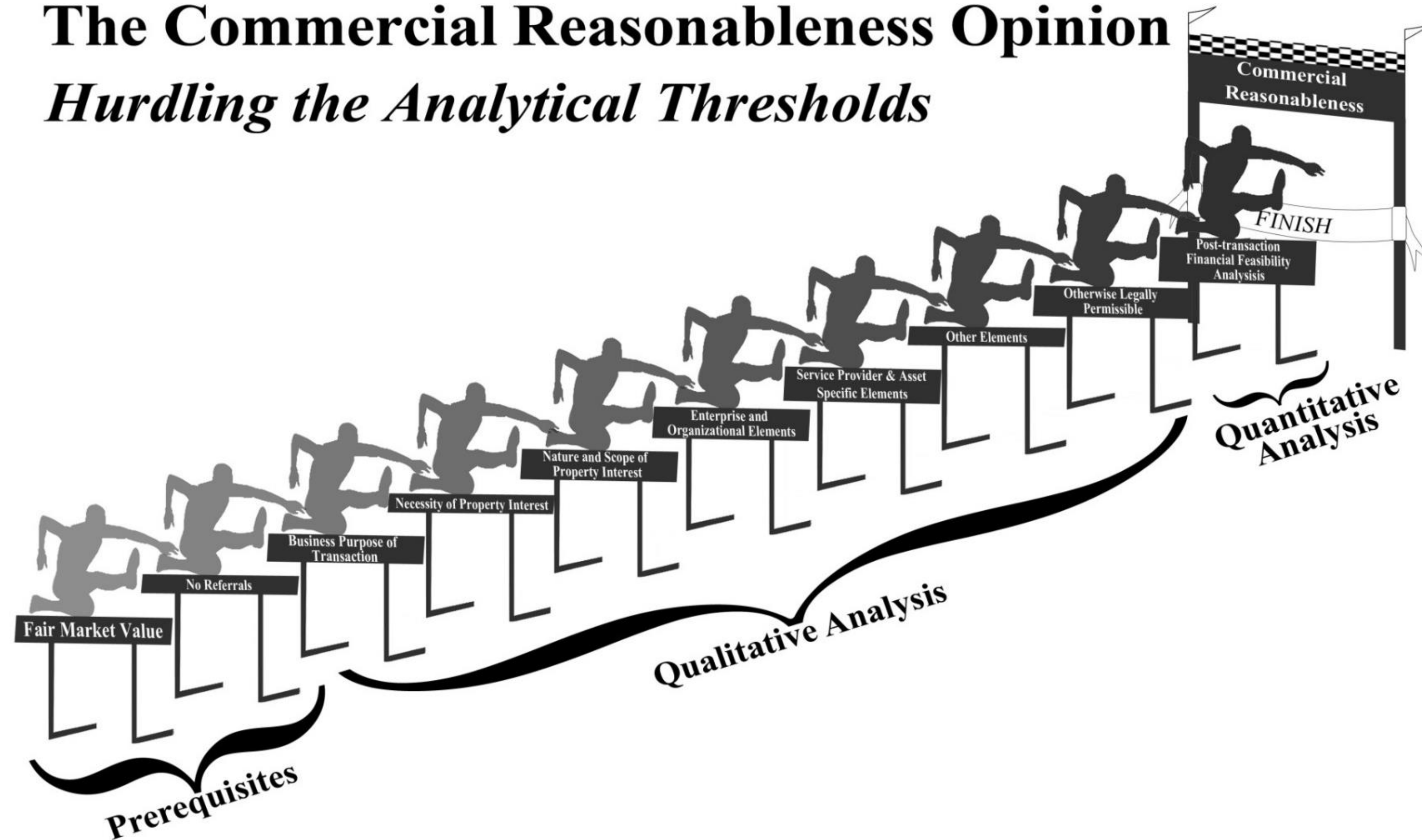
- Department of Health and Human Services (HHS)
  - An arrangement which appears to be "…*a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals*" is *commercially reasonable*

- 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.*"

- 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."

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

The Commercial Reasonableness Analysis



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

(A)
Physician wRVU Cash Compensation

Retention Bonus

Medical, Retirement, etc. Benefits

Nose Coverage

(B)
Physician wRVU Related Economic Operating Expense

Physician wRVU Related Economic Capital Expense

(C)
Total Physician wRVU Related Expense

(E)
Unallocated Financial Deficit

Attributed under PLP as "Practice Losses"

(D)
"Receipts" to Hospital

Total Physician wRVU Reimbursement from all Payors

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

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 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*
- 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).

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

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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).

Thank you