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Beyond FMV: Commercial Reasonableness of Physician Compensation Post-MACRA

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The influx of federal money over the past several decades to healthcare providers, and the allocation of those dollars, drastically transformed the healthcare delivery system in a way that has had dramatic impact on the economic and financial value of healthcare enterprises, assets, and services. The recent paradigm shift in the reimbursement environment, from volume to value, has had perhaps the greatest impact on the processes and outcomes of valuation assignments, as the reimbursement environment significantly affects the flow of revenue to healthcare providers. The emergence of value-based reimbursement (VBR) (most recently manifested through the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 [MACRA]), has driven the pursuit of closer relationships between hospitals and physicians. Corresponding with this growing trend toward hospital-physician alignment, and specifically toward vertical integration, increased regulatory oversight regarding the legal permissibility of these arrangements has occurred. This increasing focus on the related, but distinct, thresholds of fair market value (FMV) and commercial reasonableness represents a growing opportunity for valuation professionals in the healthcare industry. However, a comprehensive understanding of this inherent conflict between the fraud and abuse laws and the aims of the VBR models warrants a review of both MACRA and the threshold of commercial reasonableness.

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Introduction

The creation of the Medicare and Medicaid programs in 1965 provided a deluge of government funding to provider enterprises for the provision of healthcare services to the elderly and the indigent. Historically, Medicare and Medicaid paid for healthcare services using a cost plus method of reimbursement, wherein providers received reimbursement in excess of all of their costs.[1] In 1982, the federal government introduced a prospective payment system (PPS) in an effort to remedy the rising healthcare costs.[2] The PPS, which reimbursed providers a predetermined, fixed amount per service,[3] initially applied only to hospitals but was later developed for hospital outpatient services, ambulatory surgery centers, home healthcare, rehabilitation facilities, and skilled nursing facilities.[4] This substantial influx of federal money to healthcare providers, and the allocation of those dollars, drastically transformed the healthcare delivery system in a way that has had dramatic impact on the economic and financial value of healthcare enterprises, assets, and services. Both healthcare appraisers and business valuation professionals, as well as real estate and personal property appraisers, have consequently realized the necessity of developing and maintaining a robust understanding of the four paramount market influences of the healthcare industry—the Four Pillars: reimbursement, regulatory, competition, and technology—to provide a credible healthcare valuation opinion.[5] This paradigm shift in the reimbursement environment, from volume to value, has had perhaps the greatest effect on the processes and outcomes of valuation assignments because the reimbursement environment significantly affects the flow of revenue to healthcare providers and any changes tend to increase the uncertainty related to the anticipated reimbursement for physician clinical services.

The emergence of value-based reimbursement (VBR) (most recently manifested through the implementation of the Medicare Access and CHIP Reauthorization Act of 2015 [MACRA]), upon which the concepts of VBR in emerging reimbursement models rely on incentivizing providers to achieve better outcomes at lower cost, have driven the pursuit of closer relationships between hospitals and physicians through strategies such as practice acquisitions, direct employment, provider services agreements, co-management, and joint venture arrangements.[6] Correspondingly, office-based physicians are experiencing tightening reimbursement at the same time that they are being required to heavily invest in healthcare information technology (e.g., electronic health records [EHRs]) that aggregates the requisite data and information required to report the metrics to the federal government (or commercial insurers). These providers are similarly seeking to relieve these financial and administrative burdens, in part through employment with healthcare enterprises such as hospitals, that have the intellectual and management capital (e.g., resources, knowledge, skills, and ability), as well as the financial capital to adjust, and even prosper, in the face of this paradigm shift.

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,"[7] an increased federal, state, and local regulatory oversight regarding the legal permissibility of these arrangements has occurred.[8] Most notably, there has been 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

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[1]"Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated," Office of Inspector General, Office of Evaluation and Inspections, Region IX, OEI-09-00-00200, August 2001, 1.

[2]Ibid., Under the PPS, hospitals are reimbursed an average, qualified, and predetermined fee for every recognized diagnostic related group (DRG), which classifies patients based on the average per discharge cost of caring for their diagnosis.; "Hospital Acute Inpatient Services Payment System," MedPAC, Payment Basics, October 2016, accessed at http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_16_hospital_final.pdf, September 22, 2017, 1.

[3]"Prospective Payment Systems—General Information," Centers for Medicare and Medicaid Services, September 6, 2017, accessed at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/index.html, October 4, 2017.

[4]"Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated," Office of Inspector General, Office of Evaluation and Inspections, Region IX, OEI-09-00-00200, August 2001, 1.

[5]Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, *Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*, Volume 1 (Hoboken, New Jersey: John Wiley & Sons, 2014), 1–2.

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

[7]"The Value of Provider Integration," *American Hospital Association*, March 2014, accessed at http://www.aha.org/content/14/14mar-provintegration.pdf, January 14, 2016, 2.

[8]*See*, U.S. Department of Health and Human Services and U.S. Department of Justice, "Health Care Fraud and Abuse Control Program Report," accessed at https://oig.hhs.gov/reports-and-publications/hcfac/, May 18, 2017.

under the False Claims Act (FCA).[9] 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.[10] This increasing focus by government regulators on the related but distinct thresholds of FMV and commercial reasonableness represents a growing opportunity for valuation professionals in the healthcare industry.

The application of these fraud and abuse laws has, at times, been at odds with the goals of healthcare reform. Specifically, the discord between the objectives of fraud and abuse laws and the objectives of VBR models, such as those promulgated through MACRA, reflect the disjointed approach to healthcare reform by the numerous federal agencies tasked with oversight of the healthcare industry, including the Department of Health and Human Services (HHS), the Office of Inspector General (OIG) of HHS, and the Department of Justice (DOJ), whereby "the left hand doesn't know what the right hand is doing" (see Fig. 1).

A comprehensive understanding of this inherent conflict between the fraud and abuse laws enforced by the DOJ and the aims of the VBR models being implemented by HHS warrants a review of both MACRA and the threshold of commercial reasonableness.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

On November 4, 2016, the Centers for Medicare and Medicaid Services (CMS) issued the final rule implementing MACRA.[11] This piece of legislation repealed the beleaguered sustainable growth rate (SGR) formula and replaced it with scheduled updates to the Medicare Physician Fee Schedule and the creation of the Quality Payment Program (QPP).[12] The intent of the QPP is to transition reimbursement for the provision of healthcare services from volume-based to value-based models, in which providers are reimbursed "based on quality, value, and results of the care they deliver and not piecemeal for individual services regardless of clinical need for or appropriateness of those services."[13] With CMS projecting that up to 90 to 95% of Medicare Part B billings (i.e., billings for physician services) will meet the criteria for inclusion in the QPP,[14] reimbursement of a majority of healthcare providers will be affected by the provisions of MACRA.

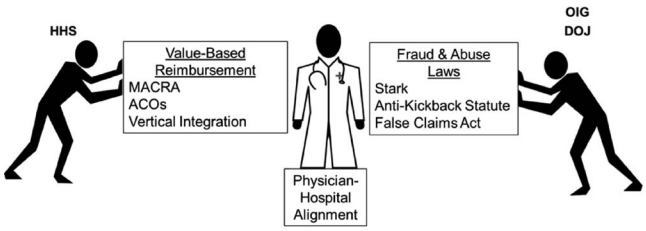

Figure 1
The Left Hand Doesn't Know What the Right Hand Is Doing

Regulatory components

Medicare Access and CHIP Reauthorization Act (MACRA)

MACRA in part shifts physician reimbursement from a volume-based approach to a value-based approach.[15] It repealed the SGR formula and replaced it with scheduled updates to the Medicare Physician Fee Schedule. Figure 2 shows the structure of MACRA. It also created the Quality Payment Program (QPP).[16]

[9]The Department of Health and Human Services & The Department of Justice, "Health Care Fraud and Abuse Control Program: Annual Report for FY 1997," Report for the United States Congress, Washington, D.C., 1998; The Department of Health and Human Services & The Department of Justice, "Health Care Fraud and Abuse Control Program: Annual Report for FY 2007," Report for the United States Congress, Washington, D.C., 2008; The Department of Health and Human Services & The Department of Justice, "Health Care Fraud and Abuse Control Program: Annual Report for FY 2013," Report for the United States Congress, Washington, D.C., 2014.

[10]"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); Robert A. Wade, Esq. and Marcie Rose Levine, Esq., "FMV: Analysis and Tools to Comply with Stark and Anti-kickback Rules," Audio Conference, Marblehead, Massachusetts: HCPro, Inc., March 19, 2008, accessed at http://content.hcpro.com/pdf/content/207583.pdf, October 29, 2015, 6, 48.

[11]"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 (November 4, 2016), 77010.

[12]Ibid., 77010, 70515.

[13]Steve Findlay, "Implementing MACRA," *Health Affairs* (March 27, 2017), 1, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, April 3, 2017.

[14]"Implementing MACRA," *Health Affairs* (March 27, 2017), 4, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, May 24, 2017; Gabriel Perna, "CMS Seeks to Make MACRA Manageable for Small Practices," *Physicians Practice*, Conference Report, March 2, 2017, accessed at http://www.physicianspractice.com/himss2017/cms-seeks-make-macra-manageable-small-practices, May 24, 2017.

[15]"Implementing MACRA," *Health Affairs* (March 27, 2017), 7, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, May 16, 2017.

[16]"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 (November 4, 2016), 77010, 70515.

Exhibit 2: The Structure of MACRA

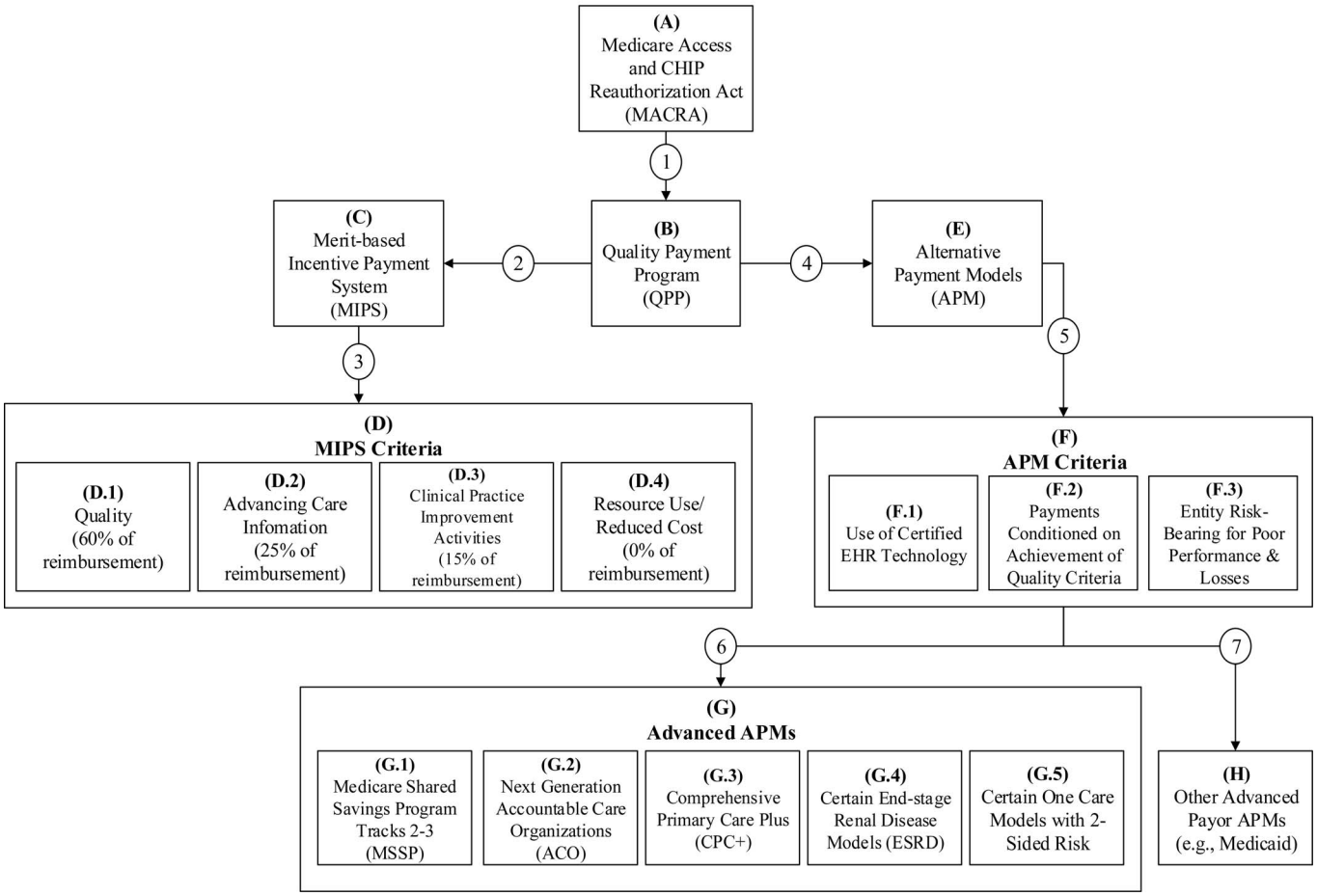

Figure 2
The Structure of MACRA

Quality Payment Program (QPP)

The QPP attempts to improve Medicare by focusing on quality-based reimbursement.[17] There are two tracks healthcare providers can choose from: the Merit-based Incentive Payment System (MIPS) and the Alternative Payment Model (APM).[18] Qualified practitioners (physicians, physician assistants [PAs], nurse practitioners [NPs], clinical nurse specialists, and certified registered nurse anesthetists [CRNAs]) are included in this program if they bill Medicare more than $30,000 *and* provide care for more than 100 Medicare patients a year.[19]

Merit-based Incentive Payment System (MIPS)

Eligible healthcare providers can participate in MIPS to earn a payment adjustment based on evidence-based and practice-specific quality data.[20] Payment adjustments are based on four categories: quality, improvement activities, advancing care information, and resource use.[21]

MIPS criteria

Subject to payment adjustments (starting in 2019, based on 2017 data).

Quality—This category replaced the Physician Quality Reporting System (PQRS).[22] Quality measures currently

[17]Steve Findlay, "Implementing MACRA," *Health Affairs* (March 27, 2017), 1, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, May 16, 2017.

[18]"Quality Payment Program," CMS, Quality Payment Program, accessed at https://qpp.cms.gov/, May 16, 2017.

[19]Ibid.

[20]"Quality Payment Program," Centers for Medicare and Medicaid Services, accessed at https://qpp.cms.gov/, April 3, 2017.

[21]"Quality Payment Program," CMS, Quality Payment Program, accessed at https://qpp.cms.gov/, May 16, 2017.

[22]"What's the Merit-based Incentive Payment System (MIPS)?" CMS, Quality Payment Program, accessed at https://qpp.cms.gov/learn/qpp, May 16, 2017.

determine 60% of reimbursement from Medicare under MIPS.[23] Healthcare providers must choose 6 out of 200 measures (including one outcome measure) to report to CMS in order to receive full credit for MIPS participation.[24] Measures can be specialty-specific and are ranked according to priority.[25]

Advancing care information—This category replaced the Medicare EHR Incentive Program, also known as "meaningful use."[26] Advancing care information currently determines 25% of reimbursement from Medicare under MIPS.[27] Depending on an organization's EHR edition, clinicians have two reporting options to choose from.[28] Clinicians must complete all measures from one of the options to receive full credit for MIPS participation.[29] Measures align with the Office of the National Coordinator for HIT's 2015 HIT certification criteria. Criteria must be met for 90 days.[30]

Clinical practice improvement activities—These activities currently determine 15% of reimbursement from Medicare under MIPS.[31] Clinicians must complete 4 out of the 90 improvement activities for a minimum of ninety days to receive full credit for MIPS participation.[32] Groups with fewer than fifteen participants, located in rural areas, and/or located in areas with professional shortages only need to complete two of the activities to receive full credit.[33]

Resource use/reduced cost—This category replaced the value-based modifier.[34] Resource use currently determines 0% of reimbursement from Medicare under MIPS.[35] However, it will determine up to 30% of reimbursement starting in 2018 (while quality measures will determine only up to 30% instead of 60%).[36] Performance in this category will be measured by total per capita cost, Medicare spending per beneficiary, and ten measures related to specific episodes.[37]

Alternative Payment Models (APMs)

APMs are an alternative payment approach that gives added incentive payments to provide high-quality and cost-efficient care.[38] APMs can apply to a specific condition, care episode, or population.[39] The three main participation requirements for APMs include the follwoing.

APM criteria

Use of certified EHR technology—To receive an incentive payment, clinicians must use EHR technology that is certified specifically for EHR incentive programs.[40] Certification ensures that the EHR system is compatible with other EHR systems, will secure patient data, and can be used meaningfully.[41]

Payments conditioned on achievement of quality criteria—Each type of APM has unique and specific guidelines on what quality data must be reported.[42]

Entity risk-bearing for poor performance and losses—Risk is defined as financial losses tied directly to performance of the APM.[43] The entity that bears risk can either be the APM itself or an APM eligible clinician.[44]

Advanced APMs

Advanced APMs encourage early clinician participation in an APM by offering extra incentives.[45] Clinicians

[23]"Quality Measures," CMS, Quality Payment Program, accessed at https://qpp.cms.gov/measures/quality, May 16, 2017.

[24]Ibid.

[25]Ibid.

[26]"What's the Merit-based Incentive Payment System (MIPS)?" CMS, Quality Payment Program, accessed at https://qpp.cms.gov/learn/qpp, May 16, 2017.

[27]"Advancing Care Information," CMS, Quality Payment Program, accessed at https://qpp.cms.gov/measures/aci, May 16, 2017.

[28]Ibid.

[29]Ibid.

[30]David Wofford and John Redding, "Navigating the Medicare Access and CHIP Reauthorization Act and Its Quality Payment Program," 2017 Congress on Healthcare Leadership, Chicago, Illinois, March 29, 2017, 12.

[31]"Improvement Activities," CMS, Quality Payment Program, accessed at https://qpp.cms.gov/measures/ia, May 16, 2017.

[32]Ibid.

[33]Ibid.

[34]"What's the Merit-based Incentive Payment System (MIPS)?" CMS, Quality Payment Program, accessed at https://qpp.cms.gov/learn/qpp, May 16, 2017.

[35]David Wofford and John Redding, "Navigating the Medicare Access and CHIP Reauthorization Act and Its Quality Payment Program," 2017 Congress on Healthcare Leadership, Chicago, Illinois, March 29, 2017, 12; "What's the Merit-based Incentive Payment System (MIPS)?" CMS, Quality Payment Program, accessed at https://qpp.cms.gov/learn/qpp, May 16, 2017.

[36]David Wofford and John Redding, "Navigating the Medicare Access and CHIP Reauthorization Act and Its Quality Payment Program," 2017 Congress on Healthcare Leadership, Chicago, Illinois, March 29, 2017, 12.

[37]Ibid.

[38]"What Are Alternative Payment Models (APMs)?" CMS, Quality Payment Program, accessed at https://qpp.cms.gov/learn/apms, May 16, 2017.

[39]Ibid.

[40]"Certified EHR Technology," Centers for Medicare and Medicaid Services, EHR Incentive Programs, accessed at https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/certification.html, May 16, 2017.

[41]Ibid.

[42]"What Are Alternative Payment Models (APMs)?" Centers for Medicare and Medicaid Services, Quality Payment Program, accessed at https://qpp.cms.gov/learn/apms, May 16, 2017.

[43]Farzad Mostashari and Travis Broome, *MACRA Part 1: What Are Advanced Alternative Payment Models?* Accessed at https://www.aledade.com/macra-part-1-what-are-advanced-alternative-payment-models/, May 16, 2017.

[44]Ibid.

[45]Steve Findlay, "Implementing MACRA," *Health Affairs* (March 27, 2017), 4, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, May 16, 2017.

who join an APM between 2019 and 2024 can get an extra 5% bonus payment based on their Medicare billings.[46] After 2026, the 5% bonus period ends; however, physicians in an advanced APM will receive a flat fee increase of .75% instead of the standard .25%.[47] Clinicians will also be exempted from participating in MIPS as long as some of their care is reimbursed through a value-based payment system.[48]

Medicare shared savings program (MSSP) tracks 2–3—The MSSP tracks 2 and 3 aim to encourage coordination and cooperation among providers to improve quality of care for Medicare fee-for-service beneficiaries and to reduce unnecessary costs through the participation in an accountable care organization (ACO).[49] The MSSP rewards ACOs that lower growth in healthcare costs while meeting performance standards of quality care.[50] Track 2 allows an organization to operate on a one-sided arrangement in which the organization does not incur penalties if cost savings are not realized within the first three years.[51] These organizations can earn a maximum of 50% of savings each year.[52] Track 3 allows an ACO to share in both savings and losses in return for a higher share of any savings it generates (up to 60% of savings each year).[53]

Next generation ACOs—A next generation ACO is an initiative for ACOs that are experienced in coordinating care for populations of patients.[54] They allow provider groups to assume higher levels of financial risk and reward than is currently available under the current MSSP.[55]

Comprehensive Primary Care Plus (CPC+)—CPC+ is an advanced primary care medical home model that aims to strengthen primary care through regionally based multipayer payment reform and delivery transformation.[56] This model includes two track options with incrementally advanced care delivery requirements and payment options.[57]

Certain end-stage renal disease (ESRD) models—The ESRD model identifies, tests, and evaluates new ways to improve care for Medicare beneficiaries with ESRD.[58] CMS partners with health providers will test the effectiveness of a new payment and service delivery model in providing beneficiaries with person-centered, high-quality care.[59]

Certain one care models with two-sided risk—These models aim to provide higher quality, more highly coordinated care at the same or lower cost to Medicare.[60] Health organizations enter into payment arrangements that include financial and performance accountability for episodes of care.[61]

Other payor-advanced APMs

An other payor-advanced APM is an APM in which a payment arrangement is made with a payor other than Medicare.[62] These models are still subject to following the APM criteria listed previously.[63]

Under the QPP, required participants can choose between two payment tracks for Medicare reimbursement: MIPS or APM.[64] Required participants include those providers who are already participating in an advanced APM or who meet the minimum billing/patient population requirements, i.e., annually billing Medicare more than $30,000 in Part B-allowed charges and annually care for more than 100 Medicare patients.[65] Additionally, to participate in MIPS, the provider must be a Medicare provider prior to 2017 and be one of the following:

- Physician,
- PA,
- NP,
- Clinical nurse specialist, or
- CRNA.[66]

Starting in 2017, three performance categories will determine MIPS payment adjustments:

- *Quality* (through six physician-selected clinical quality measures), which replaces the PQRS;

[46]Ibid.

[47]Ibid.

[48]Steve Findlay, "Implementing MACRA," *Health Affairs* (March 27, 2017), 4, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, May 16, 2017.

[49]"Shared Savings Program," CMS, January 18, 2017, accessed at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html, April 10, 2017.

[50]Ibid.

[51]Ibid.

[52]Ibid.

[53]Ibid.

[54]"Next Generation ACO Model," CMS, April 7, 2017, accessed at https://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/, April 10, 2017.

[55]Ibid.

[56]"Comprehensive Primary Care Plus," CMS, March 23, 2017, accessed at https://innovation.cms.gov/initiatives/comprehensive-primary-care-plus, April 10, 2017.

[57]Ibid.

[58]"Comprehensive ESRD Care Model," CMS, April 10, 2017, accessed at https://innovation.cms.gov/initiatives/comprehensive-esrd-care/, April 10, 2017.

[59]Ibid.

[60]"Oncology Care Model," CMS, April 7, 2017, accessed at https://innovation.cms.gov/initiatives/oncology-care/, April 10, 2017.

[61]Ibid.

[62]"Other Payer Advanced APMs," 42 C.F.R. § 414.1420.

[63]Ibid.

[64]"Quality Payment Program," CMS, Quality Payment Program, accessed at https://qpp.cms.gov/, April 3, 2017.

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

[66]Ibid.

- *Improvement activities*, i.e., activities that physicians perform to improve their clinical practice (up to 4 for a minimum of 90 days); and,
- *Advancing care information* (i.e., whether certified health ERT [CEHRT] is used meaningfully to advance care information), which replaces the Medicare EHR Incentive Program.[67]

In 2018, CMS will consider publicly reporting a fourth category—cost (i.e., resource use) data—under MIPS.[68] This will be calculated by CMS from adjudicated claims, in contrast to the other three categories, which require physicians to report data to CMS.[69]

Quality currently determines 60% of Medicare reimbursement adjustments (but is decreasing to 30% starting in 2019); *improvement activities* determine 15% of reimbursement adjustments; *advancing care information* determines 25% of reimbursement adjustments; and *cost* currently determines 0% of reimbursement adjustments (and is increasing to 30% starting in 2019).[70] Additionally, a 0.5% "inflationary adjustment" will be applied to reimbursement each year, irrespective of performance on quality metrics.[71]

Whereas participation in MIPS incentivizes quality, efficient care through a performance-based payment adjustment, participants in APMs earn incentive payments for partnering with CMS to participate in innovative care models that provide incentives for higher quality and cost-efficient care.[72] The three main participation requirements for APMs include the following:

- Use of CEHRT technology;
- Reimbursement of base payments tied to quality measures comparable to those utilized in MIPS; and,
- Agreement by clinicians to take responsibility for financial losses or meeting the specifications of a *Medical Home* model.[73]

Examples of advanced APM models include the following:

(1) MSSP tracks,
(2) Next generation ACOs,
(3) CPC+,
(4) ESRD model, and
(5) One care models with two-sided risk.[74]

Because APMs are currently under development, most clinicians are expected to participate in MIPS during the early years of QPP implementation.[75] Effective January 1, 2017, clinicians have three options regarding participation in MIPS:

- Opt out of participation,
- Limited participation, or
- Full participation.[76]

If clinicians *choose not to participate*, they will experience an annual negative payment adjustment of 4% starting in 2019.[77] Those clinicians who *participate on a limited basis*, by either submission of fewer than all of the performance metrics or by participation in the program for more than 90 days but less than a full year, will not incur a negative payment adjustment but are not guaranteed a positive payment adjustment.[78]

Clinicians who *fully participate* in the MIPS program are subject to payment adjustments based on their performance on the quality metrics in each of the three aforementioned performance categories (i.e., *quality*, *improvement activities*, and *advancing care information*).[79] Adjustment payments will start at up to 4% in 2019, continue to grow to up to 9% by 2022, and will be based on evidence-based and practice-specific quality data linked to physician performance.[80] Clinicians have from January 1, 2017, to October 2, 2017, to collect performance data

[67]"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 (November 4, 2016), 77010.

[68]Ibid., 77395–77396.

[69]Ibid., 77395–77396.

[70]John Redding and David Wofford, "Navigating the Medicare Access and CHIP Reauthorization Act and Its Quality Payment Program," American College of Healthcare Executives 2017 Congress on Healthcare Leadership, Chicago, Illinois, March 30, 2017, slide 12.

[71]Josh Sober et al., "Who Will Pay the MACRA Penalties? Disproportionately, Small Practices," September 12, 2016, accessed at http://health.oliverwyman.com/transform-care/2016/09/who_will_pay_themac.html, April 14, 2017.

[72]"Quality Payment Program," CMS, accessed at https://qpp.cms.gov/, April 3, 2017; Steve Findlay, "Implementing MACRA," *Health Affairs* (March 27, 2017), 4, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, April 3, 2017.

[73]Steve Findlay, "Implementing MACRA," *Health Affairs* (March 27, 2017), 4–5,accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, April 3, 2017.

[74]"Quality Payment Program," CMS, Quality Payment Program, accessed at https://qpp.cms.gov/learn/apms, April 3, 2017.

[75]Rich Daly, "Move to Value-Based Payment to Continue: CMS Medical Director," *Healthcare Financial Management Association* (April 5, 2017), 2, accessed at http://www.hfma.org/Content.aspx?id=53602&utm_source=Real%20Magnet&utm_medium=email&utm_campaign=110522593, April 10, 2017.

[76]"Quality Payment Program," CMS, accessed at https://qpp.cms.gov/, April 3, 2017.

[77]Ibid.

[78]Clinicians can best maximize their chances of receiving a positive payment adjustment if they choose to participate in MIPS for at least 90 days. "Quality Payment Program," CMS, accessed at https://qpp.cms.gov/, April 3, 2017.

[79]"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 (November 4, 2016), 77010–77011.

[80]"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 (November 4, 2016), 77332.

Table 1
MACRA Payment Structure and 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

for MIPS, and such data must be submitted by March 31, 2018, to receive adjusted reimbursements in 2019 (adjustments are shown in Table 1).[81] As stated previously, clinicians will not be financially penalized so long as they submit data related to at least one *Quality, Advancing Care Information,* or *Improvement Activity* measure.[82]

Both benefits and concerns regarding QPP implementation occur. Providers can expect a certainty of payments for the next ten years (although those payments may be less than what they might have made pre-MACRA);[83] however, providers have concerns regarding whether the automatic 0.5% payment increase for MIPS will keep up with the combined cost of inflation and QPP participation.[84] Additionally, many small and/or rural practices are concerned that they do not possess the requisite resources to meet the MIPS reporting requirements, although MACRA grants (i.e., funding from CMS to local organizations providing assistance to clinicians transitioning to MACRA), are expected to lessen the burden.[85] Those small, rural providers have expressed the same concerns regarding participation in an APM, as APM participation requires the purchase (or upgrade) and implementation of an EHR that has the capacity to aggregate and report the required metrics.

Much debate still occurs surrounding MACRA and the QPP and 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 complete the following:

> mark up their employed physicians' services as "provider based" and [could] charge technical fees for their services. This in turn enable[d] hospitals to offer some physicians salaries that significantly exceed[ed] what they [could] earn in private practice. These physicians [then] refer[ed] patients to the higher-reimbursed hospital ancillaries, whose profits hospitals use to support physician compensation.[86]

MACRA ostensibly rectified this underlying "payment anomaly," i.e., "physician services are worth more to Medicare in hospital employment than in private practice."[87] 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."[88]

With the regulations for the second year of QPP implementation currently being drafted, an opportunity exists for organizations to suggest changes to the final

[81]"Quality Payment Program," CMS, accessed at https://qpp.cms.gov/, April 3, 2017.

[82]Ibid.

[83]Peter S. Hussey, Jodi L. Liu, and Chapin White, "The Medicare Access And CHIP Reauthorization Act: Effects On Medicare Payment Policy And Spending," *Health Affairs*, 36(4) (April 2017):702, accessed at http://content.healthaffairs.org/content/36/4/697.full.pdf, May 16, 2017.

[84]Kent Bottles, "How to Engage Physicians in Best Practices to Respond to Healthcare Transformation," Georgia Society of Certified Public Accountants' (GSCPA) 2016 Healthcare Conference, Atlanta, Georgia, February 11, 2016, accessed at https://www.slideshare.net/PYAPC/how-to-engage-physicians-in-best-practices-to-respond-to-healthcare-transformation, April 12, 2017, slide 37.

[85]Rich Daly, "Move to Value-Based Payment to Continue: CMS Medical Director," *Healthcare Financial Management Association* (April 5, 2017), 2, accessed at http://www.hfma.org/Content.aspx?id=53602&utm_source=Real%20Magnet&utm_medium=email&utm_campaign=110522593, April 10, 2017; Heather Landi, "CMS Offers $10M in Grants to Help Pay Physicians Transition to MACRA," *Healthcare Informatics* (June 13, 2016), accessed at https://www.healthcare-informatics.com/news-item/payment/cms-offers-10m-grants-help-physicians-transition-macra, April 13, 2017.

[86]Jeff Goldsmith, Nathan Kaufman, and Lawton Burns, "The Tangled Hospital-Physician Relationship," *Health Affairs Blog* (May 9, 2016), accessed at http://healthaffairs.org/blog/2016/05/09/the-tangled-hospital-physician-relationship/, May 16, 2017.

[87]Ibid.

[88]Ibid.

rules through the comment and mark-up period.[89] During the first year of QPP implementation, physician groups, such as the American Medical Association (AMA), successfully persuaded CMS to loosen MIPS participation specifications, with modifications such as,

> reducing reporting requirements for physicians to avoid penalties, creating a more realistic and flexible transition period, increasing the low-volume threshold that exempts more physicians, and eliminating the cost category in calculating the 2017 composite performance scores.[90]

For year two of QPP implementation, physician groups, including the Association of American Physicians and Surgeons (AAPS) and the Medical Group Management Association (MGMA), are arguing that HHS is restricting freedom in medicine in countless ways and are advocating for MACRA participation to be voluntary to "allow patients and physicians to decline MACRA and adopt payment based on patient value rather than by bureaucratically dictated value."[91] Other trade associations, such as the American Hospital Association (AHA), are urging CMS to expand the definition of APMs to include more physicians who partner on those models to qualify for incentives.[92] AHA is also advocating for CMS to create a hospital-based reporting option.[93]

It is up to the Trump Administration to decide which suggestions from industry stakeholders will be implemented. MACRA received bipartisan support, passing 392–37 in the US House of Representatives, including an affirmative vote by HHS Secretary Tom Price, MD.[94] However, Secretary Price has stated his belief that "challenges remain with respect to provider burden," and he has suggested more lenient QPP specifications for physicians.[95] Additionally, CMS Administrator Seema Verma has stated support for VBR initiatives such as those included in MACRA, articulating,

> There are concerns with fee-for-service, in terms of rewarding volume over quality. I do support efforts that hold providers accountable for outcomes and increasing the coordination of care.[96]

However, Ms. Verma has also expressed concerns over the increasing financial risk placed on physicians under certain VBR models.[97] As a response to these concerns, Voluntary Bundled-Payment models and a Track +1 ACO will be added as APM models.[98]

Of note, on November 16, 2017, CMS issued the final rule for the second year of the QPP.[99] The final rule allows for more flexibility related to physician participation and quality metric reporting. For example, under the final rule, the "low-volume threshold" would be expanded to exempt those providers who bill less than $90,000 for Medicare Part B or provide care for less than 200 Medicare beneficiaries from required participation in the QPP.[100] Currently (as noted above), clinicians must participate in the program if they bill more than $30,000 and provide care for more than 100 Medicare patients in a year.[101] For the first time, individual physicians and physicians in groups of ten or fewer can band together virtually to report MIPS quality metrics measures.[102] Additionally, there are more bonus opportunities for physicians—groups of fewer than 15 physicians may earn five additional points if they submit data in at least one performance category; all physicians may earn up to five additional points for

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[89]Rich Daly, "Move to Value-Based Payment to Continue: CMS Medical Director," *Healthcare Financial Management Association* (April 5, 2017), 2, accessed at http://www.hfma.org/Content.aspx?id=53602&utm_source=Real%20Magnet&utm_medium=email&utm_campaign=110522593, April 10, 2017; Steve Findlay, "Implementing MACRA," *Health Affairs* (March 27, 2017), 9, accessed at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_166.pdf, April 3, 2017.

[90]"Medicare Access and CHIP Reauthorization Act (MACRA) Quality Payment Program Final Rule," American Medical Association, Summary October 19, 2016, 1 accessed at https://www.ama-assn.org/sites/default/files/media-browser/public/physicians/macra/macra-qpp-summary.pdf, December 18, 2017.

[91]Diana Strubler, "What Will Happen to MACRA Under a Trump Administration?" *Nephrology News & Issues* (February 22, 2017), accessed at http://www.nephrologynews.com/will-happen-macra-trump-administration/, April 12, 2017.

[92]Rich Daly, "Move to Value-Based Payment to Continue: CMS Medical Director," *Healthcare Financial Management Association* (April 5, 2017), 2, accessed at http://www.hfma.org/Content.aspx?id=53602&utm_source=Real%20Magnet&utm_medium=email&utm_campaign=110522593, April 10, 2017.

[93]Ibid.

[94]Carter Gaddis, "MACRA's Future Seems Solid-for now-under the Trump Administration," *Health Data Management* (March 24, 2017), 2, accessed at https://www.healthdatamanagement.com/opinion/macrasfutureseemssolidfornowunderthetrumpadministration, April 11, 2017.

[95]Ibid.

[96]Rajiv Leventhal, "Seema Verma, CMS Administrator Nominee, Discusses MACRA, M.D. Burden in First Senate Hearing," *Healthcare Informatics* (February 16, 2017), accessed at https://www.healthcare-informatics.com/article/payment/seema-verma-cms-administrator-nominee-prioritizes-deregulation-patient-centered-care, April 12, 2017.

[97]Ibid.

[98]Rich Daly, "Move to Value-Based Payment to Continue: CMS Medical Director," *Healthcare Financial Management Association* (April 5, 2017), 2, accessed at http://www.hfma.org/Content.aspx?id=53602&utm_source=Real%20Magnet&utm_medium=email&utm_campaign=110522593, April 10, 2017.

[99]"Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year," Federal Register, Vol. 82, No. 220 (November 16, 2017), p. 53568.

[100]Ibid., 53576–53577.

[101]"Quality Payment Program" CMS, Quality Payment Program, accessed at https://qpp.cms.gov/, May 16, 2017.

[102]"Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year," Federal Register, Vol. 82, No. 220 (November 16, 2017), p. 53575.

treating especially complex patients.[103] These changes will become effective on January 1, 2018.[104]

The Threshold of Commercial Reasonableness

A healthcare *c*ommercial-reasonableness opinion has been likened to an activity more widely known in the financial community known as a fairness opinion. Since the 1985 Delaware Supreme Court Case of Smith v. Van Gorkom,[105] valuation professionals have been called upon to express fairness opinions, which state "…a view as to whether the consideration offered in a deal is within the range of what would be considered 'fair.'"[106] The healthcare commercial reasonableness opinion, which has evolved over the past two decades, has several similarities to the more traditional financial fairness opinion, e.g., each contains a description of "…the necessary qualifications of persons … and, the process … [used in] the valuation analysis."[107] However, fairness opinions, the content of which is derived from decades of case law[108] and the performance of which is informed by securities statutes,[109] are distinct from the concept of healthcare commercial reasonableness thresholds, which are informed by the evolving guidance derived from healthcare-related statutes, rules, and regulatory pronouncements, as well as some minimal indications, to date, from pertinent case law (see Tables 2 and 3).[110]

In addressing the applicability of the threshold of commercial reasonableness related to a healthcare transaction, it is prudent and useful exercise to review *all* indications derived from statutory and regulatory sources, case law, and other secondary references, some of which sources may have some implication to the particular facts and circumstances related to the transaction at issue. While there is no single, universally accepted, definition for commercial reasonableness, guidance in defining this threshold may be found in statutory and regulatory sources, such as the following:

- The Stark Law;
- The AKS;
- Guidance from (see Table 2):
  - o HHS,
  - o The OIG of HHS, and
  - o the Internal Revenue Service (IRS);
- Case law (see Table 3); and
- Commentary published by the American Law Institute.

HHS has interpreted the term "commercially reasonable" to mean an arrangement that appears to be "… a sensible, prudent business agreement, *from the perspective of the particular parties involved*, even in the absence of any potential referrals."[111] [Emphasis added.] In 2004, HHS expanded this definition of commercial reasonableness in its Stark II, Phase II commentary. In response to a comment that questioned the subjective nature of the threshold, HHS stated that:

> 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.[112] [Emphasis added.]

While this expansion by HHS of the commercial reasonableness definition provides some guidance as to the perspective from which the commercial reasonableness of a transaction may be scrutinized, HHS did not define the terms "reasonable" or "similar." This expanded definition does not address the consideration of specific inherent synergies between the parties to the transaction (aside from the decree that patient referrals may not be considered); accordingly, an abundance of caution should be utilized in focusing on "reasonable," "similar" entities or physicians, instead of on the relationship(s) between the specific parties to the transaction.

The OIG and IRS have also provided guidance in defining commercial reasonableness. The OIG has defined a commercially reasonable transaction as one in which

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[103]Ibid., 53576.

[104]Ibid., 53568.

[105]"Smith v. Van Gorkom" 488 A.2d 858, 868 (Del. 1985).

[106]"Self-Regulatory Organizations: National Association of Securities Dealers, Inc. (n/k/a Financial Industry Regulatory Authority, Inc.): Notice of Filing of Amendment Number 4 and Order Granting Accelerated Approval of Proposed Rule Change as Modified by Amendment Numbers 1, 2, 3, and 4, Relating to Fairness Opinions," Federal Register, Vol. 72, No. 202 (October 19, 2007), 59317–59318.

[107]"Regulatory Notice 07-54: Fairness Opinions," Financial Industry Regulatory Authority, November 2007, p. 7.

[108]For example, see "Smith v. Van Gorkom" 488 A.2d 858, 868 (Del. 1985); "In re Netsmart Tech. Shareholders Lit." 924 A.2d 171 (Del. Ch. 2007); "In re Checkfree Corp. Shareholders Lit." 2007 WL 3262188 (Del. Ch. 2007).

[109]"Regulatory Notice 07-54: Fairness Opinions," Financial Industry Regulatory Authority, November 2007, 2.

[110]Some limited guidance from case law is given at present (e.g., U.S. v. SCCI Hospital Houston Central – See Table 3). Further guidance from case law is expected as the regulatory enforcement of the *commercial reasonableness* threshold evolves.

[111]"Medicare and Medicaid Programs: Physicians' Referrals to Health Care Entities with which They Have Financial Relationships," Federal Register, Vol. 63, No. 6 (January 9, 1998), 1700.

[112]"Medicare Program: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II) Interim Final Rule," Federal Register, Vol. 69, No. 59 (March 26, 2004), 16093.

Table 2
Statutory and Regulatory Guidance Related to Commercial Reasonableness

	A Date	B Commonly Referred to as:	C Source	D Term Defined	E Definition
1	January 23, 2002	Internal Revenue Code, Regulations	"Excess Benefit Transaction," 26 CFR Section 53.4958-4(ii) (2012).	Reasonable compensation	"... the amount that would ordinarily be paid for like services by like enterprises (whether taxable or tax-exempt) under like circumstances."
2	February 12, 2015	Internal Revenue Service, Publication 535	"Publication 535—Business Expenses." Internal Revenue Service, January 19, 2017, accessed at https://www.irs.gov/pub/irs-pdf/p535.pdf, December 18, 2017, 7.	Reasonable compensation	"... the amount that a similar business would pay for the same or similar services."
3	January 9, 1998	Stark II, Phase I, Proposed Rules	"Medicare and Medicaid Programs: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships," Federal Register, Vol. 63, No. 6 (January 9, 1998), 1700.	Commercial reasonableness	"a sensible, prudent business arrangement from the perspective of the particular parties involved, even in the absence of potential referrals."
4	January 4, 2001	Stark II, Phase I, Final Rule	"Medicare and Medicaid Programs: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships," Federal Register, Vol. 66, No. 3 (January 4, 2001), 944.	Commercially reasonable	"... comparable to what is ordinarily paid for an item or service in the location at issue, by parties at arm's length transactions who are not in a position to refer business to one another."
5	March 26, 2004	Stark II, Phase II, Interim Rules	"Medicare Program: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships," Federal Register, Vol. 69, No. 59 (March 26, 2004), 16093.	Commercially reasonable	"... in the absence of referrals ... 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 referrals."
6	November 19, 1999	Anti-Kickback Regulations, Final Rule	"Summary of Final Rule" in "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," Federal Register, Vol. 64, No. 223 (November 19, 1999), 63525.	Commercially reasonable	"We are replacing the phrase 'legitimate business purpose' with the phrase 'commercially reasonable business purpose' in each safe harbor to make clear that the test is not whether a business arrangement is lawful, but whether it serves a commercially reasonable business purpose, that is, whether the space and equipment leased or the services purchased have *intrinsic commercial value* to the lessee or purchaser." [Emphasis added.]
7	November 19, 1999	Anti-Kickback Regulations, Final Rule	Response in "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," Federal Register, Vol. 64, No. 223 (November 19, 1999), 63525.	Commercially reasonable	"... the purpose must be *reasonably calculated* to further the business of the lessee or purchaser." [Emphasis added.]

Table 2
Continued

	A Date	B Commonly Referred to as:	C Source	D Term Defined	E Definition
8	November 19, 1999	Anti-Kickback Regulations, Final Rule	Response in "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," Federal Register, Vol. 64, No. 223 (November 19, 1999), 63525.	Commercially reasonable	"... the rental or purchase must be of space, equipment, or services that the lessee or purchaser needs, intends to utilize, and does utilize *in furtherance of its ... business objectives*." [Emphasis added.]
9	September 30, 1986	Public Health Code	"Principles of Reasonable Cost Reimbursement: Payment for End-Stage Renal Disease Services, Optional Prospectively Determined Payment Rates for Skilled Nursing Facilities," 42 CFR § 413.106(c)(2) (2012).	Reasonable cost of services	"If therapy services are performed under arrangements at a provider site on a full-time or regular part-time basis, the reasonable cost of such services may not exceed the amount determined by taking into account the number of hours of services furnished ..., the adjusted hourly salary equivalency amount appropriate for the particular [service] in the geographical area in which the services are furnished..."
10	September 30, 1986	Public Health Code	"Principles of Reasonable Cost Reimbursement: Payment for End-Stage Renal Disease Services, Optional Prospectively Determined Payment Rates for Skilled Nursing Facilities," 42 CFR § 413.102(b)(2)(i) (2012).	Reasonable compensation	"... an amount as would ordinarily be paid for comparable services by comparable institutions."
11	January 29, 1992	OIG Authorities	"Subpart C: Permissive Exclusions—Exceptions," 42 CFR § 1001.952 (2012).	Commercially reasonable	"the aggregate services contracted do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service."
12	September 27, 2007	OIG Advisory Opinion 07-10	"OIG Advisory Opinion No. 07-10" Office of Inspector General, US Department of Health and Human Services, September 27, 2007, accessed at https://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf, December 18, 2017, 6.	Commercially reasonable	"... the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services."

Table 3
Case Law Guidance Related to Commercial Reasonableness

	A	B	C	D	E	F	G
					Legal Citations		
	Case Citation	Year of Decision/ Settlement	Status of Case	Key Points	Statutory	Regulatory	Case Law
1	U.S. ex rel. Richard Rauh v. McLeod Regional Medical Center, 3:98-cv-03178-CWS, D.C. SC	2002	Settled with United States for $16 million	Medical center purchased physician practices and agreed to pay doctors' salaries that far exceeded the FMV of the practices and subsequent employment agreements with the physicians. Overpayment, i.e., payment in excess of FMV, violates any applicable Stark exception and the Anti-Kickback Statute's prohibition against paying in excess of FMV for physician practices.	Social Security Act (Stark II), 42 U.S.C. § 1395nn; Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)		
2	U.S. ex rel. Darryl L. Kaczmarczyk, et al. v. SCCI Health Services Corp., 4:99-cv-01031, S.D. TX, Houston Div.	2006	Settled with United States for $10.7 million	An analyst "... generally considers ... (1) size of facility, number of patients, patient activity levels, and patient needs; (2) the quality of medical staff; (3) the number of regular committees and meetings; and (4) the quality of management and interdisciplinary coordination" in determining whether a lessee or purchaser needs medical director services. Lessees or purchasers should "... conduct a regular assessment of the duties performed by the medical director ... [that make it] clear how effective the medical director is doing his assigned job and if there is a need to continuing the services." "The responsibilities of the medical director should not be part of his/her customary duties as a treating physician nor should they mirror the required responsibilities outlined in the hospital's medical staff bylaws."	Social Security Act (Stark II), 42 U.S.C. § 1395nn; False Claims Act, 31 U.S.C. §§ 3729-33; 42 U.S.C. §§ 1395f(b) (Conditions of and Limitations on Payment for Services - Amount Paid to Provider of Services), 1395g (Payments to Providers of Services); Anti-Kickback Statute, 42 U.S.C. 1329a-7b(b)	Prohibition on Certain Referrals by Physicians and Limitations on Billing (Stark), 42 C.F.R. § 411.353; Payments to Providers, 42 C.F.R. §§ 413.1, 413.20, 413.40(c)-(d), 413.60, 413.64; Contractor Determination and Notice of Amount of Program Reimbursement, 42 C.F.R. §§ 405.1803; Reasonable and Necessary Services, 42 C.F.R. § 411.15(k); Basic Conditions for Medicare Payment, 42 C.F.R. § 424.5(a)	

Table 3
Continued

	A	B	C	D	E	F	G
					Legal Citations		
	Case Citation	Year of Decision/ Settlement	Status of Case	Key Points	Statutory	Regulatory	Case Law
3	U.S. v. Covenant Medical Center, N.D. IA	2009	Settled with United States for $4.5 million	DOJ cited significant discrepancies between the compensation paid to physicians at Covenant in comparison to the compensation paid to physicians in the region and around the country, leading the DOJ to allege that the hospital was paying the physicians for referrals in violation of the Stark Law. Proper valuation of physicians' compensation, especially if it exceeds the 90th percentile or there is another basis for challenge, is suspect under the FMV and commercial reasonableness tests.	Social Security Act (Stark II), 42 U.S.C. § 1395nn		

Table 3
Continued

	A	B	C	D	E	F	G
					Legal Citations		
	Case Citation	Year of Decision/ Settlement	Status of Case	Key Points	Statutory	Regulatory	Case Law
4	U.S. ex rel. Singh, et al. v. Bradford Regional Medical Center, et al., 04-186 Erie, W.D. PA	2010	Motions for summary judgment denied, remanded for trial on AKS/ FCA	The Court looked to the Defendant's expert report, which specifically stated that referrals were taken into account when valuing the consideration paid, making this analysis critical for a determination of *commercial reasonableness* because if the consideration takes into account the value or volume of referrals, then the arrangement is not consistent with FMV and not commercially reasonable.	Social Security Act (Stark II), 42 U.S.C. § 1395nn; Anti-Kickback Statute, 42 U.S.C. § 1329a-7b	Compensation Arrangement & Special Rules on Compensation (Stark), 42 C.F.R. § 411.354(c), (d); Exceptions to Referral Prohibition Related to Compensation Arrangements - Rental of Office Space, Rental of Equipment, Fair Market Value, Indirect Compensation Arrangements (Stark), 42 C.F.R. § 411.357(a), (b), (l), (p); Physician Referrals to Healthcare Entities with which They Have Financial Relationships, 66 Fed. Reg. at 855, 867, 877-88, 919, 944 (January 4, 2001); Exceptions - Space Rental, Equipment Rental, Personal Services and Management Contracts (Anti-Kickback Statute), 42 C.F.R. § 1001.952 (b), (c), (d)	U.S. ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88 (3d Cir. 2009); U.S. ex rel. Villafane v. Solinger, 543 F.Supp.2d 678 (W.D.Ky. 2008)

Table 3
Continued

	A	B	C	D	E	F	G
					Legal Citations		
	Case Citation	Year of Decision/ Settlement	Status of Case	Key Points	Statutory	Regulatory	Case Law
5	U.S. v. Campbell, 2:2008-cv-01951, D.C. NJ	2011	Jury verdict of No Cause For Action	Healthcare entities should monitor employees to ensure that they "actually perform the duties outlined in their contract."	False Claims Act, 31 U.S.C. §§ 3729-33; Social Security Act (Stark II), 42 U.S.C. § 1395nn; Anti-Kickback Statute, 42 U.S.C. § 1320a-7b	Physician Referrals to Healthcare Entities with which They Have Financial Relationships, 66 Fed.Reg. 941 (January 4, 2001); Exclusions from Coverage, Conditions for Medicare Payment, 42 C.F.R. 411, 424 (2001)	U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235 (3d Cir. 2004); U.S. v. Rogan, 459 F.Supp.2d 692 (N.D. Ill. 2006); U.S. ex rel. Kosenske v. Carlisle HMA, Inc., 554 F.3d 88 (3d Cir. 2009)

Table 3
Continued

	A	B	C	D	E	F	G
					Legal Citations		
	Case Citation	Year of Decision/ Settlement	Status of Case	Key Points	Statutory	Regulatory	Case Law
6	U.S. ex rel. Drakeford v. Tuomey Healthcare System, 3:05-cv-02858-MJP, D.C. SC, Columbia Div.	2013	Settled with United States for $237 million	Court relied on the OIG commentary stating "... when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity ... However, in the context of inpatient and outpatient hospitals services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service." Failure by a physician to personally perform the technical components of treating a patient constitutes a noncompliant referral under the Personal Services Arrangement exception to the Stark Law because "the personal services exception does not extend to a facility fee a hospital bills for a facility component resulting from a personally performed service" Defendant took into account the value and volume of anticipated physician referrals by considering the hospital's technical and facility fees earned each time the physicians performed an outpatient surgery to be offsets for Defendant's annual operating losses.	False Claims Act, 31 U.S.C. §§ 3729 et seq.; Social Security Act (Stark II), 42 U.S.C. § 1395nn	Exceptions to Referral Prohibition Related to Compensation Arrangements - Indirect Compensation Arrangements (Stark), 42 C.F.R. § 411.357(p); Physician Referrals to Healthcare Entities with which They Have Financial Relationships, 66 Fed. Reg. at 941 (January 4, 2001).	U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394 (4th Cir. 2012) *on appeal*; U.S. v. Rogan, 517 F.3d 449 (7th Cir. 2008); U.S. ex rel. Roberts v. Aging Care Home Health, Inc., 474 F.Supp. 2d 810 (W.D. La. 2007); U.S. ex rel. Ketroser v. Mayo Foundation, 2013 WL 4733986 (8th Cir. 2013)

Table 3
Continued

	A	B	C	D	E	F	G
					Legal Citations		
	Case Citation	Year of Decision/ Settlement	Status of Case	Key Points	Statutory	Regulatory	Case Law
6	U.S. ex rel. Parikh v. Citizens Medical Center, 6:10-cv-64, S.D. TX, Victoria Div.	2015	Defendant motions to dismiss granted/ denied in part	Salaries of physicians that "more than doubled" from the time when they were employed privately to when they were employed by a healthcare entity, even though the entity had systematically lost money. Provides a strong inference of the existence of a kickback scheme due to the lack of apparent economic sense for their employment of the physicians at a loss unless there was a desire to induce referrals. An inference exists that "book financial losses" generated by a vertically integrated physician practice may signal the payment of compensation, remuneration and consideration to physicians as an inducement of legally impermissible referrals from physicians.	False Claims Act, 31 U.S.C. §§ 3729, et seq., 3730(b)(2), (d)(1), (e)(4)(A)-(B); Anti-Kickback Act, 42 U.S.C. § 1320a-7b(b); Social Security Act (Stark II), 42 U.S.C. § 1395nn(a)(1)(B), (a)(2)	Exceptions to Referral Prohibition Related to Compensation Arrangements - Bona Fide Employment Relationships (Stark), 42 C.F.R. § 411.357(c)(2)(i)-(ii); Principles of Reimbursement, 42 C.F.R. §§ 413.1(a)(2), 413.23(f)(4)(ii); Exceptions - Personal Services and Management Contracts (Anti-Kickback Statute), 42 C.F.R. § 1001.952(d)(5); Limitations on Billing, 42 C.F.R. § 411.353(b)	U.S. ex rel. Hafter v. Spectrum Emergency Care, Inc., 190 F.3d 1156 (10th Cir. 1999); Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899
7	U.S. ex rel. Barker v. Columbus Regional Healthcare System et al., 4:14-cv-304, M.D. GA	2015	Settled for over $25 million	Healthcare entities should assess "whether its purchase of the [subject entity] addressed any particular community need or improved its quality of . . . services provided in its market." "One of the key factors used to determine commercial reasonableness, is to determine whether a hospital needs, intends to use, and actually utilizes the asset it purchases."	False Claims Act, 31 U.S.C. §§ 3729-33; Social Security Act (Stark II), 42 U.S.C. § 1395nn	Adjustments to Civil Monetary Penalties, 28 C.F.R. § 85.3; Exceptions - Remuneration to Employees (Anti-Kickback Statute), 42 C.F.R. § 1001.952(i); Compensation Arrangement & Special Rules on Compensation (Stark), 42 C.F.R. § 411.354	U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc., 675 F.3d 394 (4th Cir. 2012)

Table 3
Continued

A	B	C	D	E	F	G
				Legal Citations		
Case Citation	Year of Decision/ Settlement	Status of Case	Key Points	Statutory	Regulatory	Case Law
8 U.S. ex rel. Reilly v. North Broward Hospital District, 10-60590-cv, S.D. FL	2015	Settled for $69.5 million	Employing physicians at more than FMV and more than the hospital can receive for their personal services is sustainable only by anticipating and allocating hospital referral profits to cover the massive direct losses from the excessive physician compensation and violates the commercial reasonableness and FMV provisions of federal law. The profitability (or lack thereof) of the physicians' professional services, independent of the economic performance of the vertically integrated health system, of which those professional services were an integral part, is a sign that the physicians are being paid more than FMV.	False Claims Act, 31 U.S.C. §§ 3729-32; Anti-Kickback Statute, Social Security Act (Stark II), 42 U.S.C. § 1395nn (e) (2), (3), (g) (1), (3); Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)	Exceptions (Anti-Kickback Statute), 42 C.F.R. § 1001.952; Payments to Providers, 42 C.F.R. §§ 413.1, 413.60, 413.64.; Basic CHAMPUS Program Benefits, TRICARE, 32 C.F.R.§ 199.4(a), 199.6	
9 U.S. ex rel. Payne, et al. v. Adventist Health System, et al., 3:12cv856-W, W.D. NC	2015	Settled for $115 million	Physicians received bonuses that were tied to the number of tests and procedures ordered, and allegedly coded their services improperly in order to obtain a higher reimbursement amount for the services rendered, thus violating the Stark Law by authorizing commercially unreasonable compensation arrangements that exceeded FMV with physicians to the extent that the hospital would have been forced to operate at a loss, but for the profits generated by the physician referrals.	False Claims Act, 31 U.S.C. § 3729 et seq; Social Security Act (Stark II), 42 U.S.C. § 1395nn	Prohibition on Certain Referrals by Physicians and Limitations on Billing - Refunds; 42 C.F.R. § 411.353(d); Compensation Arrangement & Special Rules on Compensation (Stark), 42 C.F.R. § 411.354(d)(4)(iv)(B)	

> the aggregate services contracted do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service.[113]

Additionally, IRS guidance regarding commercial reasonableness may be derived from IRS pronouncements on reasonable compensation, including:

- The 1993 Exempt Organizations Continuing Professional Education text titled "Reasonable Compensation," which states

> reasonable compensation is … the amount that would ordinarily be paid for like services by like organizations in like circumstances. Thus, the concept has two prongs: 1) an amount test, focusing on the reasonableness of the total amount paid; and 2) a purpose test, examining the services for which the compensation was paid;[114]

- Chapter 2, titled "Employees' Pay," of Publication 535, titled "Business Expenses," which states "… reasonable pay is the amount that a similar business would pay for the same or similar services"[115]; and
- Section 53.4958-4 of the Internal Revenue Code (IRC), containing the Federal Regulations on "Excess Benefit Transactions," which states,

> reasonable compensation [is] … the amount that would ordinarily be paid for like services by like enterprises (whether taxable or tax-exempt) under like circumstances.[116]

While none of the IRS pronouncements set forth for addressing reasonable compensation specifically address commercial reasonableness in the healthcare industry, the above factors provide indications as to the manner of assessing commercial reasonableness thresholds in an anticipated healthcare transaction. Justification for reliance on IRS regulations in defining and determining the threshold of commercial reasonableness may be warranted in light of the 2001 Stark II, Phase I final regulations promulgated by HHS, to wit:

> As for using the IRS guidelines for determining fair market value that applies to tax exempt organizations, we recognize that in some cases they may not be appropriate for for-profit entities. Nonetheless, it is our view that some elements of the IRS guidelines could be applied under certain circumstances, depending upon the specifics of any particular agreement. We do not wish to either mandate their use or rule them out if they can be appropriately used to demonstrate fair market value.[117]

Additional guidance related to the definition of commercial reasonableness may be derived from statutory and regulatory guidance, which are listed in Table 2.

Further guidance indicating that, beyond the individual transaction elements, the entirety of a subject transaction should be reviewed in the aggregate (inclusive of all elements for which consideration is given) is found in the Personal Services exception of the Stark Law. This exception requires that "[t]he aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s)."[118]

In addition to the statutory and regulatory sources noted above, guidance as to the application of the commercial reasonableness threshold in healthcare transactions may also be found in relevant case law, including that listed in Table 3: Case Law Guidance Related to Commercial Reasonableness.

Further guidance as to certain elements related to the healthcare commercial reasonableness threshold may also be found in other sources, e.g., commentary published by the 2006 American Law Institute, which address the necessity threshold of commercial reasonableness to wit:

> Each financial and contractual connection between [hospitals and physicians] should be scrutinized to ensure that goods or services changing hands are being provided at FMV, and at *a level no more than necessary for the business purposes of the arrangement*."[119] [Emphasis added.]

The commercial reasonableness analysis comprises 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); and
- Developing a quantitative analysis focusing on the transaction's financial feasibility.

It should be noted that the qualitative and quantitative factors described below are not intended to be considered in isolation; rather, the valuation analyst should consider both the individual merits of each factor, as well as the interaction between the factors in assessing the commercial reasonableness of the anticipated transaction. As

[113]"Subpart C: Permissive Exclusions – Exceptions," 42 C.F.R. § 1001.952 (2012).

[114]Jean Wright and Jay H. Rotz, "Reasonable Compensation," Exempt Organizations Continuing Professional Education, 1993, accessed at http://www.irs.gov/pub/irs-tege/eotopici93.pdf, September 4, 2012, 3.

[115]Internal Revenue Service, "Publication 535-Business Expenses," January 19, 2017, 7, accessed at https://www.irs.gov/pub/irs-pdf/p535.pdf, December 18, 2017.

[116]"Excess Benefit Transaction," 26 C.F.R. § 53.4958-4(b)(1)(ii) (2014).

[117]"Medicare and Medicaid Programs: Physicians' Referrals to Health Care Entities with which They Have Financial Relationships," Federal Register, Vol. 66, No. 3 (January 9, 1998), 944.

[118]"Exclusions from Medicare and Limitations on Medicare Payment," 42 C.F.R. § 411.357(d)(1)(iii) (2012).

[119]Alson R. Martin, "Healthcare Joint Ventures," American Law Institute-American Bar Association Continuing Legal Education, September 28–30, 2006.

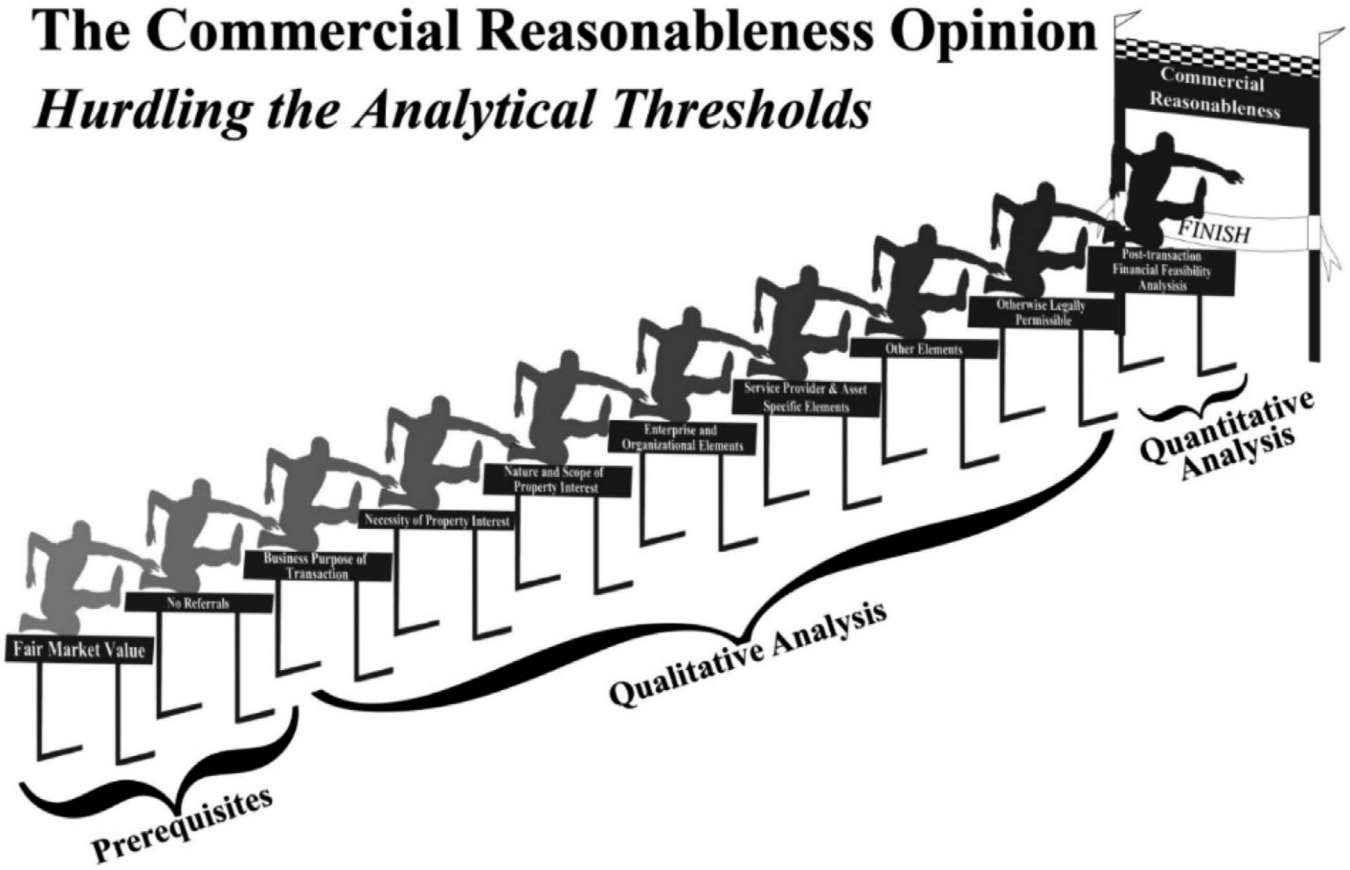

Figure 3
The Commercial Reasonableness Opinion: Hurdling the Analytical Thresholds

illustrated in Figure 3, the thresholds of the *commercial reasonableness* analysis are analogous to hurdles which the anticipated transaction must overcome before reaching the finish line, i.e., being deemed commercially reasonable.

To assess the commercial reasonableness of a proposed transaction, the valuation analyst, in light of these definitions, should begin with certain transactional prerequisite elements, including the following:

- Whether each element of a prospective transaction does not exceed FMV; and
- That the prospective transaction is a sensible, prudent business arrangement even in the absence of referrals.[120]

While the analysis of the threshold of commercial reasonableness is separate and distinct from the development of a FMV analysis, requiring consideration of different aspects of the property interest included in the transaction, they are related thresholds, and the consideration and analysis of one threshold does *not* preclude the analysis of the other threshold. For example, a necessary condition for an anticipated transaction to be commercially reasonable is that each element of that transaction must not exceed FMV; however, even in the event that each element of an anticipated transaction does not exceed FMV, the anticipated transaction may still *not* be commercially reasonable in that it does not meet the remaining analytical hurdles of a commercial reasonableness analysis. Consequently, finding that an enterprise, asset, or service meets the FMV threshold is not, in and of itself, sufficient to establish commercial reasonableness.[121]

After ensuring that each transactional prerequisite of the prospective transaction is met, further analysis of both the qualitative and quantitative aspects of the proposed

[120]"Medicare Program: Physicians' Referrals to Healthcare Entities with which they have Financial Relationships (Phase II)," 63 Fed. Reg. 16093 (March 26, 2004).

[121]Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, *Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*, Vol. 2, 937–938 (Hoboken, New Jersey: John Wiley & Sons, Inc.), 2014.

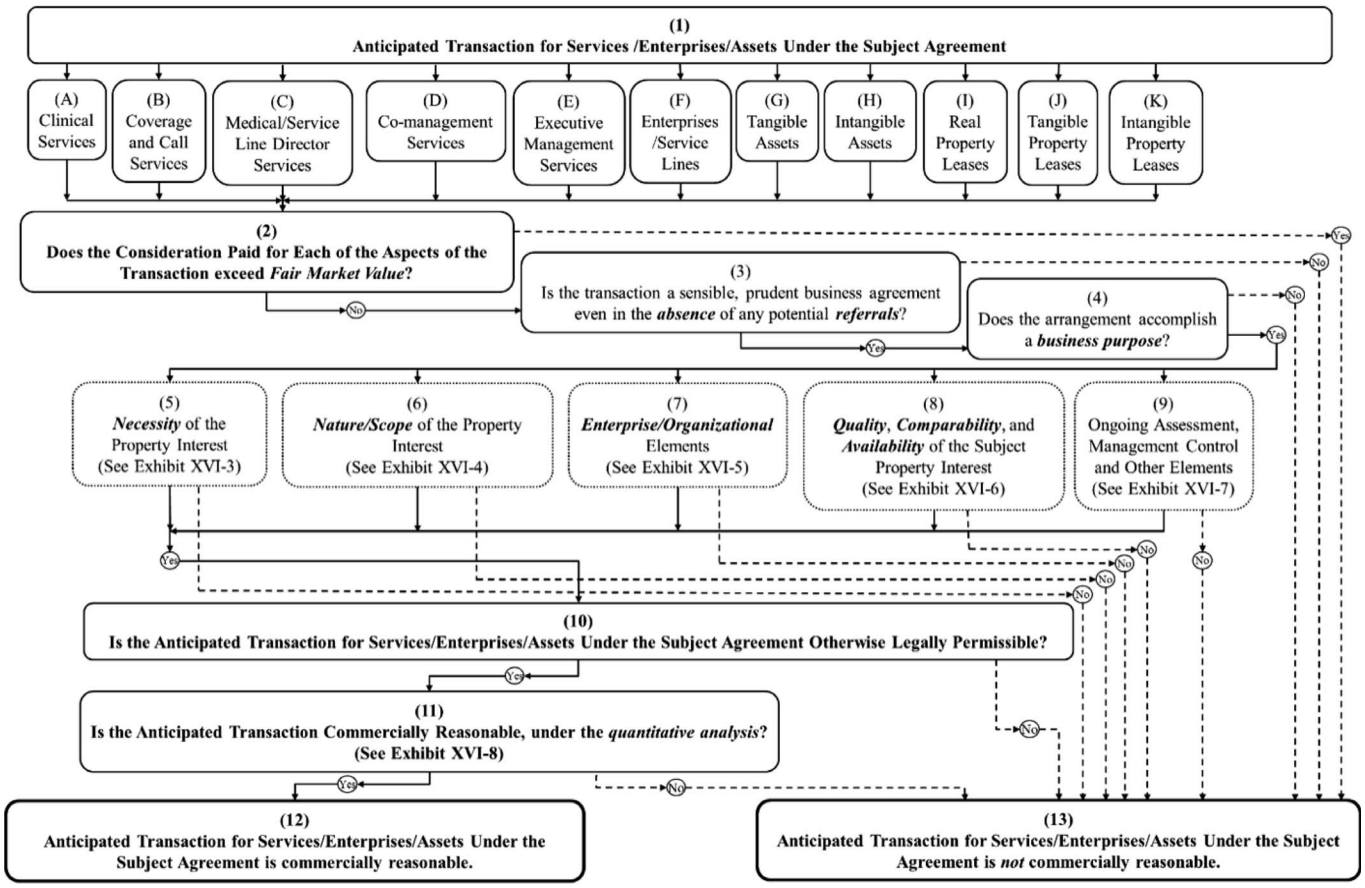

Figure 4
Qualitative Analytical Steps in the Commercial Reasonableness Threshold

transaction is warranted to determine its commercial reasonableness.

The steps involved in the qualitative assessment of commercial reasonableness focus on determining the acquirer's business purpose(s) and the way in which the anticipated transaction assists in meeting that purpose. The specific qualitative thresholds are as follows.

- Is the integration transaction necessary to accomplish the business purpose of the client?
- Does the nature and scope of the underlying elements of the integration transaction meet the business needs of the client?
- Does the enterprise and organizational elements of the integration transaction make business sense to the client?
- Does the quality, comparability, and availability of the underlying elements of the integration transaction make business sense for the client?
- Are there sufficient ongoing assessments, management controls, and other compliance measures in place related to the underlying elements of the integration transaction?
- Is the transaction otherwise legally permissible?[122]

A process for analyzing the various qualitative factors related to the commercial reasonableness threshold is illustrated in Figure 4.

In addition to the qualitative analysis, a quantitative analysis of both the discrete elements and the entirety of the anticipated transaction should be undertaken. This analysis, which is referred to as a post-transaction financial feasibility analysis, takes into account all consideration to be paid by purchasers and lessees to sellers and lessors. The elements of the post-transaction financial feasibility analysis are not intended to be considered in isolation; rather, the analyst should consider both the individual merits of each analytical technique and the relationships between the analytical techniques employed.

[122]Ibid., 941. For a detailed discussion on the qualitative factors of the commercial reasonableness analysis, see "Threshold of Commercial Reasonableness: The Qualitative Analysis," *Health Capital Topics*, 7(11), December 2014, accessed at http://www.healthcapital.com/hcc/newsletter/12_14/QUALITATIVE.pdf, January 12, 2015.

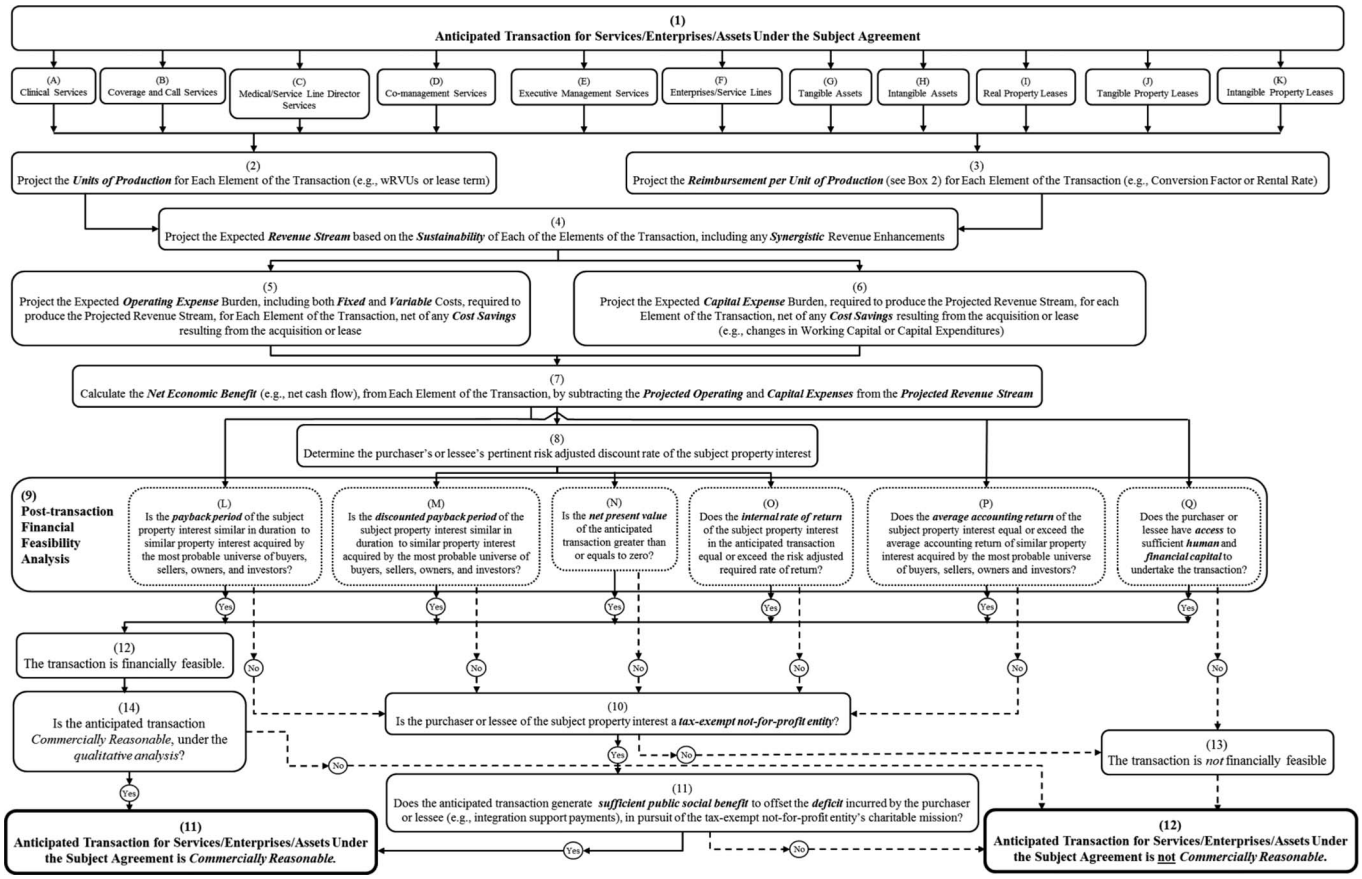

Figure 5
Analytical Process for Quantitative Analysis

A process for quantifying the various elements of the subject transaction, e.g., the services to be provided and the assets and enterprises to be acquired, is illustrated in Figure 5. When performing a cost/benefit analysis for a particular buyer, a valuation analyst may also want 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;[123]
- Internal rate of return analysis, which calculates the discount rate necessary to result in a *zero* NPV, whose rate can be compared to an investor's required rate of return for a specific property interest to determine the viability of the investment;[124]
- Average accounting return 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;[125]
- *Payback period analysis*, which calculates the number of discrete periods necessary for "the cumulative forecasted [undiscounted] cash flow [to] equal the initial investment;"[126] and
- Discounted payback period analysis, which is similar to a payback period analysis, calculates the number of discrete periods "... until the sum of the

[123]Stephen Ross et al., *Fundamentals of Corporate Finance*, Second Edition (Boston: Irwin, 1993), 220.

[124]Richard Brealey et al., *Principles of Corporate Finance*, Ninth Edition (New York: McGraw-Hill Irwin, 2008), 122.

[125]Stephen Ross et al., *Fundamentals of Corporate Finance*, Second Edition (Boston: Irwin, 1993), 231.

[126]Richard Brealey et al., *Principles of Corporate Finance*, Ninth Edition (New York: McGraw-Hill Irwin, 2008), 120.

> *discounted* cash flow is equal to the initial investment" [emphasis added].[127]

Each of the value metrics that results from the cost/benefit analyses described previously should be considered within the context of the qualitative factors of the commercial reasonableness analysis.[128] This is especially true when the cost/benefit analysis reflects a financial (cash) loss, as a transaction may still be commercially reasonable after the nonmonetary 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.[129]

Inherent Conflict between MACRA and Fraud and Abuse Laws

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.[130] This misguided theory overly simplifies the commercial reasonableness analysis, such that the threshold, in many instances, 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.[131]

This conflict between the interpretation of the commercial reasonableness threshold by regulators and the application of MACRA[132] is partly because the goals of VBR and fraud and abuse laws are fundamentally at odds with one another. MACRA has furthered the healthcare industry's transition to VBR, in which payment models seek to reduce the overutilization of healthcare services by incentivizing the provision of efficient, evidence-based care to reduce healthcare costs (in part by utilizing technologies, such as big data analysis techniques and artificial intelligence), through the sharing of savings and losses by the providers and CMS.[133] To meet these goals and take advantage of the VBR reforms, many healthcare organizations are considering various alignment strategies that amass the needed knowledge, skills, and abilities required to provide for the full continuum of a patient episode of care.[134]

As mentioned previously, one result of provider alignment in pursuit of VBR goals, particularly when aligning through employment arrangements with hospitals and health systems, may be that hospitals or health systems sustain practice losses.[135] This may be attributable to a number of reasons, including (a) encountering a more adverse payor mix in a hospital setting, (b) needing

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[127]Ibid., 228.

[128]For a detailed discussion on the qualitative factors of the commercial reasonableness analysis, see "Threshold of Commercial Reasonableness: The Qualitative Analysis," *Health Capital Topics*, 7(11), December 2014, accessed at http://www.healthcapital.com/hcc/newsletter/12_14/QUALITATIVE.pdf, January 12, 2015); or, Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, *Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*, Volume 2 (Hoboken, New Jersey: John Wiley & Sons, Inc., 2014), 940–963.

[129]See further examples described in Health Capital Consultants, "Threshold of Commercial Reasonableness: The Qualitative Analysis," December 2014; Larry Scanlan, *Hospital Mergers: Why They Work, Why They Don't* (Chicago, Illinois: Health Forum Inc., 2010), 27; Patrick Gaughan, *Mergers, Acquisitions, and Corporate Restructurings* (Hoboken, New Jersey: John Wiley & Sons, Inc., 2011), 14; Kenneth Marks, *Middle Market M&A: Handbook for Investment Banking and Business Consulting* (Hoboken, New Jersey: John Wiley & Sons, Inc., 2012), 28; Internal Revenue Service, "IRS Revenue Ruling 69-545, 1969-2 C.B. 117," accessed at http://www.irs.gov/pub/irs-tege/rr69-545.pdf, January 22, 2014; Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, *Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*, Volume 2 (Hoboken, New Jersey: John Wiley & Sons, Inc., 2014), 183.

[130]"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, 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), Relator's 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), Relator's Amended Complaint, 56; Eric B. Gordon and Daniel H. Melvin, "Health System Practice 'Losses' Make Headlines, Plaintiffs Make New Stark 'Law,'" BNA's Health Care Fraud Report, Bloomberg BNA, November 25, 2015, accessed at http://www.mwe.com/files/Publication/a1a5d17c-3c79-4380-baef-0d11822334a1/Presentation/PublicationAttachment/5bb1e6ca-6491-4907-9a57-1049c2f3eec6/Gordan-Melvin.pdf, December 15, 2015.

[131]Thomas P. Nickels, American Hospital Association Letter to US Senate, "Letter to The Honorable Orrin Hatch and The Honorable Ron Wyden, re Stark Law," January 29, 2016.

[132]For more information on MACRA, see the first installment of this two-part series, entitled "Value-Based Payments Under MACRA – Outlook," *Health Capital Topics*, 10(4), May 2017, accessed at https://www.healthcapital.com/hcc/newsletter/04_17/PDF/MACRA.pdf, May 23, 2017.

[133]Maggie Van Dyke, "MACRA and the Giant Move into Value-based Payment," *Hospitals & Health Networks*, December 13, 2016, accessed at http://www.hhnmag.com/articles/7832-the-giant-move-into-value-based-payment-via-macra, May 23, 2017.

[134]Daniel W. Kiehl, JD, LLM, Coker Group, "Remaining Stark-Compliant with 'Practice Losses' and Ancillary Services," November 2016, accessed at http://cokergroup.com/wp-content/uploads/2016/11/Remaining-Stark-Compliance-with-Practice-Losses-and-Ancillary-Services_November-2016.pdf, May 3, 2017.

[135]Ibid.

to pay more competitive salaries to employed providers, and (c) treatment of ancillary services by the hospital or health system (i.e., treating vertically integrated physician practices as stand-alone economic enterprises, which, when stripped of their ancillary services and technical component (ASTC) revenue and relying solely on professional services, i.e., work relative value unit [wRVU] related revenue, and paying physicians at FMV, are almost certain to generate "book financial losses").[136]

This inherent conflict has been recognized by lawmakers and other healthcare stakeholders, with hearings being held on Capitol Hill in 2015 and 2016 related to potential modifications to the Stark Law.[137] House and Senate committees solicited input from industry leaders related to Stark law challenges, such as its integration with MACRA.[138] As noted in the white paper published by the Senate Finance Committee Majority Staff:

> 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.[139]

This sentiment was echoed by Thomas P. Nickels, Executive Vice President of Government Relations and Public Policy for the American Hospital Association:

> 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*.[140] [Emphasis added.]

Troy A. Barsky, Esq.[141] testified that Congress should amend the Stark Law by defining *commercial reasonableness*,[142] stating:

> 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*.[143] [Emphasis added.]

These comments indicate an understanding by many healthcare industry stakeholders of inherent failure of the PLP's argument regarding commercial reasonableness, namely, that financial (cash) 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 the following:

- Emergency rooms, trauma services, pathology labs, and neonatal intensive-care units;
- 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 of therapeutic benefits to patients.[144]

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[136]Ibid.; David N. Gans, MSHA, FACMPE, MGMA Connexion, "Why Hospital-Owned Medical Groups Lose Money," April 2012, 20, accessed at http://www.mgma.com/Libraries/Assets/Practice%20Resources/Publications/MGMA%20Connexion/2012/Data-Mine-Why-hospital-owned-medical-groups-lose-money—MGMA-Connexion-magazine-April-2012.pdf, March 29, 2016.

[137]For more information on these hearings, please see the article entitled, "Stark Law Reform Debated by Senate Committee," *Health Capital Topics*, 9(8), August 2016.

[138]James Swann, "Lawmakers Consider Changes to Physician Self-Referral Law," Bloomberg BNA, February 1, 2016, accessed at https://www.bna.com/lawmakers-consider-changes-n57982066790/, May 3, 2017.

[139]"Why Stark, Why Now?" Senate Finance Committee Majority Staff (2016), 2, 15–16.

[140]Thomas P. Nickels, American Hospital Association Letter to US Senate, "Letter to The Honorable Orrin Hatch and The Honorable Ron Wyden, re Stark Law," January 29, 2016.

[141]Mr. Barsky is a noted private healthcare attorney with Crowell & Moring, LLP, and previously served as the Director of the Division of Technical Payment Policy at CMS for four of his eleven years at HHS.

[142]Congressional Record, Vol. 162, No. 112 (July 12, 2016), S5010; "Examining the Stark Law: Current Issues and Opportunities," U.S. Senate Committee on Finance, July 12, 2016, accessed at http://www.finance.senate.gov/hearings/examining-the-stark-law-current-issues-and-opportunities, August 31, 2016.

[143]Troy A. Barsky, Crowell & Moring LLP, "Testimony Before the Committee on Finance," July 12, 2016, accessed at http://www.finance.senate.gov/imo/media/doc/12jul2016Barsky.pdf, July 20, 2016.

[144]Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, *Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*, Vol. 2 (Hoboken, New Jersey: John Wiley & Sons, 2014), 321, 946; William E. Berlin, Esq.,"Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" *The Health Lawyer*, 20(5):9 (June 2008); Amanda Gardner, "Helping Patients Heal Through the Arts" CNN, July 5, 2013, 1, accessed at http://www.cnn.com/2013/07/05/health/arts-in-medicine/ August 18, 2014.

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 (such as satisfying MACRA standards.[145]

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, e.g., whether or not it is commercially reasonable to compensate or share MACRA reimbursement increases with physicians who are not directly responsible for improving quality.[146] Further, 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, in which rules must be strictly complied to guarantee protection from fraud and abuse violations.[147] 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.

Conclusion

As succinctly stated by Professors Timothy S. Jost[148] and Ezekiel J. Emanuel, MD, PhD,[149] in their *Journal of the American Medical Association* (JAMA) essay almost a decade ago:

> The 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.[150]

The current trend in the regulatory application of the PLP to challenge healthcare VBR models that incentivize vertical integration in healthcare, e.g., those models promoted by MACRA, 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 *promotion of an enterprise's charitable mission*, and the generation of *social benefit*.

The threshold of commercial reasonableness relies on more than simply *accounting* conventions, such as "book financial losses"; it requires consideration of the broader concept of *economic utility*, not simply immediate or direct *financial (cash)* returns. Accounting documents, such as an income statement, balance sheet, or general ledger, rarely account for *non-monetary (non-cash) economic* benefits in ways that accurately reflect the overall *utility* produced by an enterprise, asset, or service that may support the commercial reasonableness of the vertical integration transaction. The sole reliance on *accounting* documents that demonstrate "book financial losses" as evidence against the commercial reasonableness of a vertical integration transaction erodes the *economic* underpinnings of the threshold of commercial reasonableness in healthcare transactions, which requires the analysis and consideration of both the qualitative and quantitative economic benefits that vertical integration may provide.

Note that many of the economic benefits of healthcare vertical integration may be *nonmonetary (noncash)*, in contrast to *monetary (cash)* benefits.[151] Although these *nonmonetary (noncash)* benefits do not provide immediate *monetary (cash)* returns on and returns of the requisite investment in the integration, they may still provide economic *utility*, i.e., "the ability of a product to satisfy a human want, need, or desire."[152] It is essential to understand this distinction, as it highlights a primary difference between *financial economics*, which focuses on a broader sense of *utility*,

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

[146]Christy Street, "3 Big Themes at the 2017 AHLA Physicians and Hospitals Law Institute," *HORNE*, February 3, 2017, accessed at http://blog.hornellp.com/healthcare/3-big-themes-at-the-2017-ahla-physicians-and-hospitals-law-institute, May 3, 2017.

[147]"Fraud and Abuse Waivers," CMS, accessed at https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/fraud-and-abuse-waivers.html, May 19, 2017; Christy Street, "3 Big Themes at the 2017 AHLA Physicians and Hospitals Law Institute," *HORNE*, February 3, 2017, accessed at http://blog.hornellp.com/healthcare/3-big-themes-at-the-2017-ahla-physicians-and-hospitals-law-institute, May 3, 2017.

[148]"Timothy S. Jost," Washington and Lee University School of Law, accessed at https://law2.wlu.edu/faculty/profiledetail.asp?id=24, June 2, 2017.

[149]Ezekiel J. Emanuel, "Bio," accessed at http://www.ezekielemanuel.com/bio, June 2, 2017.

[150]Timothy S. Jost and Ezekiel J. Emanuel, "Legal Reforms Necessary to Promote Delivery System Reform Innovation," *Journal of the American Medical Association*, 299(21):2561 (2008).

[151]Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, Todd A. Zigrang, MBA, MHA, ASA, FACHE, John R. Chwarzinski, MSF, MAE, and Jonathan T. Wixom, MBA, "Valuation of Healthcare Intangible Assets in the Absence of Positive Net Cash Flows," *Business Valuation Review*, 34(3):140 (Fall 2015).

[152]"The Appraisal of Real Estate," Appraisal Institute, Tenth Edition (Chicago, Illinois), 1992 (originally published in 1951), 24.

and *accounting conventions*, which focus narrowly on *financial (cash)* considerations. Further, because not all forms of *utility* accruing to a vertically integrated healthcare system, such as satisfaction of the Triple Aim and the improved care coordination across the continuum of care, may be fully reflected on the financial reports for the enterprise, the analysis of healthcare vertical integration transactions may be biased as to the conclusions drawn regarding FMV and commercial reasonableness, consequently as to the legal permissibility of the transaction.

Business valuation professionals who develop and render FMV and commercial reasonableness opinions related to these healthcare enterprises, assets, and services should not consider just quantitative factors such as accounting-based "book financial losses" but should consider *all* quantitative and qualitative economic benefits of the transaction, including the *avoidance of cost* and the generation of *social benefits*, some of which economic benefits do not immediately (or may never) yield direct *financial (cash)* returns on or returns of their investment.