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Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang MBA, MHA, ASA, FACHE, Publisher

Value-Based Payments Under MACRA – Tension with Fraud & Abuse Laws (Part Two of a Two-Part Series)

In response to the advent of *value-based reimbursement* (VBR), most recently through the implementation of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA),[1] which reimbursement models rely on incentivizing providers to achieve better outcomes at lower cost, hospitals are increasingly seeking closer relationships with physicians, including practice acquisitions, direct employment, *provider services agreements* (PSAs), co-management, and joint venture arrangements.[2] 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*,"[3] there has been increased federal, state, and local regulatory oversight regarding the legal permissibility of these arrangements.[4] 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 under the *False Claims Act* (FCA).[5] 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*.[6] 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 a disjointed approach to healthcare reform by numerous federal agencies, 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.*"

A comprehensive understanding of this tension between the *fraud and abuse* laws enforced by the DOJ, and the VBR models being implemented by HHS, warrants, in addition to an examination of MACRA (which was conducted in the first installment of this two-part series),[7] a review of the threshold of *commercial reasonableness*. While definitions of the *commercial reasonableness* threshold are similar among the various federal agencies responsible for enforcing regulations affecting the healthcare industry, there are subtle nuances between each agency's interpretation of the term "*commercial reasonableness*." The *Department of Health and Human Services* (HHS) has interpreted the term "*commercially reasonable*" to mean an arrangement which appears to be *"…a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals."*[8] Additionally, HHS's *Stark II, Phase II* commentary suggests 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.*"[9]

The *Office of the Inspector General* (OIG) and *Internal Revenue Service* (IRS) have also provided guidance in defining *commercial reasonableness*. The OIG has defined a *commercially reasonable* transaction as one in which "*…the aggregate services contracted do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the service.*"[10]

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

(1) The 1993 Exempt Organizations IRS text titled "*Reasonable Compensation*," which states that "*reasonable compensation is…the amount that would ordinarily be paid for like services by like organizations in like circumstances*;"[11]
(2) Chapter 2 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*;"[12] and,
(3) Federal Regulations on "*Excess Benefit Transactions*," which state, "*reasonable compensation [is]…the amount that would ordinarily be paid for like services by like enterprises (whether taxable or tax-exempt) under like circumstances.*"[13]

It should be noted that no IRS pronouncement defining *reasonable compensation* specifically addresses the healthcare industry. However, these factors provide

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indications as to the manner of assessing *commercial reasonableness* thresholds in an anticipated healthcare transaction.

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).*"[14]

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

(1) Whether each element of a prospective transaction does not exceed FMV; and,
(2) That the prospective transaction is a sensible, prudent business arrangement even in the absence of referrals.[15]

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, a finding that an enterprise, asset, or service meets the FMV threshold is not, in and of itself, *sufficient* to establish *commercial reasonableness*.[16]

After ensuring that each transactional prerequisite of the prospective transaction is met, further analysis of both the *qualitative* and *quantitative* aspects of the proposed 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 how the anticipated transaction assists in meeting that purpose. The specific *qualitative* thresholds are as follows:

(1) Is the integration transaction necessary to accomplish the business purpose of the client;
(2) Does the nature and scope of the underlying elements of the integration transaction meet the business needs of the client;
(3) Does the enterprise and organizational elements of the integration transaction make business sense to the client;
(4) Does the quality, comparability, and availability of the underlying elements of the integration transaction make business sense for the client;
(5) Are there sufficient ongoing assessments, management controls, and other compliance measures in place related to the underlying elements of the integration transaction; and,
(6) Is the transaction otherwise legally permissible?[17]

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.

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

(1) *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;[18]
(2) *Internal rate of return (IRR) analysis*, which calculates the discount rate necessary to result in a **zero** *net present value*, which rate can be compared to an investors required rate of return for a specific property interest to determine the viability of the investment;[19]
(3) *Average accounting return (AAR) analysis*, which determines the average of the *net income* arising from the assets or services to be acquired in the anticipated transaction *for each discrete accounting period*, divided by the book value of those subject property interest(s) acquired *for each of the corresponding accounting periods*;[20]
(4) *Payback period analysis*, which calculates the number of discrete periods necessary for *"the cumulative forecasted [undiscounted] cash flow [to] equal the initial investment*;"[21] and,
(5) *Discounted payback period analysis*, which is similar to a *payback period analysis*, calculates the number of discrete periods *"…until the sum of the **discounted** cash flow is equal to the initial investment*" [emphasis added].[22]

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Each of the *value metrics* that results from the *cost/benefit analyses* described above should be considered within the context of the *qualitative factors* of the *commercial reasonableness* analysis.[23] This is especially true when the *cost/benefit analysis* reflects a *financial (cash) loss*, as a transaction may still be *commercially reasonable* after the *non-monetary benefits* that may arise from the anticipated transaction are taken into consideration. For example, the benefits produced by a transaction that results in an expansion into new geographic areas and/or new service lines or an improvement in the access to technology and/or innovation may provide substantial evidence of a prudent business decision, i.e., *commercial reasonableness*.[24]

Government regulators (more specifically, the OIG and the *U.S. Department of Justice* [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.[25] 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*."[26]

This tension between the interpretation of the *commercial reasonableness* threshold by regulators and the application of MACRA[27] is partly because the goals of *value-based reimbursement* (VBR) and *fraud and abuse laws* are fundamentally at odds with one another. MACRA has furthered the healthcare industry's transition to VBR, 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.[28] In order 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.[29]

As mentioned above, 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*.[30] This may be due to a number of reasons, including: (1) encountering a more adverse payor mix in a hospital setting; (2) needing to pay more competitive salaries to employed providers; and, (3) the 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 ASTC revenue, and relying solely on professional services, i.e., *work relative value unit* [wRVU] related revenue, and paying physicians at *fair market value*, are almost certain to generate "*book financial losses*").[31]

This tension 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.[32] House and Senate committees solicited input from industry leaders related to Stark law challenges, such as its integration with MACRA.[33] 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*."[34]

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*."[35] [Emphasis added.]

Troy A. Barsky, Esq.[36] testified that Congress should amend the Stark Law by defining *commercial reasonableness*,[37] 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*."[38] [Emphasis added]

These comments indicate an understanding by many healthcare industry stakeholders of the inherent failure of the PLP's argument regarding c*ommercial reasonableness*, namely, that *financial (cash) losses* on vertically integrated physician practices do not contraindicate the threshold of *commercial*

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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:

(1) Emergency rooms, trauma services, pathology labs, and neonatal intensive-care units (NICU);
(2) Research labs and clinical studies;
(3) Principal research investigators, medical directors, and other types of physician executives;
(4) Education of residents; and,
(5) Artwork and other aesthetics with the aim of therapeutic benefits to patients.[39]

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.[40]

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.[41] Further, in order to encourage participation, CMS and the OIG have issued certain *fraud and abuse waivers* for advanced APMs, but each model has a different set of waiver rules, with which rules must be strictly complied to guarantee protection from fraud and abuse violations.[42] 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.

In summary, 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 ***avoidance of cost***, and the generation of ***social benefit***. Should the PLP continue to evolve into accepted "*legal doctrine*," and ultimately the "*law of the land*," the result may be to impede the development of innovative new structures of payment models to the extent that it would cause significant harm to the healthcare economy. This may lead regulators, legislators, legal professionals, and analysts to lose sight of the overall benefits of vertical integration; in essence, they are misled by a myopic fixation on the immediacy of red ink derived from a compartmentalized, stand-alone segment of the overall enterprise, such that they "*cannot see the forest for the trees.*" This potential impediment to sound decision-making on policy and case law is particularly troubling, given the acute need to improve the quality, accessibility, and efficiency of the U.S. healthcare delivery system, which MACRA attempts to do.[43] If there was ever a time for the legal and economic communities to collaborate to address these important issues impacting the U.S. economy, and more particularly the U.S. healthcare delivery system, it would be now.

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

Mr. Cimasi holds a Master in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA – American Society of Appraisers); Fellow Royal Institution of Chartered Surveyors (FRICS – Royal Institution of Chartered Surveyors); Master Certified Business Appraiser (MCBA – Institute of Business Appraisers); Certified Valuation Analyst (CVA – National Association of Certified Valuators and Analysts); and, Certified Merger & Acquisition Advisor (CM&AA – Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics, and is the author of several books, the latest of which include: "*The Adviser's Guide to Healthcare – 2nd Edition*" [2015 – AICPA]; "*Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*" [2014 – John Wiley & Sons]; "*Accountable Care Organizations: Value Metrics and Capital Formation*" [2013 - Taylor & Francis, a division of CRC Press]; and, "*The U.S. Healthcare Certificate of Need Sourcebook*" [2005 - Beard Books].

Mr. Cimasi is the author of numerous additional chapters in anthologies; books, and legal treatises; published articles in peer reviewed and industry trade journals; research papers and case studies; and, is often quoted by healthcare industry press. In 2006, Mr. Cimasi was honored with the prestigious "*Shannon Pratt Award in Business Valuation*" conferred by the Institute of Business Appraisers. Mr. Cimasi serves on the Editorial Board of the Business Appraisals Practice of the Institute of Business Appraisers, of which he is a member of the College of Fellows. In 2011, he was named a Fellow of the Royal Institution of Chartered Surveyors (RICS). In 2016, Mr. Cimasi was named a "*Pioneer of the Profession*" as part of the recognition of the *National Association of Certified Valuators and Analysts* (NACVA) "*Industry Titans*" awards, which distinguishes those whom have had the greatest impact on the valuation profession.

Todd A. Zigrang, MBA, MHA, ASA, FACHE, is the President of **HEALTH CAPITAL CONSULTANTS** (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 1,000 transactions and joint ventures. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the co-author of "*The Adviser's Guide to Healthcare – 2nd Edition*" [2015 – AICPA], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*. In addition to his contributions as an author, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); the National Association of Certified Valuators and Analysts (NACVA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter, and is current Chair of the ASA Healthcare Special Interest Group (HSIG).

John R. Chwarzinski, MSF, MAE, is Senior Vice President of **HEALTH CAPITAL CONSULTANTS** (HCC). Mr. Chwarzinski's areas of expertise include advanced statistical analysis, econometric modeling, as well as, economic and financial analysis. Mr. Chwarzinski is the co-author of peer-reviewed and industry articles published in *Business Valuation Review* and *NACVA QuickRead*, and he has spoken before the Virginia Medical Group Management Association (VMGMA) and the Midwest Accountable Care Organization Expo.

Mr. Chwarzinski holds a Master's Degree in Economics from the University of Missouri – St. Louis, as well as, a Master's Degree in Finance from the John M. Olin School of Business at Washington University in St. Louis. He is a member of the St. Louis Chapter of the American Society of Appraisers, as well as a candidate for the Accredited Senior Appraiser designation from the American Society of Appraisers.

Jessica L. Bailey-Wheaton, Esq., is Vice President and General Counsel of **HEALTH CAPITAL CONSULTANTS** (HCC), where she conducts project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions and provides research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services. Ms. Bailey-Wheaton is a member of the Missouri and Illinois Bars and holds a J.D., with a concentration in Health Law, from Saint Louis University School of Law, where she served as Fall Managing Editor for the *Journal of Health Law & Policy*.

Daniel J. Chen, MSF, is a Senior Financial Analyst at **HEALTH CAPITAL CONSULTANTS** (HCC), where he develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition he prepares, reviews and analyzes forecasted and pro forma financial statements to determine the most probable future net economic benefit related to healthcare enterprises, assets, and services and applies utilization demand and reimbursement trends to project professional medical revenue streams and ancillary services and technical component (ASTC) revenue streams. Mr. Chen has a M.S. in Finance from Washington University St. Louis.