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Definitions of Commercial Reasonableness and ACOs (Part One of a Three-Part Series)

In response to the advent of *Accountable Care Organizations* (ACOs) and value-based reimbursement models, which focus on achieving better health outcomes at lower cost, hospitals are increasingly seeking closer relationships with physicians, including direct employment, co-management arrangements, and joint ventures.[1] Corresponding with this growing trend toward hospital-physician alignment, there has been increased federal and state regulatory oversight regarding the legal permissibility of these arrangements. Most notably, there has been more intense regulatory scrutiny related to the *Anti-Kickback Statute* (AKS) and the *Stark Law*, especially as they relate to potential liability under the *False Claims Act* (FCA).[2] As a result of this increased scrutiny, in fiscal year 2014, the U.S. *Department of Justice* (DOJ) opened 924 new criminal healthcare fraud investigations and 782 new civil healthcare fraud investigations, recovering $3.3 billion.[3]

The *Medicare Shared Savings Program* (MSSP), established as part of the *Patient Protection and Affordable Care Act* (ACA), created the first ACOs, and additional regulations have driven the evolution of ACOs since.[4] ACOs consist of physicians, hospitals, and other healthcare providers who contract with a payor, and agree to be held to hold accountable for providing more efficient, quality services at a lower cost.[5] ACOs accepted to participate in the MSSP, which is managed by the *Centers for Medicare and Medicaid Services* (CMS), may obtain incentives from the Medicare program for providing efficient, quality healthcare services, at lower costs. When ACOs are successful in reducing the cost of care and meeting certain quality care benchmarks, they benefit by sharing in the savings achieved by the Medicare program.[6] CMS has established many ACO models, including: (1) the MSSP; (2) the *ACO Investment Model*; (3) the *Pioneer ACO Model*; and, (4) the *Next Generation ACO Model*.[7] To encourage participation in the MSSP, CMS issued a number of fraud and abuse waivers through an interim final rule, which allowed providers to avoid potential liability under the *Stark*, the AKS, and the *Civil Monetary Penalties* (CMP) law.[8] Most notably, the *ACO Participation Waiver* relieves MSSP participants from the AKS and *Stark* law requirements of proving *fair market value* (FMV) and *commercial reasonableness*.[9] However, providers utilizing this waiver must meet strict guidelines to qualify and maintain the waiver protection, or they may be subject to liability under the fraud and abuse laws. CMS has issued extensions to the 2011 interim rule that established the MSSP waivers, but without a final rule to guarantee the continued permissibility of these waivers, the future of these waivers is uncertain.[10] In addition to federal ACOs, there are also many commercial ACOs that share in other savings; however, no waivers exist to protect these from fraud and abuse liability.

Given the uncertain future of the Participation Waiver and the lack of a similar waiver for other federal and commercial ACOs, it is important for ACO participants to monitor their compensation arrangements to verify that they comply with the FMV and *commercial reasonableness* requirements of AKS and *Stark*. This three-part Health Capital Topics series will address the components of a defensible *commercial reasonableness analysis* and the importance of this analysis in relation to ACOs.

For ACOs, it is critical to obtain and maintain appropriate documentation that any given physician compensation arrangement (whether it be for clinical services, administrative services, on-call services, or a combination of services) meets both the standard of FMV and the separate but related threshold of *commercial reasonableness*, in order to withstand regulatory scrutiny. Typically, legal counsel does not provide opinions as to the *commercial reasonableness* of a compensation arrangement,[11] and legal counsel will most often retain and rely upon an independent valuation consultant to provide a certified valuation opinion that the arrangement does not exceed FMV. Due to the increase in healthcare transactions in recent years,[12] opinions related to the threshold of *commercial reasonableness* of healthcare transactions are becoming an "*increasingly important service offered by healthcare valuation professionals*."[13]

Rendering a *commercial reasonableness* opinion requires that a specific set of *core competencies* be mastered by the valuation analyst *apart from*, but *related to*, the more traditional *knowledge*, *skill set*, and *experience* required in rendering FMV opinions related to the appraisal of the *enterprises*, *assets* and/or *services* being transacted. The key components of a *commercial reasonableness* analysis include both a consideration of

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the *qualitative* factors that affect the *commercial reasonableness* opinion, as well as a *quantitative* analysis of the elements of the anticipated transaction of the subject enterprise, asset or service.[14]

While definitions of the *commercial reasonableness* threshold are similar among the various federal agencies tasked with 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."*[15] 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.*"[16]

The *Internal Revenue Service* (IRS) and *Office of the Inspector General* (OIG) have also provided guidance in defining *commercial reasonableness*. 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*;"[17]

(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*;"[18] 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*."[19]

It should be noted that the IRS has not yet issued final guidance defining *reasonable compensation* specifically addressing the healthcare industry or ACOs.[20] However, these factors provide indications as to the manner of assessing *commercial reasonableness* thresholds in an anticipated healthcare transaction.

Additionally, 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*."[21]

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).*"[22]

For transactions involving *aggregate* services, analysts must account for all elements of the integrated transaction in their *commercial reasonableness* opinions. Commonly referred to as a "*wrap around*" *commercial reasonableness* opinion, this type of analysis includes and considers *all elements* of the integration transaction in the *aggregate*, subsequent to the determination that each discrete, individual element of the transaction meets the thresholds of the standards of FMV and *commercial reasonableness*. With complex acquisitions involving multiple property interests, a "*wrap around*" *commercial reasonableness* analysis provides a foundation upon which to establish and defend that the healthcare transaction is legally permissible and will withstand government scrutiny.

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*.[23]

A further distinction between a *commercial reasonableness* analysis and the development of a FMV opinion is that the *commercial reasonableness* thresholds include consideration of the "*…value to the entity paying for…*"[24] the enterprise, assets or services being transacted, while the FMV opinion requires that a *universe of hypothetical buyers, sellers, owners* and *investors* be considered. For example, consider the acquisition of ten linear accelerators by a purchaser. If the purchaser has need of only one linear accelerator, the purchase of ten linear accelerators even at a FMV price would not meet the *necessity of the assets purchased* threshold of the *commercial reasonableness* analysis.[25]

Mastering the foundational principles for a *commercial reasonableness* analysis – including accurately understanding the definitions of *commercial*

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reasonableness, as well as the differences between an FMV opinion and a *commercial reasonableness* analysis – is essential before an analyst undertakes a *commercial reasonableness* analysis on behalf of an ACO client. In an era of increasing regulatory scrutiny and growing healthcare transaction volume, accurately grasping the nuances of *commercial reasonableness* definitions in relation to ACOs can improve the analyst's understanding of the scope and objectives of a certified *commercial reasonableness* opinion regarding an ACO transaction. Further, properly applying these definitions within the *qualitative* and *quantitative* analyses can increase the defensibility of the opinion, thereby supporting efforts of healthcare providers to establish a defensible position that their proposed transaction is in compliance.

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