Commercial Reasonableness:

Defining Practical Concepts and Determining Compliance in Healthcare Transactions for Physician Services

This white paper is an adaptation of a chapter from a book forthcoming summer 2017, *BVR/AHLA Guide to Valuing Physician Compensation and Healthcare Service Arrangements*. The information provided herein is of a general nature and cannot be substituted for the advice of an actual commercial reasonableness opinion in which specialized knowledge is applied to a particular circumstance. Therefore, nothing in this paper should be construed to offer or render an opinion of commercial reasonableness, and neither the authors nor PYA can take any responsibility for an attempt to use or adopt the information or disinformation presented in this paper.

Introduction

Financial relationships between hospitals and physicians must be *both* commercially reasonable and at fair market value (FMV) to meet certain regulatory requirements. Ensuring compliance with these requirements is critical—failing to do so could invoke sanctions and penalties related to the Stark Law, the Anti-Kickback Statute, the False Claims Act (FCA), and Internal Revenue Service 501(c)(3) status for tax-exempt entities. As such, a thorough understanding of these requirements is necessary to ensure compliance in transactions between hospitals and physicians, as well as other parties with referral relationships within the healthcare environment.

While valuators and healthcare entities have refined FMV assessments over the past several years, the concepts and methodologies for determining commercial reasonableness (CR) on its own terms have not yet been defined. However, increased government commentary underscores the need to understand and ensure that this requirement is met for all financial arrangements between parties in a referral position.

It is important to note that CR in the context of a healthcare industry transaction is distinctly different from CR in the context of a business transaction due to the highly regulated nature of the healthcare industry. Another critical difference, as discussed in greater detail later in this paper, is that the analysis and methodologies for determining CR are separate and distinct from the analysis and methodologies for determining FMV. A CR analysis is inherently based on the specific terms and conditions of the agreement and does not lend itself to "standard" approaches and methodologies as can be employed in an FMV compensation analysis.

In general terms, all business transactions (*i.e.*, including scenarios outside of the healthcare arena) must aid organizations in accomplishing their strategic, operational, and/or financial objectives. For instance, parties at arm's length to a non-healthcare real estate transaction would not enter into an arrangement in which they would not be awarded some benefit in pricing, operational improvements, accomplishment of strategic objectives, etc. The same logic should apply to financial arrangements between referral-related parties, such as hospitals and physicians. As such, compensation arrangements for physician services, for example, must effectuate a furtherance of business objectives on

the part of the healthcare entity entering into the arrangement. In this way, CR assesses the overall arrangement, including qualitative considerations such as strategy and operations, whereas FMV primarily assesses the financial aspects of the arrangement (*i.e.*, the range of dollars). However, unlike non-healthcare transactions, in evaluating the CR of transactions between hospitals and physicians, consideration cannot be given to the volume or value of referrals from physicians to hospitals.

When evaluating qualitative matters such as strategic and operational benefits, CR considers the aggregate terms of the overall arrangement and asks the question, "Does this deal make sense even if no consideration is given to the volume or value of referrals?" In other words, an evaluation regarding an arrangement's CR is broad in scope and considers the deal in the aggregate. Thus, FMV represents a component of determining CR because the range of dollars represents one part of an overall contract, the entirety of which must be assessed to determine whether a transaction is commercially reasonable. Given its broader scope, including assessment of financial factors and qualitative matters (*i.e.*, strategy, operations, etc.), one could say that CR observes an entire contract and represents a critically important and applied assessment to ensure that arrangements between parties in a referring position within the healthcare environment meet regulatory requirements and, thus, avert potential civil and criminal penalties.[1] As such, this paper will clearly identify key factors that should be assessed and considered thoroughly and practically to evaluate CR in healthcare transactions, rather than assuming such factors to be true, as may be the case in stand-alone FMV evaluations.

1 *Editor's note: This is critical. A common error in valuation practice is to treat the valuation of business assets and post-transaction compensation separately and to fail to identify income from the asset purchase that does not violate Stark, AKS, or some other statute or regulation.*

Regulatory Guidance and Definitions of Commercial Reasonableness

Several key definitions related to the standard of CR in healthcare agreements have been delineated in legislation and by regulatory authorities. In particular, the following definitions summarize the essential meaning of *commercial reasonableness*.

The Centers for Medicare & Medicaid Services (CMS) initially defined *commercially reasonable* as:

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."[2]

This definition is similar to subsequent commentary on the Stark Law, which states that:

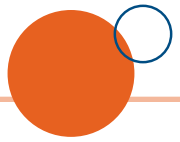
An arrangement will be considered commercially reasonable in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential designated health services (DHS) referrals.[3]

Additionally, the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) also provided guidance on the meaning of CR:

In order to meet the threshold of commercial reasonableness, compensation arrangements with physicians should be "reasonable and necessary."[4]

With these definitions in mind, the fundamentals for ensuring that an arrangement is commercially reasonable appear to include: **(1)** a sensible and prudent business agreement; **(2)** commercial sense; **(3)** parties contracting from a perspective of no referrals; and **(4)** reasonable and necessary services.

Given these fundamentals, the standard of CR should be conceived as broad in scope and as requiring assessment of the overall arrangement, including its quantitative and qualitative components. As such, individuals evaluating the CR of proposed arrangements between parties with referral relationships should consider whether the transaction represents a prudent business decision. In other words, legitimate reasons should exist for entering into the arrangement, excluding the potential for referrals. Such reasons may vary depending upon each unique situation, but will likely consider aspects inclusive of economic matters (*e.g.*, financial gains/losses and return on investment over time), strategy (*e.g.*, community access to care, service line development, competition for certain services, and supply and demand of physicians), and operations (*e.g.*, recruitment and mentoring of physicians, services management, and achievement of quality indicators).



2 63 *F.R.* 1700 (Jan. 9, 1998).

3 69 *F.R.* 16093 (March 26, 2004).

4 "OIG Compliance Program for Individual and Small Group Physician Practices," Notice, 65 *F.R.* 59434 (Oct. 5, 2000); OIG Advisory Opinion No. 07-10, Sept. 20, 2007, pg. 6, 10; "OIG Supplemental Compliance Program Guidance for Hospitals," Notice, 70 *F.R.* 4858 (Jan. 31, 2005).

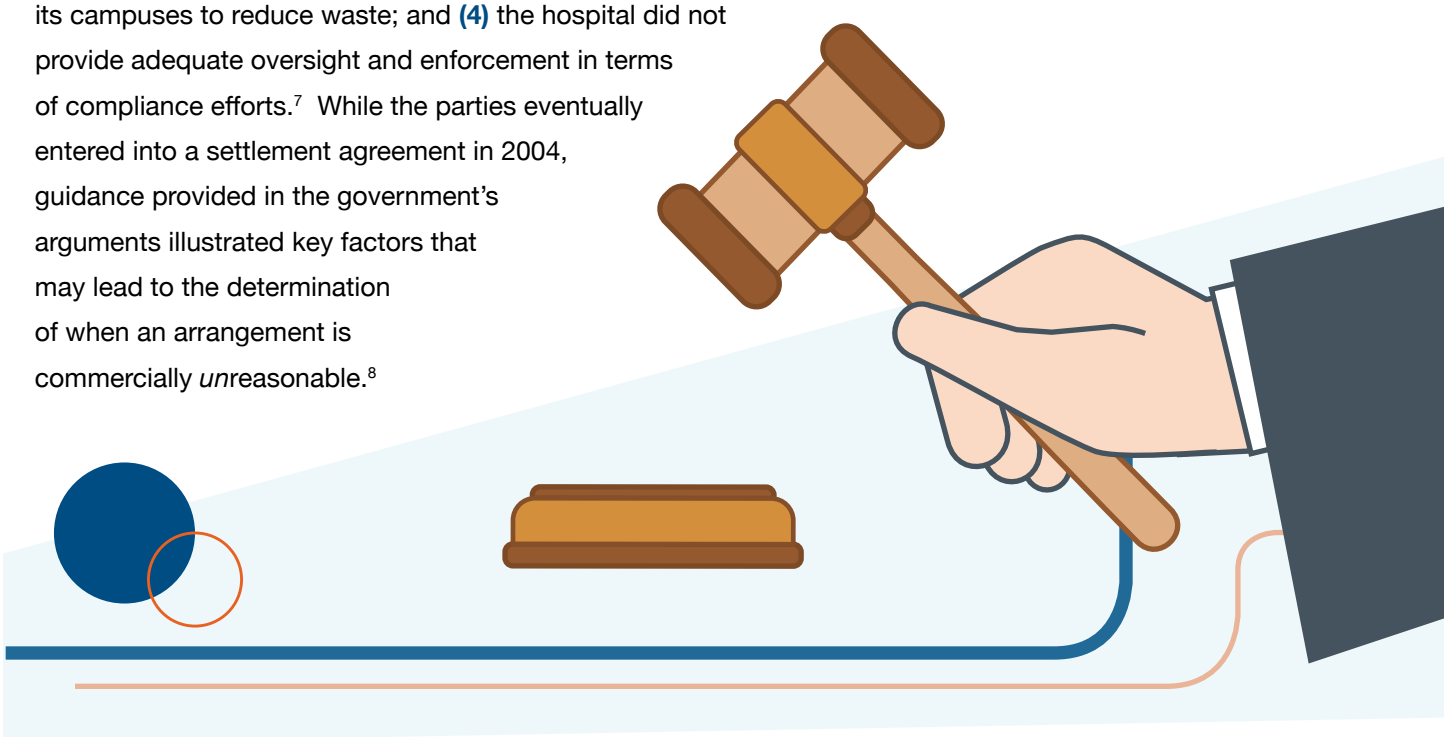
Guidance from Court Cases Involving Commercial Reasonableness

While assessing the relatively broad concept of CR requires specific fact-based assessments that are unique to each arrangement, the associated definitions, regulations, and evaluation criteria of certain key court rulings provide actual examples and further clarification of the concept. Accordingly, critical facts and analyses of four such cases pertaining to CR are outlined in the following sections.

United States ex. rel., Kaczmarczyk v. SCCI Hospital Ventures

The first case providing clarification involves a *qui tam* action in which the FMV and CR of compensation paid by a hospital in Texas to physician medical directors were at issue.[5] In this matter, the United States' expert suggested a more specific test to determine whether an arrangement meets the threshold of CR. This test was based on two criteria: **(1)** the agreement is essential to the functioning of the hospital; and **(2)** sound business reasons exist for payment to referring physicians.

To address these requirements, the government's experts relied on several factors that collectively spoke to the hospital facility, its current resources, and its oversight protocols for assessing such arrangements.[6] In this particular instance, the government argued that: **(1)** the hospital's low patient census did not warrant numerous medical directors; **(2)** physicians should not have been paid for certain duties that overlapped with medical staff bylaws; **(3)** the hospital needed to have coordinated protocols across its campuses to reduce waste; and **(4)** the hospital did not provide adequate oversight and enforcement in terms of compliance efforts.[7] While the parties eventually entered into a settlement agreement in 2004, guidance provided in the government's arguments illustrated key factors that may lead to the determination of when an arrangement is commercially *un*reasonable.[8]



5 Lewis Lefko, "Fair Market Value in Health Care Transactions," July 20, 2007, www.worldservicesgroup.com/publicationspf.asp?id=2086, citing *United States of America ex. rel., Darryl L. Kaczmarczyk, et al., v. SCCI Hospital Ventures, Inc. d/b/a SCCI Hospital Houston Central*, U.S. District Court, Southern District of Texas, Houston, Division No. H-99-1031, July 14, 2004.

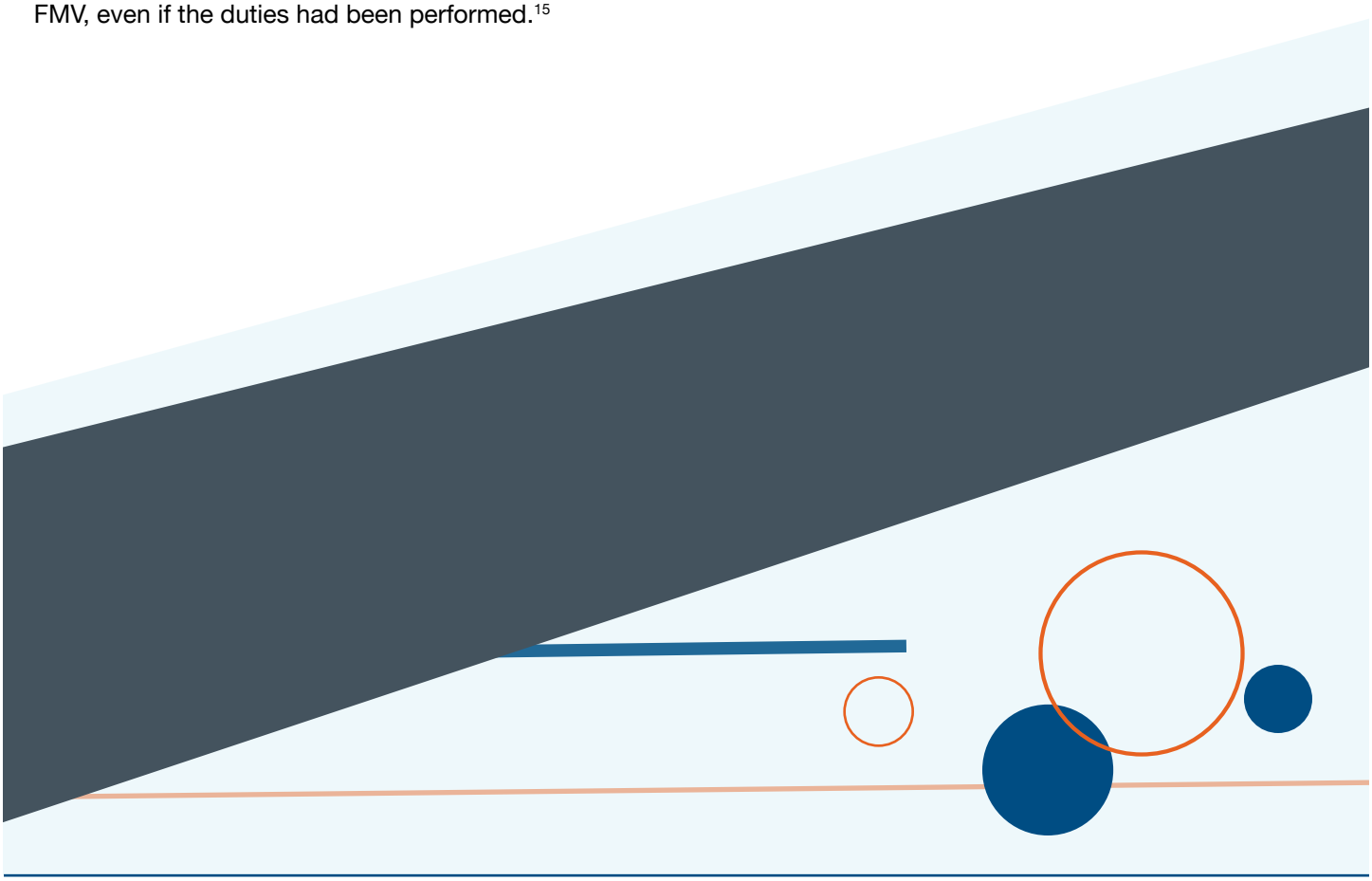
6 Ibid.

7 Ibid.

8 Ibid.

United States v. Campbell

A second case that provides further insight into applying the CR threshold was decided in 2011 and involved the compensation paid to a physician at a teaching hospital in New Jersey.[9] According to the 2011 published opinion, the hospital partnered with local cardiologists in private practice to increase the number of cardiothoracic patients that were referred to the hospital.[10] These cardiologists were offered part-time positions to provide principally academic services.[11] The defendant, one of the previously mentioned cardiologists, accepted such a position and was compensated at a flat annual amount to perform duties such as teaching, attending weekly conferences, and completing Medicare time studies.[12] However, according to the United States, the arrangement did not meet the CR threshold because the physician was not required to, nor did he, perform the majority of the duties outlined in the contract.[13] It also should be noted that the United States demonstrated that the physician had few qualifications to be a professor, including lack of teaching experience and published works.[14] Accordingly, the court reasoned that the physician's title and compensation were commercially *un*reasonable, regardless of whether the compensation was at FMV, even if the duties had been performed.[15]



9 David Pursell, "Commercial Reasonableness: The New Target," *Journal of Health Care Compliance*. March-April 2011, citing *U.S. v. Campbell*, 2011 WL 43013, No. 08-1951 (D. N.J., Jan. 4, 2011).

10 *U.S. v. Campbell,* 2011 WL 43012, No. 08-1951 (D. N.J., Jan. 4, 2011).

11 Ibid.

12 Ibid.

13 Ibid. The author notes that FMV contemplates compensation that is commensurate with the actual performance of such services. In other words, FMV determination assumes exchange of appropriate payment for actual services rendered.

14 Ibid.

15 Ibid., see also *U.S. v. Rogan*, 459 F. Supp. 2d at 716 (N.D. III. Sept. 29, 2006). See prior commentary (refer to Footnote 13) regarding substantial performance of services in connection with FMV determination.

United States and Elin Baklid-Kunz v. Halifax Hospital Medical Center and Halifax Staffing, Inc.

A case settled in 2014 examined characteristics of certain employment compensation and bonus agreements between six medical oncologists, as well as three neurosurgeons, at Halifax Hospital. A compliance officer at the hospital filed the *qui tam* action, alleging that the agreements were in excess of FMV and not commercially reasonable.[16] According to the government's expert witness report, several factors questioned the CR of the transactions. Specifically, the physicians' contracts contained unreasonably vague terms, with one clause stating that the physicians could receive "any other reasonable compensation from time to time."[17] The report also noted that the physicians were being paid well in excess of the 90th percentile benchmark compensation data for the specialty, despite collections well below the corresponding ranking.[18]

In addition, using individual physician Current Procedural Terminology codes and the *Harvard Time Study*, it was determined that one of the physicians had worked 8,739 hours that year (almost 24 hours per day, 7 days per week, 365 days per year). This was found to be partly due to physician-assistant-generated work relative value units (wRVUs), which were wrongly attributed to physicians and resulted in payment for work they did not personally perform.[19] The physicians also enjoyed benefits not available to other physicians including a risk-free signing bonus, compensation for each day he or she provided call coverage (without any gratis call required), and vehicle allowances.[20] These issues ultimately led to a settlement between the parties; however, the government's expert witness provided several compelling factors to the issue at point, as noted above.

United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.

In 2013, the final appeal involving Tuomey Healthcare System Inc. was decided in favor of the government. This case centered on compensation that Tuomey agreed to pay a group of specialist physicians pursuant to their exclusive part-time agreements.[21] In this case, the facts showed that the physicians' part-time schedules were largely open-ended, with no specific schedule, or for any particular duration.[22] In addition, and as the government's expert witness noted, the employment agreements included an "atypical" 10-year term, full-time benefits to part-time employees, total compensation equal to nearly 100% of their net collections, and bonus incentives not typical in part-time employment, among others.[23] Although not dispositive of any one conclusion to the CR of the agreements, the government's witness also pointed to the lack of community need for the physicians' employment, citing the physicians' own admission that none intended to leave the community.[24] To date, much debate has arisen and continues surrounding this case and the ramifications it holds for the existence of CR. However, as the settlement noted, both parties weighed the factors the government's expert witness brought forth, and ultimately the parties settled.

16 Second Amended Complaint: *United States ex. rel Baklid-Kunz v. Halifax Hospital Medical Center, et al*., No. 6-09-CV-1002 (M.D. Fla.).

17 Kathleen McNamara: Expert Report, *United States of America ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, et al.* (Dec. 21, 2012).

18 Ibid.

19 W.C. Hisao, P. Braun, E.R. Becker, and S.R. Thomas, "The Resource-Based Relative Value Scale Toward the Development of an Alternative Physician Payment System," *JAMA,* 1987.

20 Ibid. at 19.

21 *U.S. ex rel. Drakeford v. Tuomey Healthcare System*, 2013 WL 5503695 (D.S.C. 2013).

22 Ibid.

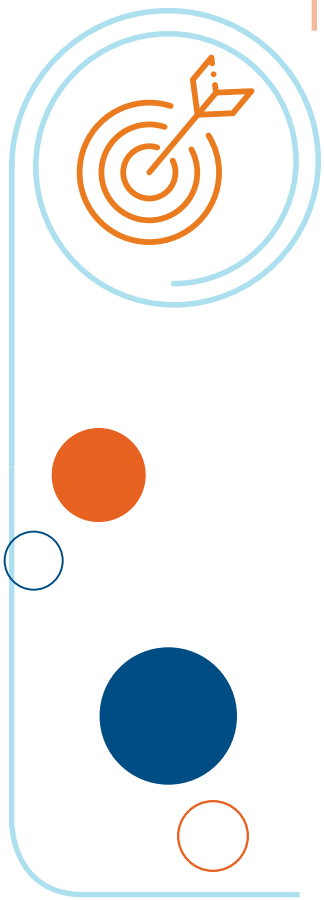
23 Kathleen A. McNamara, Myers and Stauffer Fair Market Value, Commercial Reasonableness Assessment, *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*

24 *Tuomey 2*, Trial Testimony.

Applying Guidance to Assess Commercial Reasonableness

Given the aforementioned regulatory definitions and guidance from court cases, healthcare organizations and providers should deploy several analyses to determine whether an arrangement meets the standard of CR. In particular, the analyses include inquiries relating to the specific terms of a proposed arrangement in relation to the transaction's: **(1)** business purpose; **(2)** provider of service; **(3)** appropriateness with regard to the healthcare provider's facility and patient population; **(4)** suitability, considering the human and capital resources of the healthcare entity; and **(5)** aptness related to current and proposed methods for independence and oversight. These assessments each address various aspects of potential transactions, including overall economic sense (*e.g.*, a hospital's return on investment) and relationship to the business goals of the organization proposing to enter into a physician arrangement.[25]

Business Purpose Analysis



According to the OIG, arrangements between physicians and hospitals should be reasonably necessary to effectuate appropriate patient care and a commercially reasonable business purpose without inducing prohibited referrals and compensation arrangements.[26] In a 2007 advisory opinion, the OIG found a physician compensation arrangement to be reasonable despite the fact that it did not meet a safe harbor requirement of the federal Anti-Kickback Statute. Crucial to this finding was the fact that the arrangement effectively facilitated the promotion of "an obvious public benefit" while instituting actual safeguards against prohibited referrals and improving physician performance and "overall patient satisfaction." Thus, applying a totality of the circumstances test, the OIG found the arrangement to be reasonable and stated that it would not subject the hospital to administrative sanctions.[27] While OIG opinions are merely advisory and apply only to the particular parties and specific facts involved, such determinations provide guidance as to the structure and reasonableness of other agreements, including a hypothetical proposed arrangement. Thus, if an arrangement facilitates quality patient care and is essential to the functioning of the healthcare provider, it may be presumed reasonable pending further evaluation.[28]

25 The key questions for consideration in this section offer different perspectives for various types of arrangements. As such, not all inquiries will be applicable to the specific transaction being assessed for commercial reasonableness. For example, administrative time cited in the resource analysis may apply more to a medical director agreement than to a production-based clinical agreement.

26 "Reasonable and necessary" items or services are those "for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." "OIG Compliance Program for Individual and Small Group Physician Practices," Notice, 65 *F.R.* 59434 (Oct. 5, 2000); OIG Advisory Opinion No. 07-10, Sept. 20, 2007, pg. 6, 10; "OIG Supplemental Compliance Program Guidance for Hospitals," Notice, 70 *F.R.* 4858 (Jan. 31, 2005) citing 42 U.S.C.1395y(a)(1)(A).

27 OIG Advisory Opinion No. 07-10, Sept. 20, 2007.

28 Lewis Lefko, "Essential to the Functioning of the Hospital" discussed in *Fair Market Value in Health Care Transactions,* July 20, 2007, www.worldservicesgroup.com/publicationspf.asp?id=2086, citing *United States of America ex. rel., Darryl L. Kaczmarczyk, et al., v. SCCI Hospital Ventures, Inc. d/b/a SCCI Hospital Houston Central*, U.S. District Court, Southern District of Texas, Houston, Division No. H-99-1031, July 14, 2004 (settled by the parties).

In addition, several key definitions and recognizable standards exist with regard to evaluating the commercially reasonable business purpose of a proposed transaction. First, as referenced above, according to an OIG Notice published in the *Federal Register,* medical services that are reasonable and necessary include those that are "for the diagnosis or treatment of an illness or injury."[29] Finally, for any business-related arrangement to be considered *reasonable*, it should make sense from a general business perspective, not only fulfilling an essential need, but also effectuating and furthering the strategic and legitimate financial goals (*i.e.*, excluding referrals) of an organization. Given this regulatory guidance, a CR analysis related to business purpose may include a description of and inquiries/requests such as the following**:**

1. Describe the environment in which the proposed arrangement will operate. Include:

a. An overview of the entity's mission, vision, values, and objectives.
b. A description of the size of the entity's primary and secondary service areas.
c. An overview of the applicable service line offerings.
d. A summary of the relevant organizational history leading up to the need for the arrangement.
e. An overview of the arrangement's importance to the service line affected; description of national/state-specific market trends; and how the arrangement may impact the cost, quality, and/or access of patient care.

2. Delineate how the proposed arrangement further effectuates a legitimate business purpose,[30] which is essential to the functioning of the entity. Include:

a. An overview of the business alternatives.
b. A description for how the arrangement helps the organization take advantage of its strengths/opportunities while mitigating weaknesses/threats.
c. An explanation of why the selected arrangement is the best alternative for the entity.

3. Outline how the services contemplated in the proposed arrangement relate to the business and/or clinical plans and strategies of the organization. For example, if the arrangement is for physician employment, describe the community need in terms of current physician supply versus demand.

4. Describe how the proposed services contribute to the organization's profits and/or the development of a particular service line without requiring income from proscribed referrals.

5. If collections are anticipated in association with the provision of services under the agreement, explain whether the cost of the agreement is expected to exceed the collection levels; and, if so, list the business reasons for the cost exceeding collections.

29 "OIG Compliance Program for Individual and Small Group Physician Practices," Notice, 65 *F.R.* 59434 (Oct. 5, 2000); OIG Advisory Opinion No. 07-10, Sept. 20, 2007, pg. 6, 10; "OIG Supplemental Compliance Program Guidance for Hospitals," Notice, 70 *F.R.* 4858 (Jan. 31, 2005) citing 42 U.S.C. 1395y(a)(1)(A).

30 As described in this paper, business purposes may include strategic, operational, or other qualitative considerations given the mission and regulatory compliance matters of the particular arrangement under analysis.

Provider Analysis

In terms of ordinary business principles, arrangements characterized as unnecessary, or those creating excessive waste or abuse are presumably neither reasonable nor economically sensible. As such, the government generally views arrangements involving excess waste, duplication, or abuse as commercially *un*reasonable.[31] Accordingly, hospitals and other providers must carefully consider whether *physician* services are necessary to carry out the purposes of a proposed arrangement or whether non-physician providers can satisfactorily perform the services. Furthermore, providers must contemplate whether a certain position requires the services of a physician trained in a particular specialty. For instance, if a primary care physician can successfully perform specified services, a hospital may be acting in a commercially *un*reasonable manner by paying a premium to retain the services of a specialty physician. These types of provider-specific analyses are essential to determine whether a proposed arrangement is reasonable because the medical provider will remain the central figure related to the provision of such services. Accordingly, a CR analysis related to the provider of a transaction may include inquiries such as the following**:**

1. **If the proposed arrangement requires a clinical skillset, can the services be performed by a midlevel provider in lieu of a physician? If a physician is needed, describe why a midlevel provider is not sufficient to perform the clinical services.**
2. **If the proposed arrangement requires a physician of a certain specialty to perform the services, identify the specialty, and describe how the specialist's training, experience, and qualifications make him or her the best candidate to perform these services.**
3. **Describe in detail:**
    a. The provider's duties under the proposed arrangement.
    b. The procedures and measures to be used to hold the provider accountable for performance of those duties.
    c. The method for determining the performance measures.
4. **Explain how much time is required of the physician under the proposed arrangement and how such time was determined.**
5. **Describe what resources have been utilized (*e.g.*, salary surveys) to date to compare the provider to other providers of similar specialty and experience and set the salary levels for the transaction.**
6. **Delineate the type and amount of costs budgeted for the provider's services under the proposed arrangement.**

31 Lew Lefko, "All Eyes on Physician-Hospital Arrangements," *HealthLeaders Media*, Jan, 24, 2008.

Facility Analysis

As noted in the discussion of key CR court cases, the size and patient population of a particular medical facility should be considered in assessing the reasonableness of a proposed arrangement to which that facility will be a party.[32] Specifically, according to the government's financial expert in one case, the arrangement should not only be essential to the functioning of the hospital, but there also must be sound business reasons for the arrangement at that particular facility. In other words, it is essential to evaluate a particular facility's size and patient population to determine whether sound business reasons exist for a specific services arrangement.[33] Therefore, in accordance with governmental guidance as outlined previously, medical facilities should consider their characteristics, including size and patient population, and, in turn, carefully evaluate the relevance of such factors in determining whether sound operational and/or strategic reasons exist for a proposed arrangement. Taking into account this litigation and regulatory guidance, a CR analysis of a facility may include inquiries such as the following:

1. **Explain how patient acuity levels, the size of the hospital, and/or the hospital's investment in the service line are sufficient to justify the services.**
2. **Determine whether any facility limitations would make the performance of the proposed services inappropriate or noncompliant with government regulations.**
3. **If the provision of these services requires use of facility space, explain why this service is a better use of facility space than the way the space would otherwise be utilized.**

Resource Analysis

In the assessment of CR, a potential arrangement should serve a necessary purpose in an efficient and effective manner. Specifically, a proposed transaction should not be duplicative of other positions and/or resources available to a particular organization.[34] Principally, one should be wary of situations in which an unnecessary duplication of efforts exists among professional and administrative positions entailing the involvement of a physician or physician groups. For instance, if a hospital enters into three medical directorship agreements when one such agreement would accomplish its objectives, the three agreements likely represent an unnecessary duplication of services. To best adhere

32 Lewis Lefko, "Fair Market Value in Health Care Transactions," July 20, 2007, www.worldservicesgroup.com/publicationspf.asp?id=2086, citing *United States of America ex. rel., Darryl L. Kaczmarczyk, et al., v. SCCI Hospital Ventures, Inc. d/b/a SCCI Hospital Houston Central*, U.S. District Court, Southern District of Texas, Houston, Division H-99-1031, July 14, 2004, and Mayer Hoffman McCann and Kathy McNamara, "Fair Market Valuation of Medical Director or Program Director Services," filed with Plaintiff United States Designation of Expert Witness, July 12, 2005.

33 Ibid.

34 Ibid.

to this regulatory guidance, a CR analysis of the resources associated with a transaction may include the following inquiries:

1. **Explain how the proposed arrangement is a necessary addition to the managerial and administrative efforts already required by medical staff bylaws or other contractual obligation(s).**
2. **If the agreement includes compensation related to the provision of call coverage services, explain how the agreement takes into consideration any call obligations required by medical staff bylaws. Describe any departure from obligations imposed by medical staff bylaws.**
3. **If the agreement includes compensation for meeting attendance, describe any consideration for the number of committees and/or meetings requiring physician attendance outside of the proposed arrangement.**
4. **If the entity is part of a larger health system, explain why the proposed arrangement is necessary, *i.e.*, why existing patient care protocols and procedures (if any) are insufficient and/or cannot be coordinated among the system's facilities in lieu of the proposed arrangement.**

Independence and Oversight Analysis

In *U.S. v. SCCI Hospital Ventures,* the government's financial expert asserted several oversight-specific factors that are critical to a determination of CR for physician services arrangements. These factors included whether: **(1)** the hospital performs regular evaluations of the *actual* duties the physician performed; **(2)** the hospital assesses the effectiveness of the physician's performance; and **(3)** there is a sustained, bona fide need for the physician services.[35] As related to these factors, the need should be underscored for substantial performance of services to ensure that set-in-advance payments continue to result in FMV.[36] In particular, many FMV assessments "assume" certain underlying factors (*i.e.*, often expressly as a limiting condition). Examples of these assumptions may include that the arrangement reflects an appropriate and prudent management decision and the arrangement is for a reasonable and legitimate purpose, etc. As such, from a practical standpoint, an FMV evaluation may assume certain peripheral factors relevant to the overall arrangement, whereas evaluating an arrangement's CR entails actual assessment of such factors. Likewise, the OIG has suggested that internal compliance programs may effectively assure that physician services and related compensation are indeed reasonable and necessary.[37]

In fact, to successfully uphold a standard of CR, if a hospital discovers waste or abuse associated with a particular physician arrangement, it should either reduce the amount of time spent conducting such activities or eliminate the position altogether.[38] Additionally, according to rulings in certain cases, if circumstances exist such that a physician does not *actually*

35 Lewis Lefko, "Fair Market Value in Health Care Transactions," July 20, 2007, www.worldservicesgroup.com/publicationspf.asp?id=2086, citing *United States of America ex. rel., Darryl L. Kaczmarczyk, et al., v. SCCI Hospital Ventures, Inc. d/b/a SCCI Hospital Houston Central*, U.S. District Court, Southern District of Texas, Houston, Division No. H-99-1031, July 14, 2004.

36 Also refer to discussion and footnotes in this paper describing *U.S. v. Campbell.*

37 65 *F.R.* 194 (Oct. 5, 2000); see also 70 *F.R.* 19 (Jan. 31, 2005).

38 Lew Lefko, "All Eyes on Physician-Hospital Arrangements," *HealthLeaders Media*, Jan. 24, 2008.

perform services required of him or her pursuant to a particular transaction, the arrangement does not meet the standard of CR (and also will likely result in payments in excess of FMV given the inherent relationship between services and payments as previously described).[39] Furthermore, the completion of time reports *alone* is insufficient to meet this obligation.[40] Finally, in keeping with numerous healthcare regulatory requirements as well as customary business standards, parties to a proposed transaction should, at minimum, reduce the material terms of the agreement to writing. Given this regulatory guidance, a CR analysis related to the independence and oversight of a transaction may include inquiries such as the following**:**

1. **Outline the compliance procedures, features, controls, and/or safeguards in place to limit the potential duplication or misuse of the proposed arrangement.**
2. **Explain how the entity uses its performance assessments to determine whether new or existing provider arrangements should be reduced (*e.g.*, hours condensed) or eliminated.**
3. **Describe the formal process for the entity's executive management and legal counsel to review and approve the proposed arrangement and confirm that legal counsel has, or will, review the contract to ensure compliance with applicable law.**
4. **Describe how the entity monitors the services specified in similar arrangements to determine:**
   a. Whether the services are actually performed (including the specific documentation required to be provided) during the term of the agreements.
   b. The total amount of funds spent for such services.
   c. A verifiable outcome resulting from the arrangement.
5. **Explain how the entity will regularly assess the effectiveness of the proposed arrangement and demonstrate a legitimate need for continuation and/or renewal.**
6. **Describe the board or committee responsible for establishing the proposed arrangement, and list any factors supporting its independence.**
7. **Identify the following agreement terms and assess the reasonableness of agreement provisions.**
   a. Describe how the agreement can be terminated without cause, including:
      - When, during the term, this is possible.
      - What the notice requirement is.
      - Whether the notice requirement is the same for both parties.
   b. Describe the agreement's for-cause termination provisions, including:
      - When termination is possible.
      - What the notice requirement is.
      - What the cure provisions are.
      - Whether the notice and the cure are the same for both parties.
   c. State the length of the agreement and how the appropriate length was determined, including how the length is appropriate for the needs the agreement will address.
8. **Explain whether all terms of the agreement are consistent with other similar arrangements. If there are inconsistent terms, provide the rationale for deviation from other similar agreements.**
9. **Describe any questions or concerns management may have regarding the CR of the agreement and/or circumstances of which management may be aware that might affect the CR of the arrangement.**

39 See *United States of America ex. rel. Roberts, v. Aging Care Home Health, Inc., et al.,* 474 F.Supp.2d 810, 818 (W.D. La. Feb. 16, 2007); see also *United States v. Rogan,* 459 F.Supp.2d 692 (N.D. Ill. Sept. 29, 2006). The author underscores the need for substantial performance of services to ensure that set-in-advance payments continue to result in FMV (also refer to footnotes in this paper describing *U.S. v. Campbell*).

40 Lew Lefko, "All Eyes on Physician-Hospital Arrangements," *HealthLeaders Media*, Jan. 24, 2008.

Contrasting Commercial Reasonableness and Fair Market Value

For many of the reasons cited herein, given its broad implications and larger scope pertaining to a transaction in its entirety, if an arrangement is not commercially reasonable, the issue of compensation may become irrelevant. In other words, if a financial arrangement is commercially *un*reasonable, a need to determine equitable payments may not exist.

However, given the intense focus on FMV associated with various physician arrangements, hospitals and health systems may be neglecting to assess whether such arrangements are commercially reasonable. Fundamentally, a CR analysis goes beyond the determination of FMV. In particular, while the standard of FMV assesses the appropriateness of the range of dollars exchanged between the parties, the standard of CR requires that the arrangement be sensible from an overall general business (*i.e.*, financial, operational, and strategic) perspective. As such, an arrangement could be at FMV, yet be commercially *un*reasonable.

For example, a physician may be party to an arrangement for which he or she is compensated at an amount commensurate with his position, specialty, geographic region, and other factors. However, if the hospital compensating such a physician already has access to the same or similar services and/or compensates other physicians capable of carrying out his or her contracted duties, it may not be commercially reasonable to actually make these payments. Other such risk factors may include insufficient demand, inappropriate hospital size, inadequate patient population, lack of relationship to hospital strategic and financial goals, and inadequate oversight. For additional illustrative purposes, specific examples of potentially commercially *unreasonable* arrangements may include the following:

- A hospital paying a cardiologist specialty compensation rates for administrative work requiring only a primary care physician.
- A health system maintaining medical director agreements at two of its facilities that contain duplicative protocols and policy responsibilities.
- A hospital failing to maintain proper oversight of the effectiveness and necessity of its physician services arrangement.

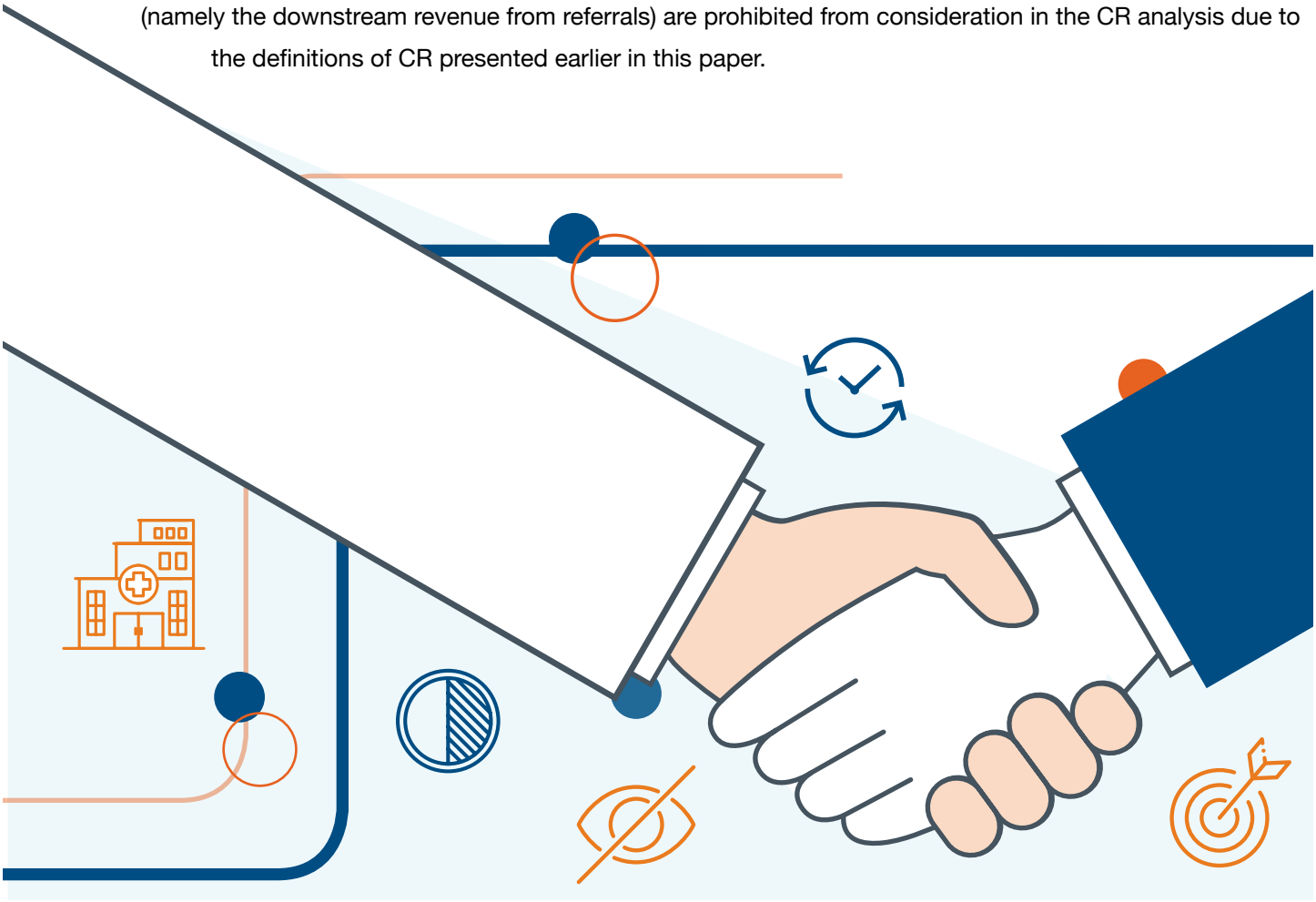
In each situation, appraisers can determine FMV rates *given the specific facts, circumstances, and assumptions their clients provide*. However, in determining FMV compensation, valuators are generally assessing the range of dollars and may not be appropriately questioning the overall reasonableness of the arrangement. Given the aforementioned risk factors and regulatory requirements, healthcare providers should carefully and practically determine (internally or through external assistance) whether their arrangements are actually commercially reasonable, not just whether a fair price is being paid for the services rendered.

Ultimately, it is important to note that any CR analysis involves multiple factors and demands assessing the legitimacy of any agreement in light of all circumstances, not simply the price paid for the services rendered. As such, some physician employment agreements may in fact be considered commercially reasonable while, at the same time, not

profitable for the hospital or practice. These agreements deserve scrutiny; however, where a particular community need calls for a particular type of physician, the agreement may be found commercially reasonable even where such agreements are not profitable.

Recent FCA cases and settlements, such as the aforementioned case against Tuomey Healthcare System Inc. and others, indicate an increased focus surrounding physician practices operating "in the red." These recent cases highlight the importance of evaluating the CR of physician arrangements, particularly when operating physician practices with economic losses. Specifically, healthcare providers should analyze whether any anticipated losses will be temporary or continuous and evaluate the legitimate business reasons for operating a practice at a loss. There may be legitimate reasons a hospital may lose money on a physician or physician practice, such as supporting a ramp-up period, providing uncompensated care, maintaining community access to qualified providers and specialists, and attempting to increase quality of care. Prior to entering any physician arrangement with anticipated losses, healthcare providers should carefully and thoroughly document their rationale for CR and FMV to support their analysis.

An additional element of challenge when a hospital contemplates acquiring and employing a physician at a financial loss is balancing the hospital executive team's fiduciary duty to make sound financial decisions with the mission needs of the organization to ensure comprehensive healthcare services are available in the community. Unfortunately, the very things that might make the acquisition/employment commercially reasonable from a financial standpoint (namely the downstream revenue from referrals) are prohibited from consideration in the CR analysis due to the definitions of CR presented earlier in this paper.



Conclusion

As a whole, the standard of CR remains broad in scope and speaks to an arrangement's general business characteristics, including matters pertaining to strategy, economic factors, and operations. However, when one wants to evaluate CR in the healthcare setting from a practical perspective, specific terms of the proposed arrangement should be examined and analyzed in relation to the transaction's: **(1)** business purpose; **(2)** provider of service; **(3)** appropriateness with regard to the provider's facility and patient population; **(4)** suitability, considering the human and capital resources of the provider; and **(5)** aptness related to current and proposed methods for independence and oversight. By following such a process, CR analyses (based on available regulatory guidance) become more concrete and help mitigate any potential ambiguity that may exist between FMV and CR.

A summary of key considerations for evaluating CR of physician-hospital arrangements may be found in PYA's "Practice Aid."

PYA's valuation experts provide FMV compensation opinions for a wide range of financial arrangements entered into by physicians, hospitals, and other healthcare entities. Most often, our reviews are used to help ensure that compensation arrangements comply with the Stark Law and the Anti-Kickback Statute, including their CR requirements, and any other regulations governing transactions in the healthcare industry. To discuss how we can be of service to your organization, please contact one of the following:

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