

FEATURE STORY

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commercially reasonable— whose responsibility is it?

Hospital finance executives can play an important role in assessing whether proposed transactions between their organizations and physicians meet regulatory standards for being commercially reasonable.

AT A GLANCE

- > According to federal regulations, any business arrangement between a hospital and a physician or physicians must comply with a set standard establishing that the arrangement is commercially reasonable.
- > The *commercially reasonable* standard can be briefly defined as the requirement that the arrangement make business sense without being contingent on physician referrals.
- > Before engaging outside expertise to assist in making the determination that an arrangement is commercially reasonable, hospital executives can address many key questions with respect to this determination themselves using a checklist of key operational, clinical, and financial considerations.

The healthcare industry has experienced significant growth in the number and types of physician integration strategies. Obvious reasons, such as declining payment, expensive IT, and anticipation of new payment methods based on quality and cost savings, are prompting both physicians and hospitals to consider new arrangements to work together. Some of these strategies have existed for years (e.g., medical directorships and direct employment), while others are relatively new (e.g., compensating physicians for quality). Regardless of the arrangement type, when hospital or health system executives contemplate entering into an agreement with a physician or physicians, they must be mindful of federal regulations mandating that these arrangements be commercially reasonable. Failure to do so could result in civil monetary penalties (see the sidebar on page 2).

Determining whether an arrangement between a hospital and a physician is commercially reasonable can be challenging. It requires an understanding of a healthcare facility's operational needs, clinical requirements, and financial alternatives. Expertise in healthcare valuation and healthcare law is also needed because compensation under an arrangement deemed to be commercially reasonable must be set at fair market value (FMV) and the agreement must be structured to be consistent with regulatory guidance.

In short, healthcare executives should understand the key considerations that attorneys and valuation firms explore as they assess whether an arrangement is commercially reasonable. Following are some of these considerations.

Regulatory Guidelines

Commercially reasonable is a critical standard that hospitals and physicians contemplating a shared transaction must meet to withstand regulatory scrutiny. This standard is relevant for both service agreements and transactions. Both the U.S. Department of Health and Human Resources (HHS) and Stark Law have provided guidance for understanding the commercially reasonable standard (see the sidebar on page 3), which can be briefly summarized as a requirement that *an arrangement make business sense without being contingent on physician referrals*.

In addition, to assist healthcare organizations in their assessment of commercial reasonableness, the IRS has suggested factors to be considered when analyzing whether a physician compensation arrangement is commercially reasonable.^a

Such an arrangement is likely to be found commercially reasonable if it is clear that the following points have been considered and adequately taken into account within the agreement:

- > The necessity of the type of duties performed and time spent on them
- > The experience of the physician
- > Market salary data for similar positions
- > Economic implications for the hospital

Case law is another great reference point for

healthcare executives responsible for making sure an arrangement is commercially reasonable.

U.S. v. SCCI Hospital Houston is a 2004 qui tam case in which the United States questioned the commercial reasonableness of an arrangement between SCCI Hospital Houston and three medical directors. Specifically, the United States argued the compensation paid to the three medical directors by SCCI was not commercially reasonable.

The government's expert witness provided valuable insight, including the observations that, to be commercially reasonable, an arrangement must:^b

- > Be essential to the hospital's operations and of sound business purpose
- > Consider factors related to patient needs
- > Identify and address the need for medical direction in coordination with hospital management

In short, the expert witness in this case concluded that there should have been an ongoing assessment of the necessity of medical director duties being provided. Based on this case, one can deduce what the courts would consider in assessing the commercially reasonable standard. From this case, it is clear that the burden of proof for what is commercially reasonable will rest primarily upon the shoulders of hospital personnel most familiar with the operations and clinical needs of the facility.

a. Zigrang, T.A., "Physician-Hospital Relationships in a Changing Regulatory Environment," Health Capital Consultants, June 16, 2010.

b. Lefko, L., *Fair Market Value in Health Care Transactions*, Haynes and Boone LLP, July 2007.

About the Commercially Reasonable Standard

Although there are no set penalties for an arrangement that is not commercially reasonable, this standard is often referenced in important regulatory guidance. Specifically, the Office of Inspector General (OIG) and the Centers for Medicare & Medicaid Services (CMS) address the need for an arrangement to be commercially reasonable through various comments. The OIG has specifically stated that it examines factors that compensation must be commercially reasonable and serve a legitimate business purpose, absent of referrals. (See, for example, "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; Final Rule," *Federal Register*, Nov. 19, 1999.) CMS notes a number of compensation exceptions under the Anti-Kickback and Stark regulations requiring that services and compensation do not exceed what is reasonably necessary. CMS also notes that this standard must be met without accounting for potential or existing referrals.

Commercially Reasonable Defined

Both the U.S. Department of Health and Human Resources (HHS) and Stark Law have provided guidance for understanding the commercially reasonable standard.

HHS has defined commercial reasonableness as “a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals” (“Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships,” *Federal Register*, Jan. 9, 1998).

Under the Stark Phase II final rule, commercially reasonable is defined as follows: “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 (or family member or group practice) of similar scope and specialty, even if there were no potential DHS referrals.” (“Medicare Program; Physicians’ Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II),” *Federal Register*, March 26, 2004).

It is therefore important that hospital and health system finance leaders understand how the standard of commercially reasonable should be addressed and why the first in determining whether an arrangement is commercially reasonable starts with hospital leadership.

Where to Start—Commercial Reasonableness or FMV?

The crucial first step for the parties to a contemplated hospital-physician transaction is to assess whether the arrangement makes good business sense prior to entering into it. This assessment, described below, may in a sense be viewed as an essential preliminary to ensuring the arrangement is commercially reasonable from a regulatory standpoint. Once the operational need has been confirmed, only then should the organization begin determining whether the proposed compensation associated with the arrangement represents FMV.

Although the ultimate determination that a transaction is commercially reasonable does depend, in part, on its meeting the requirement for FMV, the definition of *commercially reasonable* for purposes of this discussion is limited to the preliminary determination of whether the transaction meets the standards spelled out by HHS and in the Stark

law regarding commercial reasonableness.

Hospitals should begin with this assessment of the commercial reasonableness for one simple reason: As long as the facts and circumstances do not support the claim that there is a legitimate operational need for a set of services, it will matter little whether compensation is set at FMV.

Commercial Reasonableness Assessment: Practical Examples

Many physician-hospital arrangements are initiated by business development personnel. These individuals all too often do not understand what is acceptable to consider when evaluating whether an arrangement makes good business sense, absent referrals. To ensure an arrangement can be supported by defensible reasoning, healthcare executives should make sure all parties negotiating with physicians understand and anticipate questions a court would examine in determining the arrangement’s commercial reasonableness.

Considerable operational, clinical, and financial knowledge is required to understand whether a potential arrangement is necessary and serves a legitimate business purpose. It therefore is important that hospital personnel most familiar with the needs of the facility be involved in the decision.

Ideally, the organization will have completed a thorough assessment before involving legal counsel or a valuation firm. When assessing a potential arrangement, for example, an arrangement could be quickly identified as commercially unreasonable under the following circumstances:

- > The number of administrative hours, or administrative positions, in a proposed arrangement exceeds what is required based on facility needs.
- > The compensation proposed in the agreement is consistent with physician salaries, but it is proposed for a physician to provide services that do not require the expertise of a physician.
- > The agreement proposes to offer the physicians payments for quality, but lacks any mechanism to track improvement or superior performance in quality outcomes.
- > Equipment is to be leased under the agreement to a physician at below market rental rates, or from a physician at above market rental rates.
- > The agreement proposes to compensate the physicians for management services when the hospital already has staff providing the same, or very similar, services.
- > On-call payments would be made under the agreement for a specialty that does not require emergent response times.
- > The agreement calls for the purchase of a service or equipment that is not necessary for the hospital's efficient operations or ability to serve the patient population.

Clearly, hospital leaders can address these types of questions without the need for discussions with legal counsel or a valuation firm.

The Role of Legal Counsel and Valuation Firms

Nonetheless, legal counsel and valuation firms are often instrumental in ensuring certain aspects of an arrangement are commercially reasonable. Valuation firms, in particular, can help in the next step—determining whether the compensation stated in the arrangement is consistent with FMV. Experienced healthcare valuation firms also may be able to provide insight as to what has been observed in the market at comparable facilities. Caution is required, however, in engaging a

valuation firm that claims it can provide a commercially reasonable opinion. Such opinions can all too often take the form of a brief paragraph describing that hospital management has represented the terms are commercially reasonable, which may be acceptable for compliance purposes as long as the hospital leaders understand that important factors must be verified by the hospital prior to getting this opinion.

Legal counsel also serves a critical role in commercially reasonable assessments. Responsibilities include making sure the arrangements are structured appropriately from a regulatory perspective and ensuring that the services in the agreement do not overlap with existing agreements. Legal counsel also can assist a hospital by making sure the agreement's stated compensation is consistent with any FMV opinions that have been issued related to the arrangement, and not stray outside the range provided by a valuation on file.

Commercially Reasonable: A Checklist

Before involving legal counsel and valuation consultants to help make the ultimate determination of whether an arrangement is commercially reasonable, hospital and health leaders can benefit from use of a checklist of key points to consider when addressing this standard. Perhaps more important, reference to such a checklist will demonstrate to regulatory authorities the extent to which the organization's leaders exercised due diligence in an effort to adhere to this standard. The checklist should include three main categories of questions to be addressed:

- > Operational considerations
- > Clinical requirements
- > Financial considerations

Regarding operational consideration, the hospital's leaders might ask:

- > Does the subject arrangement further the strategic and/or financial goals of the hospital?
- > Does the hospital already provide the proposed services?
- > Are the physician hours required and reasonable to attain, given the other duties and services provided by the physicians?

Examples of questions related to clinical requirements include the following:

- > Is a physician required to perform the services under the subject arrangement?
- > Is a physician of a particular specialty required to perform the services under the subject arrangement?
- > Will the subject arrangement further patient care, patient satisfaction, and overall public benefit?

Questions related to financial considerations might include the following:

- > Have the economics of the arrangement been compared to other viable options in the local market and been selected as the best choice?
- > Are physicians earning compensation associated with no services or no risk?
- > Is the proposed compensation consistent with FMV?

It is important to note that not every question listed here is necessarily relevant for every arrangement, and additional questions may be warranted for some types of other arrangements.

Because a significant part of this analysis relies on answers from hospital management, commercially reasonable is a concept primarily supported by facility requirements, as opposed to valuation theory or legal guidelines. Therefore, although several parties may have input related to whether or not an arrangement is ultimately commercially reasonable, the initiation of negotiations should be prompted by those most familiar with the hospital's needs.

Bottom Line for Compliance

It is critical that healthcare executives be able to explain the reasons for initiating an arrangement with a physician. It is also important for them to

be able to step back once the terms are outlined and make sure that the agreement in no way depends on referrals to make business sense. Although many factors should be considered when determining whether an arrangement is commercially reasonable, it will most likely be considered compliant if the agreement outlines specific services that are legitimately required for the facility at reasonable compensation levels.

If an arrangement were to be scrutinized, the questions a court would ask will be directed to those who are most familiar with the operational needs, clinical requirements, and other financial alternatives of the facility. Therefore, it bears emphasizing that healthcare leaders also should make sure that any party negotiating with physicians understands the commercially reasonable standard. And ideally, this party also should have documentation related to the decision-making process.

Once a hospital has determined a subject arrangement is commercially reasonable, it also is important that the hospital leaders monitor the arrangement to ensure it continues to make business sense. Compliance will depend on two critical activities: enforcing the protocols that have been established to ensure the physicians are providing the services according to the agreement, and conducting assessments to demonstrate that the hospital continues to have a legitimate need for those services. ●

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This article is not to be construed as legal advice.