New Definitions for Key Stark Law Terms

Many of the statutory and regulatory exceptions under the Stark Law with respect to compensation arrangements include one or more of the following requirements:

1. The compensation arrangement itself is **commercially reasonable**;
2. The amount of compensation is **fair market value**; and
3. The compensation paid under the arrangement is not determined in a manner that **takes into account the volume or value** of referrals (or, in some cases, other business generated between the parties).

The health care community has long sought clear guidance from CMS as to what these standards mean and whether, for instance, compliance with one requirement is dependent on compliance with one or both of the others. In the Final Rule, CMS comes as close as it has ever come to providing something approaching clarity and definition to these terms. CMS said that it considered three basic questions in developing the new and revised definitions under the Final Rule:

- Does the arrangement make sense as a means to accomplish the parties' goals?
- Did the calculation result in compensation that is fair market value for the asset, service, or rental property?
- How did the parties calculate the remuneration?

The new and revised definitions set forth in the Final Rule, combined with the official commentary from CMS, makes it clear that the three definitions represent separate and distinct requirements, each of which must be satisfied when included in an exception.

Commercially Reasonable

Under the Final Rule, CMS defines "Commercially Reasonable" to mean that "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty."[1] CMS stated that the determination of commercial reasonableness should be made from the perspective of the actual parties involved in the actual arrangement under consideration. It is not

[1] 42 C.F.R 411.351.

a determination to be made in the abstract and by simply measuring the proposed arrangement against external, objective standards. In its commentary to the Final Rules, CMS noted that "the determination of commercial reasonableness is not one of valuation." Rather, CMS notes, the key question to ask when determining whether an arrangement is commercially reasonable is simply whether the arrangement "makes sense as a means to accomplish the parties' goals." The compensation terms are part of that inquiry, but CMS makes it clear that the determination of commercial reasonableness goes beyond valuation. And CMS's acknowledgement that an arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties provides an important defense against claims (some of which have been brought in recent years in various False Claims Act litigation) that hospital or health system acquisitions of physician practices are not commercially reasonable because the hospital was projecting a net loss after factoring in physician compensation and other practice-related expenses going forward. These claims have been hotly contested among the health law commentariat, with many pointing out that an arrangement can serve important community needs and help the parties fulfill elements of their mission or legal obligations, and can still make good commercial sense even if a party must do so at break-even or at a loss. With respect to that a "legitimate business purpose is," CMS channels Potter Stewart in all but outright saying that "you'll know it when you see it" -- except that an arrangement whose purpose is to "attract physician business" is not commercially reasonable in the absence of that physician's referrals (and, therefore, unlikely to satisfy a compensation exception).

Fair Market Value

Under the Final Rule, CMS continues to define "fair market value" largely the same as before—i.e., as "the value in an arms-length transaction, consistent with *general market value* of the subject transaction."[2] However, in the Final Rule CMS provides new detailed corollary definitions of "Fair market value" with respect to equipment lease arrangements and space lease arrangements in addition to the more general definition. Each corollary definition uses the term "the value in an arms-length transaction of rental property for general commercial purposes (not taking into account its intended use)"—language that aligns better with the statutory definition of "fair market value." Further, and following the same pattern, CMS provides an amended definition of "General market value" that includes a general definition as well as specific definitions as applied to equipment lease arrangements and space lease arrangements. The general definition provides that general market value means "the amount that would be paid at the time the

[2] 42 CFR 411.351

parties enter into the arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other." CMS also noted that while the term "fair market value" relates to the value of an asset or service "to hypothetical parties in a hypothetical transaction," the term "general market value" relates to the value of an asset or service "to the actual parties to a transaction that is set to occur within a specified timeframe." CMS stated that the general market value of a transaction is based solely on consideration of the economics of the subject transaction and should not include any consideration of other business the parties may have with one another. CMS goes on to note that this distinction may mean that a particular arrangement warrants compensation outside the range of a salary survey—possibly lower than the bottom of the range, or higher than the top of the range—depending on the actual facts on the ground.

In the Final Rule, CMS also reiterated that the fair market value requirement is separate and distinct from the "volume or value" standard. Thus, the definitions of "fair market value" and "general market value" in the Final Rule do not include any reference to the "volume or value" standard. In order to satisfy exceptions in which both of these concepts appear, an arrangement must be *both* (1) fair market value of the items or services provider *and* (2) not take into account the "volume or value." Finally, CMS resisted calls to specify particular methods for determining fair market value that would serve as safe harbors, advising that the appropriate method will vary depending on the details of the arrangement. However, CMS did specifically reject the widely-held belief that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, while compensation set above the 75th percentile is suspect. As mentioned above and as discussed in detail in the Final Rule, the determination of fair market value should go beyond mere reliance on salary surveys and should consider the specific facts and circumstances of the arrangement under review.

Takes into Account the Volume of Value

In one of the most significant developments of the Final Rule, CMS adopted a new approach to determining when an arrangement "takes into account the volume or value" of referrals or other business generated between the parties. Under the Final Rule, compensation from an entity furnishing DHS to a physician takes into account the volume or value of referrals "only if the formula used to calculate the physician's compensation includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's compensation that positively correlates with the number or value of the physician's referrals to the entity." Similarly, compensation *from a physician* to an entity furnishing DHS

takes into account the volume or value of referrals "only if the formula used to calculate the entity's compensation includes the physician's referrals to the entity as a variable resulting in an increase or decrease in the entity's compensation that negatively correlates with the number or value of the physician's referrals to the entity." These new "volume or value" standards are codified in the Final Rule as "special rules," but CMS says that it interprets them in the same manner as definitions definitions. If the methodology used to determine the physician's compensation or the payment from the physician does not fall squarely within the defined circumstances, the compensation is not considered to take into account the "volume or value."

In the official commentary to the Final Rule, CMS quotes itself as stating in the Phase I Stark rulemaking that "we believe that a compensation structure does not directly take into account the volume or value of referrals if there is no direct correlation between the total amount of the physician's compensation and the volume or value of the physician's referrals of designated health services." In particular, and counter to the "correlation theory" taken by CMS in the *Tuomey* False Claims Act litigation, CMS states clearly in the commentary to the Final Rule that a mere "association" between personally performed physician services and DHS furnished by the entity "does not convert compensation tied solely to the physician's personal productivity into compensation that takes into account the volume or value of the physician's referrals or other business generated by the physician. This is particularly important for arrangements involving physicians whose professional services (and professional fees) invariably come hand-in-hand with inpatient or outpatient hospital services (and the corresponding facility fees) or other DHS services. CMS also reiterated its previous guidance that "merely hoping for or even anticipating future referrals or other business is not enough to show that compensation is determined in a manner that takes into account the volume or value of referrals."

Set in Advance; Writing and Signature Requirements

Under the Stark Law's current "special rules on compensation," compensation is deemed to be "set in advance" if the compensation is "set out in writing before the furnishing of items or services." In the Final Rule, by contrast, the special rules state that to meet the "set in advance" requirement it is not necessary that the parties reduce the compensation to writing before the furnishing of items or services.[3] In the commentary to the Final Rule, CMS says that "compensation may be set in advance even if it is not set out in writing before the

[3] 42 CFR 411.354(d).

furnishing of items or services as long as the compensation is not modified at any time during the period the parties seek to show the compensation was set in advance." CMS explains that there can be many ways in which the amount of, or method for calculating, compensation may be documented before the furnishing of items or services. For instance, CMS notes that records of a consistent rate of payment over the course of an arrangement typically support the inference that the rate of compensation was set in advance. In addition, acceptable documentation could include informal communications via email or text, internal notes to file, generally applicable fee schedules, and other documents. Finally, CMS expanded the 90-day grace period for obtaining signatures so that it now covers the lack of a writing as well. Thus, where the parties meet the elements of a compensation exception *save for* the fact that there is no writing and/or there are no signatures, the arrangement will satisfy the relevant exception if the parties obtain the required writing(s) and/or signature(s) within 90 calendar days.