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Strengthening the relationship between DOJ attorneys and compliance professionals

an interview with
Michael D. Granston

> Healthcare providers have come to realize that not only are strong compliance programs good for business by enhancing employees' awareness of their legal obligations, but they also promote internal reporting by giving potential whistleblowers a mechanism to voice their concerns.

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by Charles Oppenheim, Esq. and Amy Joseph, Esq., CHRC

‘Commercial reasonableness’ under Stark: Fair market value’s evil twin?

» Commercial reasonableness is an important component of many Stark law exceptions.
» Commercial reasonableness and fair market value are distinct concepts.
» Recent enforcement activity signals increased scrutiny of commercial reasonableness.
» Analysis of commercial reasonableness is recommended prior to finalizing physician arrangements.
» Documentation of commercial reasonableness helps to create a defensible file.

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Most people in the healthcare industry understand the importance of remuneration being fair market value (FMV), whether in the context of a physician services agreement, practice acquisition, or other transaction with a potential referral source, to meet many exceptions of the federal physician self-referral law, otherwise referred to as the Stark Law.[1]

Two distinct concepts

However, what can get overlooked is the concept of “commercial reasonableness,” as a separate requirement that must be met for compliance with applicable fraud and abuse laws. There is some risk in conflating the two concepts—just because something is FMV does not mean it is commercially reasonable. For example, it might be FMV to pay a medical director of a service line $150 per hour for ten hours per month, but it might not be commercially reasonable to hire fifteen such medical directors for that service line, at the rate of pay. This article discusses the differences and provides some practical tips for analyzing and documenting the commercial reasonableness of arrangements.

Oppenheim

Joseph

Under the Stark Law, many of the most common exceptions relied on to protect compensation arrangements require that the compensation be FMV. The applicable regulation defines FMV as “the value in arm’s-length transactions, consistent with the general market value,” meaning the price is the result of bona fide bargaining between well-informed parties consistent with what would be paid by parties who are not otherwise in a position to generate business for the other party.[2]

Many of the most common Stark Law exceptions relied on for compensation arrangements also require that the compensation be commercially reasonable,[3] and various safe harbors to the federal Anti-Kickback Statute (AKS) contain a similar concept. The Centers for Medicare & Medicaid Services

(CMS) has defined the term *commercially reasonable* in various commentary to mean an arrangement that "appears to be a sensible, prudent business arrangement, from the perspective of the particular parties involved, even in the absence of any potential referrals."[4] CMS has also stated that an arrangement is commercially reasonable "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] referrals."[5]

In short, the concepts of FMV and commercial reasonableness are distinct, and just because an arrangement is FMV does not always mean it is commercially reasonable. In the early years of compliance with the Stark Law, there was less focus on the requirement that an arrangement be commercially reasonable in addition to being FMV. However, in more recent years, there has been a recognition that commercial reasonableness requires a separate analytical step in evaluation of arrangements. For example, an agreement for call coverage could include compensation that is FMV, but it might not be commercially reasonable if a hospital already has a sufficient number of physicians on a specialty panel to provide adequate coverage.

…just because an arrangement is FMV does not always mean it is commercially reasonable.

Case law

A recent series of cases brought by relators under the False Claims Act underscore the importance of determining whether an arrangement is commercially reasonable in addition to fair market value.[6] Although each case is unique (both as compared to the other cases and to the majority of physician arrangements, generally), a common theme is that employed physicians were being paid in excess of the collections received by a hospital or hospital affiliate for their professional services, in addition to which there was other evidence suggesting the hospital was willing to sustain these losses because of the offsetting value of the physicians' referrals. These types of cases have settled for significant amounts, ranging up to $115 million.[7]

As one example, in a case against North Broward Hospital District (Broward) that led to a settlement of $69.5 million dollars, the relator alleged that Broward's compensation to certain employed physicians was in excess of FMV and commercially unreasonable, because compensation exceeded the 90th percentile published in physician compensation surveys, while Broward sustained losses on the employment arrangement, and that Broward was factoring in the expected volume of referrals when determining compensation.[8]

As another example, in a case against Citizens Medical Center (Citizens) that led to a settlement of $21.75 million dollars, it was alleged that the hospital's compensation to employed cardiologists was in excess of FMV and commercially unreasonable, due in part to the fact that the practices were operating at a loss and the physicians received a higher level of compensation as Citizens employees as compared to their prior compensation.[9] Citizens raised the defense that the compensation paid was within FMV, because it was less than the national median level.

This defense was effectively countered in this instance by the arguments that it would not be commercially reasonable for Citizens to employ the physicians at an increased

compensation level as compared to their pre-employment compensation, given the losses sustained, unless the hospital was taking into account the physicians' referrals. In ruling on the motion to dismiss, the court stated that the "inference [of improper remuneration] is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive ...."[10]

However, there are a number of legitimate business reasons that a hospital may determine it is necessary to subsidize an individual physician's or a medical group's compensation, without taking into account any potential referrals. It may be essential for a hospital to employ certain specialists to meet community need, and in order to secure the services of such physicians, their compensation may need to exceed the physicians' professional collections. This could be for reasons such as an unfavorable payer mix, a rural location with low patient volume, or a severe shortage of physicians in the specialty in the local region. In fact, such subsidization has long been recognized for certain specialties, such as Emergency department physicians and anesthesiologists, and prohibiting such subsidization would be in conflict with public policy to provide community access to essential medical care.

Does this arrangement make clinical, operational and/or business sense, without factoring in potential referrals?

Factors that affect commercial reasonableness

Prior to entering into a physician arrangement, a key question to ask in order to evaluate commercial reasonableness is as follows: Does this arrangement make clinical, operational and/or business sense, without factoring in potential referrals? In other words, is the arrangement necessary to achieve a legitimate business purpose? To aid in such an inquiry, the following are examples of factors that could weigh for or against a finding of commercial reasonableness. These lists are not exhaustive. In addition, no one factor is conclusive, but if an unfavorable factor is present it may indicate a need for further inquiry.

Examples of potentially favorable factors:

- There is a demonstrated community need for the services;
- The arrangement furthers other provider-related goals unrelated to referrals (e.g., developing a new service line, expanding into a new geographic area, meeting regulatory requirements, improving quality or patient satisfaction, increasing efficiency, increasing diversity, streamlining scheduling);
- Existing resources are inadequate to meet patient needs;
- The arrangement reduces costs and expenses that would otherwise be incurred (e.g., per diem employment of a physician to reduce the use of locum tenens);
- Consistency in approach with physicians of various specialties, over time;
- No written record indicates that referrals have been taken into account, and there have been no oral communications to such effect; and

- A professional valuation expert has provided a written opinion that the arrangement is FMV and commercially reasonable.

Examples of potentially unfavorable factors:

- No prospect exists for breaking even on physician services alone, but the arrangement is very profitable when considering referrals;
- Compensation to the physician is significantly higher after the transaction than it was before the transaction;
- Insufficient patient demand to justify staffing level and/or underproductive physicians;
- Failure to use or consider less expensive alternatives;
- Unfavorable and unusual terms compared to typical arrangements of this type between similarly situated parties; and/or
- Written or oral communications evince a desire to incentivize referrals or consideration for their value as a justification for the compensation being paid. As an example, contribution margin reports, which track referrals to offset financial loss under the physician arrangement against revenue from referrals to a hospital, could be viewed unfavorably by a regulator.

Recommendations for documentation

Assuming it is determined that a proposed physician arrangement is commercially reasonable, documentation of the analysis should be included in the file along with fair market value support, exclusion screenings, the executed agreement itself, and any other documentation required under the organization's compliance policies. Ideally, every physician arrangement should be periodically revisited to determine whether it continues to be commercially reasonable over time. In particular, if an organization has opted to include auto-renewal provisions in its agreements to help guard against the parties operating outside of a formal written agreement, it is prudent for a mechanism to be used to periodically assess the relationship (presumably if a contract does not auto-renew, then this analysis could be engaged in prior to any renewal agreement).

Although an independent valuation firm can provide a commercial reasonableness opinion on request, and such documentation provides additional support, an organization should consider doing its own internal analysis as well, because the valuation firm likely will not have as deep an understanding of the context as the organization's operators.

In addition, an organization should determine whether a proposed arrangement is commercially reasonable as a threshold question, and would therefore analyze this internally before pursuing the arrangement further and engaging a valuation firm. Taking such steps should help to create a defensible record and establish that an arrangement is commercially reasonable, in addition to being FMV, if the arrangement is subject to subsequent scrutiny.

1. 42 U.S.C. § 1395nn (Limitation on certain physician referrals). Available at https://bit.ly/2KFI6D1
2. 42 C.F.R. § 411.351 (Definitions). Available at https://bit.ly/2uciKS3
3. See, e.g., 42 C.F.R. §§ 411.357(a), (b), (c) and (f) (Exceptions to the referral prohibition related to compensation arrangements). Available at https://bit.ly/2tZjivg
4. 63 Fed. Reg. 1700; January 9, 1998 (Medicare and Medicaid Programs: Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, aka "The Sunshine Act"). Available at https://bit.ly/2u74byY
5. 69 Fed. Reg. 16093; March 26, 2004 (Phase II: Interim Final Rule). Available at https://bit.ly/2Dmfyus
6. *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015)
7. See DOJ Justice News: "Adventist Health System Agrees to Pay $115 Million to Settle False Claims Act Allegations" September 21, 2015. Available at https://bit.ly/2uayNQg
8. *U.S. ex rel. Reilly v. North Broward Hosp. District, et al.*, Case No. 10-60590 (S.D. Fla.).
9. *U.S. ex rel. Parikh v. Citizens Medical Center*, 977 F. Supp.2d 654 (2013).
10. Idem at 670.