



What the FMV? Do you have a commercial reasonableness problem?

Hospitals and health systems have historically focused on fair market value (FMV) when there is a financial relationship with a physician. The reason for this is that the healthcare landscape is highly regulated and includes the Stark Law, the Antikickback Statute, the False Claims Act (FCA), and Internal Revenue Service 501(c) (3) status for tax-exempt entities whereas violations could result in exorbitant penalties, sanctions or even jail time. Meanwhile, these health systems are still reeling from the impact of COVID-19 and the recent changes to the Medicare Physician Fee Schedule (MPFS). In light of this, less focus has been placed on both defining and assessing commercial reasonableness. As a result, hospitals and health systems may have commercial reasonableness issues that will further be exacerbated unless a fundamental shift happens and as much focus is placed on commercial reasonableness as is currently done with ensuring compensation arrangements are consistent with FMV. Part of the challenge stems from the fact that the process of determining commercial reasonableness is not as well defined and requires a thorough understanding of the specific facts, circumstances, and rationale of the arrangement. While the healthcare valuation community has refined the FMV process and determination of value over the past decade, the concepts, and methodologies for determining commercial reasonableness on its own terms have not yet been succinctly defined or standardized. However, increased government scrutiny underscores the need to understand and ensure that this requirement is met for all financial arrangements between referring parties.

Defining Commercial Reasonableness

As previously mentioned, the definition for commercial reasonableness has historically not been explicitly defined; however, on December 2, 2020 the new Stark Law Final Rule1 provided a clearer picture with the following definition, "commercially reasonable" means "the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including size, type, scope and specialty."2 Prior to the new Stark Law Final Rule, commercial reasonableness was commonly interpreted by relying on guidance from the 1998 proposed rule which stated, an arrangement is commercially reasonable if it "appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals."3 In addition, the new Stark Law Final Rule clarified the issue of profitability. Specifically, that an arrangement may be considered commercially reasonable, even if it does not result in profit for one or more of the subject entities.

"The determination that an arrangement is commercially reasonable does not turn on whether the arrangement is profitable; compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable...4 We acknowledge that, even knowing in advance that an arrangement may result in losses to one or more parties, it may be reasonable, if not necessary, to nevertheless enter into the arrangement."5

However, one should note that commentary from prior court decisions have looked unfavorably regarding commercial reasonableness and unprofitable arrangements where physician compensation exceeded professional collections. It is yet to be determined how the courts will interpret this new guidance, but the Centers for Medicare & Medicaid Services (CMS) provided further guidance with the following statement:

"Although we believe that compensation arrangements that do not result in profit for one or more of the parties may nonetheless be commercially reasonable, we are not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to a determination of its commercial reasonableness, for instance, in a case where the parties enter into an arrangement aware of its certain unprofitability and there exists no identifiable need or justification- other than to capture the physician's referrals- for the arrangement."6

This commentary provided much needed guidance for health systems as they navigate through the complexities of physician compensation and profitably. As part of the commentary on profitability, CMS noted a non-exhaustive list of reasons why parties might appropriately enter into arrangements that result in losses, including:7

- 1. Timely access to health care services;
- 2. Community need;
- 3. Fulfillment of licensure or regulatory obligations;
- 4. The provision of charity care; and,
- 5. The improvement of quality and health outcomes.

Although, CMS has provided guidance on commercial reasonableness, it is important to note that this guidance is still limited. Therefore, it is imperative that hospitals and health systems mitigate their risk by having a systematic and standard approach to commercial reasonableness and seek the expertise and assessments from third-party valuation firms that are focused on healthcare. The process should begin with the following:

- 1. Inventory all physician compensation arrangements;
- 2. Determine internal thresholds of when an arrangement needs to be sent to a third-party valuation firm for a commercial reasonableness assessment;
- 3. Ensure the compliance plan is consistent;
- 4. Perform a risk assessment on the physician compensation arrangements; and,
- 5. Thoroughly document and support internally or send to an independent third-party valuation firm for a commercial reasonableness assessment.

When assessing the commercial reasonableness of an arrangement, a broad lens must be taken, and an analysis of both qualitative and quantitative factors must be considered. As such, when evaluating the commercial reasonableness of an arrangement, one must first start with if the arrangement represents a sensible and prudent business decision without the consideration of referrals. In other words, is there a legitimate reason as to why the parties would enter into this arrangement, excluding the potential for referrals.

Generally, VMG Health recommends documenting the commercial reasonableness of an arrangement with consideration to each of the following factors.

Fair Market Value Standards

If the compensation terms of the arrangement fail to meet FMV standards, as defined by CMS, the arrangement will also fail to meet commercial reasonableness standards. The FMV assessment should consider the specific services being provided, specialization and expertise of the provider, as well as whether the compensation paid by the parties would be the same as that resulting bona fide bargaining between well-informed parties that are not in a position to generate business for one another. A separate third-party valuation firm may be contracted to opine on the FMV of the compensation depending on the risk tolerance of the hospital or health system.

Economic & Financial Considerations

If the compensation terms of the arrangement have been determined to be within FMV, prudent practice suggests documenting both qualitative and quantitative factors driving the compensation terms. These specific factors may include some or all of the following: 1) business purpose of the arrangement, 2) the arrangement's impact on the strategic and financial goals of the contracting entity, 3) a financial analysis of the arrangement and the impact on the contracting entity, and 4) contributing national, regional, and local economic conditions. Generally speaking, economic conditions and the supply and demand for physician services will influence the financial impact to the health system. For example, a subspecialized physician with a unique skillset may fill a gap in care and allow patients to receive care within their community (business purpose and quality of care goals) but will likely demand premium compensation (low supply of subspecialists) and may not see as many

many patients as those physicians treating more general medical issues (low percentage of population with unique medical condition(s).

As noted previously, CMS has indicated that the commercial reasonableness of an arrangement does not hinge on whether one or more of the parties earn a profit. That said, should an arrangement result in a net loss to a hospital or health system, it is prudent to document the factors contributing to the loss (e.g., a physician spending 50% of their time in a non-revenue-generating directorship role) and how the loss compares to other similar arrangements with other similar providers.

Operational Considerations

Outside of the direct strategic and financial goals of the parties, the arrangement may also benefit the contracting entity in a non-financial manner; some of which may overlap with the economic considerations discussed above. These factors may include how the arrangement or subject provider supports other service lines within the organization, expected improvements in patient access or quality of care, and/or other service line development considerations.

Service Provider Considerations

Finally, a robust commercial reasonableness assessment should include documentation and commentary related to the specific provider's ability to meet the goals and provide the services outlined in the previous two sections. This type of documentation may include a summary of the provider's training and experience, operational reports for the provider demonstrating their capacity to hit projected production targets, quality scorecards, etc. Of particular importance in stacking arrangements is confirmation and attestation by management that the specific provider can perform all of the services outlined in the arrangement without compromising patient safety or quality of care. As a conservative measure, some organizations may choose to include production targets or performance measures to ensure all of the service components of the stacking arrangement are satisfied.

Conclusion

Although there has been a historical focus on assessing if an arrangement is consistent with FMV, recent enforcement and shifts in health system risk tolerance should result in a greater emphasis in both assessing and determining the commercial reasonableness of arrangement. While the vast majority of documentation and information required for a commercial reasonableness assessment will come from within an organization, an outside FMV analysis and commercial reasonableness assessment will provide independent support and assurance that the factors above have been considered and reduce an organizations' overall compliance risk.

Endnotes

- **1** 85 Fed. Reg. at 77492 (Dec. 2, 2020).
- **2** 85 Fed. Reg. at 77657, codified at 42 C.F.R. § 411.
- **3** 63 Fed. Reg. at 1700.
- **4** 85 Fed. Reg. at 77431
- **5** 85 Fed. Reg. at 77531
- **6** 85 Fed. Reg. at 77531
- **7** 85 Fed. Reg. at 77534

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