Physician Arrangements Must "Pass Go" Under the Stark Law's New Bright-Line Compensation Rules

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On January 19, 2021, health care organizations nationwide will need to start complying with new regulations aimed at modernizing and streamlining key regulations under the federal Stark Law. The Centers for Medicare & Medicaid Services ("CMS") announced the new regulations in a much-anticipated final rule ("Final Rule") on November 20, 2020. As we noted in our prior alerts (here, here and here) and webinars (here and here), the impact of the Final Rule will be significant. Health care organizations should immediately review their physician arrangements during this time, especially employment or other arrangements that include directed referrals, physician management arrangements, gainsharing arrangements, leases and any variable compensation arrangements. In addition, strategic and business planning documentation should be reviewed for implementation of physician arrangements.

The Final Rule provides a much-needed framework for developing certain value-based arrangements that incentivize care coordination, quality of care and cost containment. It also will drive physician contracting, compensation models and compliance strategies for years to come by including several new exceptions to the Stark Law and clarifying the interpretations of certain existing Stark Law exceptions, definitions and concepts.

Notably, the Final Rule establishes more bright-line rules for the "Big 3" requirements of fair market value ("FMV"), commercial reasonableness and the "volume or value" standard. These changes may ultimately reduce the compliance burden for health care organizations once existing arrangements have been brought into compliance with the new regulations. However, health care organizations will need to move very quickly to understand how the new regulations impact them so they can react and adapt their existing compensation arrangements as needed.

This article provides a detailed discussion of the "Big 3" and how the Final Rule will impact physician contracting, compensation models and compliance strategies.

New Guidance and Clarifications on the "Big 3"

The Final Rule provides extensive guidance and more bright-line, objective regulations focused on the "Big 3" Stark Law requirements of FMV, commercial reasonableness and the prohibition on "taking into account" the volume or value of a physician's referrals.

- **The "Big 3" Are Separate Requirements –** CMS acknowledged that recent False Claims Act case law has exacerbated compliance challenges and that clearer, more bright-line rules will enhance stakeholder compliance efforts and CMS's enforcement capability. This new guidance is important because health care entities typically need to establish one, two or all of the Big 3 to comply with Stark's regulatory exceptions. CMS clarified that the Big 3 are separate and distinct requirements and revised existing regulations to remove potential overlap.

- **Revised Fair Market Value Definition –** CMS restructured the definition of FMV and provided new guidance on documenting compliance.

Restructured Definition – CMS reorganized the definition of FMV into three different components (i.e., general application, equipment rentals and office/space rentals) and developed a separate definition for "general market value" made up of three components as well (i.e., assets, compensation and equipment or office space). CMS noted that this reorganization provides parties with ready access to the definition of FMV with the attendant modifiers that are applicable to their specific type of compensation arrangement at issue. As an immediate next step, health care organizations should ensure that their internal policies and procedures are reviewed and updated to reflect these new definitions.

In addition, if health care organizations have any existing relationships with physicians or immediate family members of physicians that may not fit squarely within the framework established by these definitions, those arrangements should be addressed as soon as possible. Health care organizations should also address this change with their external appraisers so the new definitions are utilized going forward.

Guidance and Examples – CMS restated some of the guidance on FMV in prior rulemaking. Notably, it included examples of extenuating circumstances that may dictate veering from values identified in health care salary surveys. In one example, CMS described a recruitment scenario involving a nationally recognized orthopedic surgeon who is highly sought after by professional athletes with knee injuries due to the surgeon's specialized techniques and success rate. In this example, CMS acknowledged that compensation exceeding typical ranges in the salary surveys may be defensible.

CMS also confirmed that health care organizations may find it necessary to pay amounts that exceed typical ranges in the salary surveys if there is a compelling need for a physician's services. CMS gave an example of a hospital with two interventional cardiologists but no cardiothoracic surgeon who could perform surgery in the event of an emergency during a catheterization. CMS further clarified that parties do not necessarily fail to satisfy the FMV requirement simply because the compensation exceeds a particular percentile in a salary schedule, nor are parties required to pay a physician what is shown in a salary survey if the specific circumstances do not warrant that level of compensation. CMS noted that each compensation arrangement is different and must be evaluated based on its unique factors. The examples show that a variety of factors impact whether the amount shown in a salary survey is an appropriate range for FMV. Health care organizations should consider how this new guidance will impact their physician recruitment, contracting and day-to-day compliance strategies.

Processes for Documenting FMV – Prior Stark guidance indicated that health care organizations should have appropriate processes for making and documenting reasonable, consistent and objective determinations of FMV. CMS confirmed again in the Final Rule that it will accept a range of methods for determining FMV and that the appropriate method will depend on the nature of the transaction, geographical considerations and other factors. Although CMS did not endorse a specific amount or type of documentation that will be sufficient to confirm FMV, it did allude to

prior rulemaking, which included extensive discussion on potentially acceptable valuation methods. For example, CMS stated again that parties do not need to obtain an independent appraisal to document FMV for every arrangement.

Moving Forward – Although CMS did not provide a safe harbor method for determining and documenting FMV, many health care organizations will appreciate the flexibility provided by CMS. Now may be a good time to reassess and enhance your organization's current FMV processes. In 2020, most health care organizations experienced significant disruption to their compensation plans due to COVID-19. That disruption likely will continue in 2021, and health care organizations could face even more disruption due to changes coming under the 2021 Medicare Physician Fee Schedule ("MPFS"). Although daunting, many health care leaders are viewing Stark reform as an opportunity to reengage their physicians to develop compliant and sustainable models that address pandemic-related coverage challenges, changes to the MPFS in 2021 and care coordination, quality and cost-containment.

- **New Commercial Reasonableness Definition** – The Final Rule introduces the first regulatory definition of commercial reasonableness under Stark.

New Definition and Losses – In a significant development, CMS took on what it described as a widespread misconception about the nexus between commercial reasonableness and profitability. CMS finalized the definition of commercially reasonable, including confirming that commercial reasonableness will not turn on whether an arrangement is profitable.

This definition is aligned with the longstanding view under the Anti-Kickback Statute that the concept of commercial reasonableness should be analogous to a "purpose-driven" arrangement serving a legitimate need. In proposing the new definition, CMS acknowledged that, even if parties know in advance that an arrangement may result in financial losses to one or more parties, it may be commercially reasonable, or even necessary, for the parties to nevertheless enter into the arrangement.

CMS provided examples of reasons that parties would enter into arrangements that will generate losses, including community need, timely access to health care services, the fulfillment of licensure or regulatory obligations (including EMTALA), the provision of charity care and the improvement of quality and health outcomes.

Duplicative Arrangements – CMS reiterated its concerns about duplicative arrangements. In the commercial reasonableness commentary, CMS gave an example of a duplicative medical director arrangement that failed to meet the standard even though it might appear to further a legitimate business purpose on its face. CMS explained that if a hospital needs only one medical director for its oncology department, but later enters into a second arrangement with another physician for oversight of the department, the second arrangement could potentially duplicate the existing medical directorship services and may not be commercially reasonable. CMS noted that the commercial reasonableness of multiple arrangements for the same services may be questionable depending on the facts and circumstances.

Moving Forward – As an immediate next step, health care organizations should examine their internal policies and procedures and confirm that these processes support and facilitate entry only into arrangements that further a legitimate business purpose and that are sensible, considering the characteristics of the parties (e.g., size, type, scope and specialty). The new commercial reasonableness definition may impact internal business and strategic planning documents, contracting checklists, contracting processes and current engagements with external appraisers. Along this line, it is imperative that arrangements be pursued for proper purposes.

- **Objective Volume or Value Test** – CMS finalized an objective test that defines exactly when compensation will be considered to take into account the volume or value of a physician's designated health services ("DHS") referrals or other business generated.

The New Objective Test – Under the new regulations, compensation will only be considered to take into account the volume or value of referrals or to take into account the volume or value of other business generated if the mathematical formula used to calculate the amount of the compensation includes DHS referrals or other business generated as a variable and if the amount of the compensation correlates with the number or value of the physician's referrals to, or the physician's generation of other business for, the entity.

Example Scenarios – CMS gave examples of compensation models that may fail the new objective test. In the first example scenario, CMS described a health care entity that was not a group practice as defined by the Stark Law. Under the scenario, the entity pays its physicians under a "pooling model" that calculates compensation based on a percentage of collections attributed to the physician. Some collections are from personally performed professional services, but others are from DHS furnished by the entity. CMS concluded that this model would be problematic under the objective volume or value test if the physician's pool includes amounts collected for DHS furnished by the entity that the physician orders but does not personally perform. CMS also gave a more straightforward example of an arrangement where a physician leases space from a hospital for $5,000 per month and then is provided a $5 rent reduction for each diagnostic test that the physician orders. CMS said that the mathematical formula $5,000 – ($5 x each referral) likely would fail the new volume or value test because it would include DHS referrals as a variable. Health care leaders should immediately prioritize analyzing all current compensation models and any new models under this new volume or value test. Health care organizations should also consider how this new objective test will impact their contracting processes.

Validation of Productivity-Based Models – CMS reaffirmed its historical position on productivity-based models and "shadow referrals," noting that compensation based solely on a physician's personally performed services does not take into account the volume or value of a physician's referrals. CMS confirmed that an association between personally performed physician services and DHS furnished by an entity does not mean that compensation to the physician based solely on the physician's personal productivity would be considered compensation that takes into account the volume or value of a physician's referrals to the entity.

- **New Directed Referral Guidance** – In an important development, CMS also finalized in the special rules on compensation changes to Stark's special rule on directed referrals.

> Following these changes, **neither** the existence of a physician's compensation arrangement **nor** the amount of a physician's compensation can be contingent solely on the **number** or **value** of a physician's referrals to a particular provider, practitioner or supplier. It is important to note, however, that directed referral provisions can be structured to require that a physician refer an established percentage or ratio of the physician's referrals to a particular provider, practitioner or supplier so long as the other requirements of the special rule on directed referrals are satisfied. Please note that the new Stark exception for value-based arrangements (42 C.F.R. 411.357(aa)), which permits remuneration that takes into account volume or value of referrals in certain instances, also addresses directed referrals. This exception will be discussed in upcoming Hall Render alerts.

To illustrate this change, CMS gave an example of a hospital-employed cardiologist that is paid a fixed salary with a directed referral requirement in his employment agreement with all of the appropriate carveouts for patient choice, insurance requirement or physician's medical judgment. CMS explained that the hospital could not make termination decisions or compensation increases contingent on the cardiologist achieving a targeted number of referrals. CMS also gave an example of how a directed referral requirement could provide for termination of a compensation arrangement if a physician failed to refer 90% of his or her patients within the organization. CMS described a directed referral scenario where a physician is paid different stipulated percentages of a bonus pool depending on the percentage of the physician's referrals that were "in-network." CMS said such a directed referral bonus structure would not be categorically prohibited.

The examples help to illustrate how CMS may interpret and implement the revised directed referral regulations. Health care organizations should consider how this new guidance impacts existing directed referral contract provisions and new arrangements that are under consideration.

Practical Takeaways

The Final Rule shows that CMS has delivered on its promise to work on modernizing and streamlining the Stark Law's "Big 3" requirements. It is important to note again that most of the changes in the Final Rule go into effect on January 19, 2021. Health care organizations will need to move quickly to react and adapt to the interpretations and positions taken by CMS. As a next step, please watch for our future content on fraud and abuse reform.