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Stark Contrast: CMS Proposes to Get Reasonable

Oct 28 2019

Practice Area: Health Law

On October 17, 2019, the Centers for Medicare & Medicaid Services (CMS) published its Proposed Rule[1] for modernizing and clarifying the Physician Self-Referral Regulations, commonly known as "Stark." CMS acknowledges that there have been "thousands of financial relationships ... that ran afoul of the physician self-referral law but posed no real risk of Medicare program or patient abuse."[2] The Proposed Rule seeks to address those provisions that add "unnecessary complexity without increasing safeguards for program integrity."[3]

This *Legal Update* focuses on that portion of the Proposed Rule that provides guidance on fundamental terminology regarding compensation arrangements under Stark, specifically the definition of "commercial reasonableness," the "volume or value" standard pertaining to physician referrals, and the definition of "fair market value" (FMV).[4] CMS acknowledges that this guidance is "critically necessary," an understatement in light of mounting attacks on compensation practices that until recently have been considered to be perfectly permissible.

Key Takeaways

- Commercial reasonableness of an arrangement does not turn on its profitability.
- Productivity bonuses will not take into account the volume or value of a physician's referrals solely because corresponding hospital services are billed each time the physician performs a service.
- Compensation can deviate from survey results and still be FMV.

Background

The past five years have witnessed a progression of prosecutions and settlements calling into question standard physician compensation methodologies. For example:

- It is axiomatic that physicians should be compensated at FMV. There are circumstances where this compensation might nevertheless exceed revenues derived from the physicians' services, such as where a hospital is providing a service line in a low-volume market, or in a market with an unfavorable payor mix such as an urban center with a high percentage of Medicaid patients. This is a common practice among nonprofit hospitals and systems that subsidize service lines in support of their charitable mission. *Qui tam* relators have nevertheless argued that these subsidies can be evidence that an arrangement is not FMV or "commercially reasonable" under Stark.
- Another common practice is to provide bonus compensation based on a physician's personally performed services, such as per-unit bonuses for wRVUs above a particular threshold. The RVU compensation model has gained favor due to its perceived low level of risk under Stark. Nevertheless, and particularly in the case of surgeons and other proceduralists, relators have asserted that a correlation exists between those personally performed services and corresponding referrals for facility fees and inpatient/outpatient services, and that this correlation is proof that compensation "varies with" the volume or value of referrals in violation of Stark.

One of the most well-known examples of this trend is the 2015 *Tuomey* decision.[5] Tuomey Healthcare entered into a series of part-time employment agreements with physicians who performed GI and other surgical procedures at Tuomey. The total compensation paid to the physicians (base + incentives) exceeded their collections, allegedly violating Stark's FMV requirements. Further, the jury found that compensation improperly varied with the volume or value of referrals given that "the more procedures the physicians performed at the hospital, the more facility fees Tuomey collected, and the more compensation the physicians received in the form of increased base salaries and productivity bonuses."[6] After a $237 million jury verdict and appeal, Tuomey settled with the government for $72.4 million. A flood of similar cases followed *Tuomey* including *Columbus Regional Healthcare System*[7], *Broward Health*[8], *Adventist Health*[9], and *Memorial Health*[10].

To be fair, each of these cases included allegations of other potentially egregious conduct, such as compensation exceeding the 90th percentile, opinion shopping among legal and valuation advisors, overt tracking of referrals, and upcoding. But the mere suggestion that claims can be based simply on a practice loss, or on a naked correlation between productivity-based compensation and revenues derived from facility fees and other hospital services, set off alarm bells throughout the industry.

The most recent example of this trend is the Third Circuit's opinion in *U.S. ex rel. Bookwalter v. UPMC*, just released in September 2019.[11] The whistleblowers asserted a correlation between neurosurgeons' compensation and the referrals that they made to UPMC hospitals since every time they performed a surgery or other procedure at a UPMC hospital they also made a referral for hospital and ancillary services. Like the Fourth Circuit in *Tuomey*, the Third Circuit acknowledged "these personally performed services almost always came with referrals for ancillary hospital services."[12] In denying UPMC's motion to dismiss, the court concluded that the mere existence of this correlation, whether or not there was a causal link, is sufficient to meet the whistleblower's obligation to allege that physician compensation "varied with" the volume or value of referrals to UPMC. The Third Circuit was also skeptical of the neurosurgeons' compensation from a FMV perspective. The court called it "suspicious" that at least three of the neurosurgeons were paid more than the Medical Center collected for their services.[13]

The *UPMC* decision also questioned the fact that the wRVU conversion factor for bonus compensation exceeded Medicare reimbursement rates for those wRVUs calling it, "yet another sign that the surgeons' pay took referrals into account."[14] The court's indictment of the neurosurgeon's compensation was devoid of any mention of possible justifications for compensation in excess of collections.

In both *Tuomey* and *UPMC*, concurring judges felt constrained to follow the majority but expressed their reservations when doing so. In *Tuomey*, Judge Wynn noted that "[t]he Stark Law is infamous among health care lawyers and their clients for being complicated, confusing and counterintuitive; for producing results that defy common sense, and sometimes elevating form over substance."[15] In *UPMC*, Judge Ambro of the Third Circuit shared similar fears:

CMS was not concerned with "the entirely standard compensation structure between UPMC and these surgeons. ... I worry that we are sending signals to hospitals throughout the Third Circuit, and the nation, that their routine business practices are somehow shady or suspicious and could leave them vulnerable to significant litigation, with all the trouble and expense that brings."[16]

Fortunately, CMS has now taken a fresh look at these fundamental concepts governing physician compensation arrangements under Stark.

Analysis
In its Proposed Rule, CMS aims to provide bright line rules for the determination of commercial reasonableness, the volume or value of referrals standard and FMV in the hopes of dispelling the confusion caused by cases like *Tuomey*.

Commercially Reasonable
CMS makes it clear that the commercial reasonableness of an arrangement does not turn on its profitability, thereby rejecting a key premise of *Tuomey* and its progeny: "We wish to clarify that compensation arrangements that do not result in profit for one or more of the parties may nevertheless be commercially reasonable."[17] CMS acknowledged that there may be circumstances where it might not only be reasonable, but indeed necessary, for parties to enter into an arrangement that may result in losses to one or more parties, citing examples involving community need, timely access to health care services, charity care, and improvement of quality outcomes. CMS re-focuses the analysis from whether the arrangement operates at a loss to whether the "arrangement makes sense as a means to accomplish the parties' goal."[18]

The Stark regulations currently do not define "commercially reasonable."[19] CMS now proposes two alternative definitions: (1) "that the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements,"[20] or (2) "the arrangement makes commercial sense and is entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty."[21] CMS seeks comment on which of the two definitions more clearly accomplishes its stated goal. While CMS aims for an objective standard, note that the second definition in particular still contains subjective components involving a "reasonable" entity and a "reasonable" physician.

Volume or Value of Referrals
The "volume or value" standard has vexed the healthcare community going back to when CMS proposed its first set of regulations in 1998; CMS notes that it has been identified as "one of the greatest risks [providers] face when structuring arrangements...."[22] CMS proposes a more objective approach when determining whether the volume or value of referrals has been taken into account. Under the new regulatory provisions, CMS would analyze the mathematical formula used to calculate compensation to see if the volume or value of referrals was taken into consideration. Under the proposal, compensation from an entity 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 correlates with the physician's referrals to the entity.[23]

CMS directly addresses *Tuomey* in the Proposed Rule. Affirming the position that it laid out in the Phase II regulations prior to *Tuomey*, CMS states that productivity bonuses *will not* take into account the volume or value of a physician's referrals solely because corresponding hospital services are billed each time the physician performs a service. This guidance applies both to employed physicians and to personal service arrangements.

The impact of this guidance on the *UPMC* decision remains to be seen, however. In that case, the Third Circuit was considering the volume or value standard in the context of the definition of indirect compensation arrangements, which refers to compensation that *varies with*, or takes into account, referrals. The court concluded that since there was an alleged correlation between physician compensation and hospital facility fees, compensation *varied with* those referrals. The Proposed Rule directly addresses only the "takes into account" portion of the volume or value test as found in various Stark exceptions but does not address the additional "varies with" language in the definition of indirect compensation arrangements. The Third Circuit found that the "takes into account" test was also satisfied, however, based in part on the allegation that physician compensation exceeded collections in some instances. That portion of the opinion is now suspect in light of the CMS guidance referenced earlier in this *Legal Update*.

The Proposed Rule also addresses fixed-rate compensation such as compensation based on wRVUs. CMS stated that a fixed-rate compensation structure would be considered to take into account the volume or value of referrals when the parties "utilize a predetermined tiered approach to compensation under which the volume or value of a physician's prior referrals is the basis for determining the unvarying rate of compensation from an entity to a physician."[24] For example, if a physician's wRVU conversion rate were adjusted based on the number of diagnostic tests ordered in the previous year, the compensation structure would be taking into account the volume of referrals. Similarly, if the rent a hospital charges a physician for medical office space varies based on the number of the physician's inpatient admissions in the preceding year, then this compensation structure would also be considered to take into account the volume of referrals.

Nevertheless, CMS confirmed that wRVU-based compensation remains a valid compensation structure under the volume or value standard, as are productivity bonuses for services the physician personally performs.

Fair Market Value

In its Proposed Rule, CMS emphasizes that the commercial reasonableness, volume or value, and FMV standards are separate and distinct tests. CMS acknowledges that the volume or value and commercial reasonableness standards have been used in the past to prove that an arrangement was not FMV. Under the Proposed Rule, FMV now stands alone.

The proposed new FMV definition does not differ in content from the current definition, but rather reorganizes the structure to improve clarity. CMS changes the definition of "general market value" that is embedded in the definition of FMV, however. The proposed definition of general market value will track the valuation industry's definition of market value.

CMS proposes to define general market value as "the price that assets or services would bring as the result of *bona fide* bargaining between the buyer and seller in the subject transaction on the date of acquisition of the assets or at the time the parties enter into the service arrangement; or, in the case of the rental of equipment or office space, the price that rental property would bring as the result of *bona fide* bargaining between the lessor and the lessee in the subject transaction at the time the parties enter into the rental arrangement."[25] CMS distinguishes general market value from FMV: FMV considers a hypothetical transaction between similar parties for similar assets in a similar market, while general market value relates specifically to the actual parties and the actual transaction in that particular moment in time. This distinction can be significant insofar as CMS recognizes that there may be circumstances where parties to an arm's length transaction might appropriately "veer" from salary surveys or other valuation data.

For example, salary surveys might indicate market compensation for an orthopedic surgeon of $450,000. However, the actual market where the hospital operates could require the hospital to offer more than $450,000 due to scarcity, reputation, or urgent community need. The higher compensation rate would be consistent with the general market value for that transaction at that moment in time and therefore not violate the new proposed rules. The same could be true if the actual market in which an entity operates would only support compensation that is lower than indicated by salary surveys, for example if the hospital's location in a setting with a poor payor mix does not permit compensation at a higher level.

Conclusion

Although the lumens of CMS's bright line rules are up for debate, CMS's concerns over recent interpretations of Stark shines through. The Proposed Rule sheds some light on the murky standards of commercial reasonableness, the volume or value of referrals, and FMV, and would make these standards clearer, distinct, and user friendly. Note that these are proposed rules subject to comment period ending December 31, 2019.

[1] 84 FR 55766 (October 17, 2019). The Proposed Rule reflects CMS's response to recommendations and input that it received following its Request for Information Regarding the Physician Self-Referral Law. 83 FR 29524 (June 25, 2018).

[2] 84 FR 55771.

[3] *Id*.

[4] This *Legal Update* is the first in a series of articles regarding the CMS Proposed Rule on Stark as well as proposed rules simultaneously released by the Office of Inspector General on the anti-kickback statute.

[5] *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (2015).

[6] *Id*.at 379.

[7] *United States ex rel. Barker v. Columbus Regional Healthcare System, et al*., Case No. 4:12-cv-108 (M.D. Ga.) and *United States ex rel. Barker v. Columbus Regional Healthcare System, et al*., Case No. 4:14-cv-304 (M.D. Ga.) (Whistleblower alleged that compensation in excess of service revenues only made sense if the system factored in the benefit of referrals; $35 million hospital settlement).

[8] *United States ex rel. Reilly v. North Broward Hospital District, et al*., Case No. 10-60590 (S.D. Fla.). (Alleged scheme of overcompensating physicians leading to significant losses that were offset by profits received from physician referrals. Physician compensation exceeded collections for services performed by physicians. $69.5 million settlement).

[9] *United States ex rel. Payne, et al. v. Adventist Health System/Sunbelt, Inc., et al*. No. 12-856 (W.D.N.C), and *United States ex rel. Dorsey v. Adventist Health System Sunbelt Healthcare Corp., et al*., No. 13-217 (W.D.N.C). (Similar allegations on excess compensation and substantial and consistent losses on physician practices. $115 million settlement).

[10] *United States ex rel., Phillip S. Schaengold v. Memorial Health, Inc. et al*., No. 4:2011cv00058 (S.D. Ga.). (DOJ maintained that paying physicians at a loss was not commercially reasonable. $9.9 million settlement).

[11] *U.S. ex rel. Bookwalter v. UPMC*, 938 F. 3d 397 (2019).

[12] *Id*. at 411.

[13] *Id*.

[14] Id. at 413.

[15] *Tuomey,* 792 F.3d at 418.

[16] *UPMC*, 938 F.3d at 418.

[17] 84 FR 55790.

[18] *Id*.

[19] The only time CMS has addressed this standard was in the 1998 proposed rule when it interpreted the phrase to mean that an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals. 63 FR 1700.

[20] 84 FR 55790.

[21] *Id*.

[22] 84 FR 55791.

[23] 84 FR 55793. CMS would apply a similar approach when compensation flows from the physician to the DHS entity.

[24] 84 FR 55794.

[25] 84 FR 55798.

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