PUBLICATION

Volume Value Take 2

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Introduction

The CMS proposed regulation issued on October 17, 2019[1] provides much needed clarity on the question of when compensation is deemed to vary with the volume or value of referrals or other business generated between the parties. A number of exceptions under the Stark Law contain a requirement that compensation paid under the arrangement may not be determined in a manner that takes into account the volume or value of referrals or other business generated. These include, for example, the employment exception, the personal services exception, and the lease exception, among others. CMS noted in the Preamble to the proposed rule that several commenters to its 2018 Request for Information (RFI) requested guidance on the question of when compensation would be deemed to so vary.

CMS agreed that there is great value in having a simple objective test to determine whether compensation is determined in a way that takes into account the volume or value of referrals or other business generated. Toward that end, CMS proposed regulatory language that defines precisely when compensation *will* be considered to violate the volume/ value standard, rather than setting forth examples of when it will not. CMS noted its belief that this approach creates a bright line rule that will be of benefit to all stakeholders.

The Proposed Volume/Value Regulation

Under the proposed definition, compensation would be considered to take into account the volume or value of referrals *only if*: (1) the formula used to calculate the compensation includes the physician's referrals as a variable; ***or*** (2) there is a predetermined, direct positive or negative correlation between the physician's prior referrals (or other business generated for the entity) and the prospective rate of compensation to be paid to or by the physician (or an immediate family member). Accordingly, under the proposed definition, compensation need not be determined based upon a mathematical formula to run afoul of the volume/value standard. Rather, there must be a predetermined, direct positive or negative correlation between the volume or value of the physician's prior referrals (or other business previously generated for the entity) and the rate of compensation paid to or by the physician (or an immediate family member of the physician).[2] Stated differently, the new language requires a direct relationship whereby if X (the volume or value of referrals) then Y (additional payment) will result. CMS cites an example whereby this could occur. In the example, CMS notes that if a physician practice pays a physician based on a percentage of collections that includes both personally performed services and services furnished by the practice, to the extent the collections includes designated health services furnished by the practice that the physician ordered but did not personally perform, the physician's compensation would take into account the volume or value of his or her referrals.

CMS goes on to define narrow circumstances in which it would consider fixed rate compensation such as a fixed annual salary or a fixed per-unit rate of compensation to be determined in a manner that runs afoul of the volume/ value standard. Under the proposed definition, this test would be met where the parties utilize a predetermined tiered approach to compensation under which the volume of value of prior referrals is the basis for determining the unvarying rate of compensation going forward. CMS notes that under this approach, the compensation need not be determined based upon a mathematical formula to violate the volume/value standard as long as there is a predetermined direct correlation between the amount paid and the prior volume or value of referrals or other business. In an example given by CMS, a physician would be paid by his/her

hospital employer $30 per wRVU if he/she had ordered 300 or more diagnostic tests per year during the prior term of employment *or* $35 per wRVU if he/she ordered more than 300 tests during the prior year. CMS notes that in this example, the use of prior referrals as a benchmark for setting the fixed per-unit compensation causes it to run afoul of the volume/ value standard.

Clarification of Currently Existing Physician Compensation Rules

CMS also took this opportunity to provide needed clarity with respect to specific questions regarding the payment of physicians on a wRVU basis. A number of commenters asked CMS to codify prior guidance related to a scenario regarding how hospitals pay employed physicians at hospital-based outpatient clinics. In that scenario, the employed physician reassigns the right to payment to the hospital-based clinic, and is paid a base salary, plus a per-wRVU bonus. The hospital bills a facility fee for all patient visits and ancillary services provided at the clinic. The question was whether the correlation between the wRVUs and the facility fees caused the compensation arrangement to run afoul of the volume/value standard. CMS noted that in the Phase II preamble[3], it stated that the fact that a corresponding hospital service may be billed when a particular employed physician personally performs work did *not* preclude that physician from being paid a productivity bonus based on the wRVUs attributable to personally performed services.

The commenters' concern regarding the continued viability of the Phase II preamble language arose from *United States ex rel. Drakeford v. Tuomey Healthcare system, Inc.*[4] In the penultimate event in the *Tuomey* saga, the Fourth Circuit Court of Appeals remanded the case which involved, among other things, part-time employment arrangements with surgeons who provided services at a hospital joint venture ASC. The surgeons were paid a base salary and a bonus, both based on total collections for their personally performed surgical services. Among the bases for the remand, the court noted that every time an employed surgeon performed a personal service, there was a corresponding facility fee charged by the hospital joint venture. The court noted that, in its view, a reasonable jury could conclude under the circumstances that the surgeons' compensation varied with the volume or value of referrals.[5] The conclusion was clearly at odds with the Phase II Preamble language noted above and sent waves of concern through the health care community.

Those waves of concern reached a crescendo with the issuance of the Fourth Circuit's opinion in *U.S. ex rel. Bookwater v. UPMC*[6] on September 17, 2019 (after the proposed regulations were drafted, but before they were issued.) UPMC, like Tuomey, was a qui tam case brought under the False Claims Act alleging violations of Stark. The Department of Justice settled the case with UPMC as to certain claims, and declined the remainder of the claims. The Relator proceeded with the declined claims. The lower court dismissed the Relator's Amended Complaint. On appeal, the Relator alleged that employed neurosurgeons were paid salaries and bonuses based on their personally performed wRVUs and thus violated Stark. UPMC argued in response that such personally performed wRVU-based compensation was expressly protected by CMS regulatory guidance. The Court disagreed, reasoning that since almost every time one of the neurosurgeons performed a wRVU service, the hospital could bill for the facility component of the surgery, the correlation between the two was sufficient to violate the volume/ value standard. The Court then reversed and remanded the case the lower court for discovery and trial.

In a strongly worded concurrence, Judge Ambro took the majority to task for its correlation analysis, noting that the majority's interpretation rendered almost every hospital in the country vulnerable to suit alleging Stark violations for a common and innocuous compensation structure.

In the Preamble to the proposed rules, CMS responded strongly to the reasoning in these two cases (albeit without mentioning them by name):

"[F]or clarity, we reaffirm the position we took in the Phase II regulation. With respect to employed physicians, a productivity bonus will not take into account the volume or value of the physicians referrals solely because

corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service."[7]

CMS further clarified that this analysis applies not only to employed physicians, but also to physicians paid under a personal services agreement, which CMS notes can be paid on a per-unit compensation formula under similar circumstances.

Takeaways

The key takeaway here is that hospitals and other health care entities can continue to compensate physicians on a per-unit basis, such as by wRVUs, even though those personally performed services may correlate to a billable designated health care service for the entity. Nonetheless, it is, worth keeping an eye on the *UPMC* case. UPMC is currently seeking a rehearing before the full court. Its request extensively cites this new CMS guidance.

[1] 84 Fed Reg. 55766 (October 17, 2019).

[2] 84 Fed Reg. 55766,55793-4 (October 17, 2019) to be codified at 42 C.F.R. 411.354(d)(5)(i)(B) and (ii)(B), and 42 C.F.R.354(d)(6)(i)(B and (ii)(B).

[3] 69 Fed Reg. 16088-9 (March 26, 2004).

[4] 792 F3d 364 (4th Cir. 2015).

[5] Technically, referrals to an ASC cannot be "referrals" under Stark because ASC services are not Designated Health Services. This nuance was missed by the court, but it does not change the analysis since the ASC services would be "other business generated."

[6] 938 F3d 397 (4th Cir. 2019).

[7] 84 Fed Reg. 55794 (October 17, 2019).