T A X P A Y E R S

A G A I N S T

F R A U D

Centers for Medicare and Medicaid Services
United States Department of Health and Human Services
Attention: CMS 1720-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244

Re: File Code: CMS 1720-P
Comments on Modernizing and Clarifying the Physician Self-Referral Regulations

To Whom It May Concern:

Taxpayers Against Fraud (TAF) respectfully submits the following comments on the Proposed Rule issued by the Centers for Medicare and Medicaid Services (CMS) entitled Modernizing and Clarifying the Physician Self-Referral Regulations and published in Volume 84 of the Federal Register at page 55766 on October 17, 2019. This letter expresses the views of TAF only, and no government attorneys participated in the drafting or submission of these comments.

TAF is the leading public interest non-profit organization dedicated to fighting fraud against the government by working to protect whistleblowers and strengthen the effective operation of the laws and programs that empower them to expose misconduct and the theft of taxpayer dollars. These include the federal and state False Claims Acts, the Securities and Exchange Commission, Commodity Futures Trading Commission and Internal Revenue Service whistleblower programs, and the Motor Vehicle Safety Whistleblower Act. These laws and programs empower and encourage citizens and organizations in the private sector to report fraud, waste, and abuse that improperly divert taxpayer funds from government agencies and programs.

TAF and its sister organization, the TAF Education Fund, are uniquely situated to comment on the Proposed Rule because it would affect the government and whistleblowers' ability to identify, remedy, and prevent fraud, waste, and abuse in the healthcare field. Since 1986, TAFEF's more than 400 members, in partnership with the Department of Justice (DOJ) and state attorneys general, have represented whistleblowers in False Claims Act (FCA) matters that have generated tens of billions of dollars in civil and criminal recoveries in healthcare cases. The FCA's whistleblower provisions are recognized as DOJ's chief civil fraud enforcement tool and have served as a model for the states and for other federal agencies that implement whistleblower

programs. FCA enforcement has also yielded serious efforts to improve internal compliance within various sectors of the U.S. economy, including the healthcare industry, and is estimated to have saved tens of billions of dollars through deterrent effects.

Many of the FCA whistleblower cases that TAFEF members have brought to the attention of the DOJ and successfully litigated have exposed arrangements that violated the Stark Law and involved healthcare providers, including hospitals, pharmacies, clinical diagnostic laboratories, nursing homes, and physicians. Consequently, TAFEF members are greatly concerned with ensuring that any changes to the Stark Law or additional proposed exceptions protect, rather than undermine, the interests of patients and providers, and of the taxpaying public.

Executive Summary

We appreciate CMS's goal of devising bright-line rules for the interpretation of the Stark Law. For the reasons set forth below, we think that certain of the proposed changes do not accomplish that goal. Moreover, we believe some of the proposed changes risk undermining the statute's purposes. TAF respectfully submits the comments and suggestions below for consideration by CMS with regard to the Proposed Rule. TAF's comments are summarized as follows:

1. Fair Market Value (proposed 42 C.F.R. § 411.351)

TAF strongly opposes the proposed changes to the definitions of "fair market value" and "general market value," which we believe are contrary to the Stark Law's purpose. The proposal improperly delinks "fair market value" from the ability to generate business which could result in comparing the subject transaction to other transactions inflated by the value of referrals.

Further, by defining "general market value" as the value determined by the parties to the subject transaction, the fair market value would cease to be an objective assessment of the value of the services without regard to distorting effects, and would now be a subjective test of how the parties to the transaction value the services, which could include additional payment for the generation of business.

2. Volume or Value Standard (proposed 42 C.F.R. § 411.354)

TAF believes that the new proposed standard to determine whether a compensation formula takes into account the volume or value of referrals creates significantly more confusion than the current standard, achieving the opposite of CMS's stated goal of clarifying the Stark Law. The proposal does not adequately explain what is meant by "includes the physician's referrals to the entity as a variable" and could allow for abusive compensation arrangements and hamper enforcement efforts.

3. Commercial Reasonableness (proposed 42 C.F.R. § 411.351)

TAF believes it is imperative that, if a definition of commercial reasonableness is added, CMS implement significant additional safeguards in order to prevent the definition from sheltering abusive arrangements.

4. Value-Based Arrangements and Value-Based Enterprises (proposed 42 C.F.R. § 411.357(aa))

Because the Proposed Rule is not addressing any specific, identifiable, beneficial practice that CMS intends to except from the Stark Law, it is so vague that it invites bad actors to attempt to conceal a variety of harmful and presently illegal practices under the veneer of VBAs. This will lead to an increase in the harms the Stark Law was intended to prevent, including overutilization of healthcare services and increased costs to Government healthcare programs.

The proposed VBA/VBE rule will also severely impede enforcement of the Stark Law. First, DOJ will be forced to find and consider the legality of a wide spectrum of complex arrangements on a case-by-case basis. Second, the Proposed Rule's deference to healthcare entities' intentions and "reasonable beliefs" may preclude the Government from addressing remuneration-for-referral arrangements that even the Government believes are abusive. Third, the uncertainty created by the breadth and vagueness of the Proposed Rule may make it prohibitively difficult, as a practical matter, to demonstrate knowledge of wrongdoing under the FCA.

5. Designated Health Services (DHS) (proposed 42 C.F.R. § 411.351)

TAF opposes the changes to the definition of "designated health services" in the Proposed Rule. The exclusion of nearly all Medicare hospitalizations from the proposed definition cannot be properly evaluated and should not be adopted. CMS asserts that "this proposed rule will have significant, ongoing benefits for the affected physicians and entities and the entire health care system," but neither the agency nor industry commenters provide significant guidance with respect to arrangements that would be DHS under existing regulations, but would *not* be DHS under the Proposed Rule. Under the Proposed Rule, physicians could own hospital services and improperly refer patients to the hospital for those services without Stark Law implications. That the cost of those services may be included in a DRG does not eliminate the potential for overutilization.

6. Personal Services Arrangements Exception (proposed 42 C.F.R. § 411.357)

TAF opposes the proposed changes to the exception for personal services arrangements. TAF believes that this proposal to eliminate the writing requirement exceeds the agency's authority because the rule contradicts the statute.

---

1. Fair Market Value (proposed 42 C.F.R. § 411.351)

For the reasons set forth below, TAF opposes the proposed changes to the definition of "fair market value," which undermine an important filter for identifying transactions that disguise payment for referrals.

The Stark statute employs the phrase "fair market value" in six places in the statutory safe harbors, requiring that excepted arrangements must be made at "fair market value." *See* 42 U.S.C. §1395nn(e)(1)(A)(iv)(rental space); 42 U.S.C. §1395nn(e)(1)(B)(iv)(rental equipment); 42 U.S.C. §1395nn(e)(2)(i), (ii)(bona fide employment); 42 U.S.C.

§1395nn(e)(3)(A)(v)(personal services); 42 U.S.C. §1395nn(e)(7)(A)(v)(group practice); 42 U.S.C. §1395nn(e)(8)(physician payments for services). The statute expressly defines "fair market value":

> *The term "fair market value" means the value in arms-length transactions, consistent with the general market value*, and with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

42 U.S.C. §1395nn(h)(3)(emphasis added).

The current regulations incorporate the statutory definition of "fair market value." The regulations also add a definition of "general market value," which the regulations define as the price an asset would bring as the result of "bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement." 42 C.F.R. §411.351. The regulation further explains that usually "the fair market price is the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals." *Id.*

This definition reflects common sense notions of fair market value in the context of a statute whose purpose is to regulate the potential for physician self-interest to interfere with healthcare decision-making. The market may well pay a very high price for physicians who are in a position to generate referrals or other business for an entity that provides designated health services. By defining fair market value to exclude the potential to general business, the current rule seeks to ensure that physicians not receive enhanced compensation because of their ability to generate business. As CMS explained at the time it adopted this definition in 1998, it would accept any method of establishing fair market value and general market value of a transaction that is commercially reasonable "and provides us with evidence that the compensation is comparable to *what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another*." 66 Fed. Reg. 944 (emphasis added).

a. The Proposed Revised Definition Dramatically Changes the Meaning of Fair Market Value.

CMS's proposed revised definition of "fair market value" dramatically changes the meaning of the term in two ways that are contrary to the core purpose of the statute. First, by delinking "fair market value" from the ability to generate business, the comparison to "like parties" and "like

circumstances" could result in comparing the subject transaction to other transactions inflated by the value of referrals. The compensation of a highly paid provider, whose pay is comparable to other highly paid providers, could be deemed to be fair market value even if the compensation of all of the providers is high because of their capacity to generate referrals or other business.

Second, by defining "general market value" as the value determined by the parties to the subject transaction, this proposed definition appears to make the subject transaction its own benchmark. Because the "fair market value" (the value established by like parties in like circumstances) must be consistent with the "general market value" (as established by the bargaining of the parties to the transaction), the value established by the parties to the transaction is likely to meet the "fair market value" test. The CMS comments provide examples of when the bargain between the parties exceeds the value of transactions between like parties, and explain that the latter is not consistent with "general market value" and therefore the "fair market value" is the value as established by the parties' transaction. (See 84 Fed. Reg. 55766, 55799 (Oct. 17, 2019).

Thus, rather than being an objective assessment of the value of the services without regard to distorting effects, fair market value would now become a subjective test of how the parties to the transaction value the services. The term "fair market value" would lose its role as a filter for conduct that raises red flags that the compensation is for something more than the value of services.

CMS notes that it sees nothing in the legislative history that would suggest that the law should deviate from general concepts and principles of fair market value. But deviate from the general concept is exactly what the proposed definition does. Fair market value is not generally measured by the value assigned to the subject transaction by the parties to the transaction. Moreover, the argument that fair market value has a different meaning under Stark than in other contexts proves too much. Stark seeks to control certain behavior that the market might reward. That is, Stark is not concerned with the market value of transactions in the abstract. The fair market value standard necessarily looks to isolate the price of services or assets without the effect of the prohibited behavior.

In the proposed regulations, CMS set out to develop very distinct definitions of the three core concepts used in the Stark Statute – fair market value, commercially reasonable, and volume or value – but TAF believes the effort to delink these concepts is ill-advised and unnecessary. As the Third Circuit observed in *United States ex rel. Bookwalter v. UPMC*, 2019 WL 7019394, *7 (3rd Cir. Dec. 20, 2019), in referring to the law's use of the terms "fair market value" and "taking into account the volume or value of referrals," the statute's

> …different treatment of these concepts does not sever them. To start, just because a statute has two elements does not mean that one can never be evidence of the other. Theft requires taking another's property with intent. Those are two elements, but the fact of taking property can be circumstantial evidence of intent.
>
> So too here. Perhaps not all payments above fair market value are evidence of taking into account the doctor's referrals. But common sense says that marked overpayments are a red flag. Anyone would wonder why the hospital

> would pay so much if it was not taking into account the doctor's referrals or other services.

Id. at 411-412.

To illustrate the dramatic departure from existing law that this proposed change to the definition of fair market value represents, consider how the new definition would have applied in two Stark cases where healthcare providers were found to have violated the Stark Law where doctors were being paid above fair market value, defined as the market value of an arms-length transaction by parties not in a position to refer or generate other business.

In *United States ex rel. Kosenske v. Carlisle HMA, Inc*., 554 F.3d 88 (3rd Cir. 2009), the appellate court overruled a district court's grant of summary judgment for a hospital system. The district court had found that the hospital met the "personal services" exception to Stark even though the hospital presented no evidence regarding the market value of the space, equipment or staff services that the hospital provided to a pain management group that referred patients to the hospital. The district court had concluded that such evidence was unnecessary because the agreement *was the result of negotiations between unrelated parties* and "[*b*]*y definition*" reflected fair market value. *Id.* at 96. (emphasis added).

The Third Circuit reversed. Rejecting the district court's assessment of the meaning of fair market value, the appellate court observed that "a negotiated agreement between interested parties does not 'by definition' reflect fair market value." As the court explained, "the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties *are often designed to disguise the payment of non-fair-market value compensation.*" *Id.* at 97 (citing regulation).

Under the proposed revised regulation, the agreement reached between unrelated parties would in fact "by definition" be fair market value by virtue of the fact that the parties entered into the agreement. *See* 84 Fed. Reg. 55766, 558 (Oct. 17, 2019) (proposed revised definition of general market value §411.351) ("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.") (emphasis added). Although the general definition of fair market value provides that one looks to arm's-length transactions with "like parties and under like circumstances," the definition also provides that this must be "consistent with" general market value, which is defined as the bargain between the involved parties. Thus, it appears the value assigned to the transaction by the parties would trump the value established by like parties in like circumstances if they were not "consistent." And if they were consistent, it might be because both are inflated due to the ability of the parties to generate business.

In *United States ex rel. Singh v. Bradford Regional Medical Center*, 752 F.Supp. 2d 602, (W.D. Pa. 2010), the district court evaluated an arrangement where a hospital compensated physicians in a way that took into account the value of anticipated referrals. The defendants had argued that their compensation arrangement was fair market value because it was a "sensible, prudent business arrangement" and did not require referrals. The court rejected that argument because, although the agreement did not require referrals, it took them into account.

The *Singh* court agreed with the plaintiff's observation that

> the reason that section 411.351 defines 'fair market value' of a compensation arrangement as the 'result of bona fide bargaining between well-informed parties to the agreement *who are not otherwise in a position to generate business for the other party* . . . where the price or compensation *has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals'* is because a compensation arrangement that takes into account anticipated referrals will necessarily be greater than what would be paid by parties who are not in a position to refer business to each other. While the value agreed upon by parties who are in a position to refer business to each other and who take into account anticipated referrals will be a fair value *as between the parties*, such an arrangement is not fair market value under the Stark Act.

752 F.Supp.2d at 633. Under the proposed revised definition of fair market value, the compensation arrangement would by definition be fair market value because the parties to the transaction entered into the arrangement.

b. The Reasons Underlying the Proposed Change Are Not Persuasive

The explanations for the proposed change to the definition of fair market value are not persuasive. First, the comments suggest that the current definition of fair market value, which requires that the price not take into account the volume or value of a physician's referrals or other business generated by the parties has the potential to inhibit innovation, such as shared savings or pay-for-performance arrangements. (*See, e.g.*, 84 Fed. Reg. 55776-77).

But laws designed to prevent financially self-interested decision-making can often be described as having the potential to inhibit innovation. The goal of public policy is to strike the right balance. Here, the legislative goal is to prevent personal financial interest from interfering with healthcare decision-making. That purpose necessarily prevents healthcare providers from doing some things that they might prefer to do. Public policy makers should identify what beneficial activity, if any, is *actually* being prevented but should not be. The Stark Law directs the Secretary to adopt an exception for any financial relationship that the Secretary "determines, and specifies in regulations, does not pose a risk of program or patient abuse." 42 U.S.C. § 1395nn(b)(4). To date, the descriptions of the beneficial activity that the current regulations purportedly chill have been notably vague. It is possible that perceived barriers to innovation may be overstated or may be addressed in a more targeted fashion. The proposed changes will no doubt remove an impediment to innovation, but will also remove an important check on self-interested financial decision-making at the expense of patients and taxpayers that the Stark Statute is intended to prevent.

Second, CMS notes that commenters have asserted that FCA case law has exacerbated the challenge of complying with core concepts like fair market value. (*See* 84 Fed. Reg. 55789). Yet the comments do not identify judicial decisions that CMS believes incorrectly interpreted the law or regulations. If there are cases that CMS believes have incorrectly interpreted the statute or regulations, the comments should identify them and explain how the

proposed regulations are addressing a specific issue. Without identifying the problem and how the proposed solution addresses it, the vague observation about FCA case law introduces more uncertainty than it eliminates.

Third, CMS suggests that it is endeavoring to develop bright line, objective rules to reduce the burden of compliance. (*See* 84 Fed. Reg. 55789). While TAF supports bright line rules that are consistent with the purpose of the statute, the new fair market value definition does not meet that test. By defining "general market value" to focus on the value arrived at by the parties to the subject transaction, the proposal eliminates an important filter for identifying suspect arrangements. And by adopting regulations that diverge from the Anti-Kickback Statute regulations, the proposed change does not simplify compliance with or enforcement of these laws.

Finally, it isn't clear that the proposed revised definition is necessary to address the problems CMS identifies. As an example, CMS describes a hospital being compelled to pay a physician *more* than the physician is worth because the current definition of fair market value would not take into account the specific market circumstances of a poor payor mix and a low reimbursement rate. (*See* 84 Fed. Reg. 55799). Being required to overpay physicians because of Stark does not seem to be a significant problem, and the existing definition of fair market value allows parties to take into account the existing market circumstances of the hospital.

The concerns that CMS identifies as having been raised by the healthcare industry could be resolved by regulatory clarifications that do not throw the baby out with the bathwater. For example, CMS notes that commenters shared a *mistaken* belief that if compensation is not fair market value CMS would automatically consider it to take into account the volume or value of referrals and vice versa. (*See* 84 Fed. Reg. 55789). CMS could explain that this is not the case and provide illustrative examples, either by a clarifying regulation or by explanatory comments. To the extent CMS seeks to respond to the concerns expressed by the regulated community that establishing fair market value of a transaction is costly and the protection uncertain, CMS could provide additional guidance or develop rules on what will be accepted as presumptive evidence of fair market value.

2. Volume or Value Standard (proposed 42 C.F.R. § 411.354)

TAF opposes the proposed definition of the volume or value standard. Rather than clarifying the standard, the proposed definition introduces additional confusion.

a. The Proposed Rule is Confusing as To When a Compensation Formula "includes the physician's referrals to the entity as a variable."

Proposed paragraph (d)(5)(i) states that compensation will take referrals into account if the formula used to calculate compensation "includes the physician's referrals to the entity as a variable, resulting in an increase or decrease in the physician's … compensation that positively correlates with the number or value of the physician's referrals to the entity."[1]

[1] Although this discussion focuses on paragraph (d)(5)(i), the same concerns exist with respect to paragraphs (d)(5)(ii) and (d)(6).

This definition is confusing in that it does not adequately explain what is meant by "includes the physician's referrals to the entity as a variable." Does the formula have to expressly use "referrals" as a variable? Or is any variable that "result[s] in an increase or decrease in the physician's … compensation that positively correlates with the number or value of the physician's referrals to the entity" deemed to "include referrals?" As discussed below, the latter interpretation is preferable, and is consistent with the Third Circuit's recent holding that "[i]f compensation tends to rise and fall as the volume or value of referrals rises and falls, then the two vary with each other." *United States ex rel. Bookwalter v. UPMC*, 938 F.3d 397, 408 (3d Cir. 2019).[2]

The first interpretation – that the formula must expressly use "referrals" as a variable – is inconsistent with the purpose of the Stark Law and would open the door for substantial abuse. The Stark Law has been in place for decades, and sophisticated providers have become acutely sensitized to the need to avoid openly tying compensation to "referrals." Consequently, it is difficult to imagine an agreement that expressly uses "referrals" as a variable in determining compensation. However, compensation agreements routinely use proxies that all parties understand will closely correlate with referrals, and thus create the same incentive for overutilization motivated the passage of the Stark Law. *See United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 97 (3d Cir. 2009) ("the Stark Act is predicated on the recognition that, where one party is in a position to generate business for the other, negotiated agreements between such parties are often designed to disguise the payment of non-fair-market-value compensation").

As an example, consider a typical employment contract between a physician and a hospital, where the physician assigns to the hospital the right to collect payment for his personally-performed services. The contract requires the physician to perform all services at the hospital's facility, subject to rare exceptions (such as where the patient requests a different facility, or where insurance requires otherwise). And whenever the physician performs a service at the hospital's facility, this results in a referral from the physician to the hospital for the facility component of the service. Thus, all parties are aware that whenever the physician performs a service, he or she automatically makes a referral to the hospital for the facility component. The hospital will also collect for the physician's personally performed service.

Every service performed by a physician is assigned a work Relative Value Unit (wRVU), which takes into account the expected physician work involved and is the basis for determining the Medicare physician payment amount. Employment agreements frequently compensate physicians, in whole or in part, based on the number of wRVUs generated by the physician. In many cases, a physician will be paid a base salary plus a "productivity bonus" for each wRVU in

[2] After CMS issued the proposed rule, the Third Circuit revised its opinion to remove the discussion of the "varies with" issue, holding that "we need not resolve the meaning of *varies with* here" because the compensation at issue "takes into account" referrals. *United States ex rel. Bookwalter v. UPMC*, 2019 U.S. App. LEXIS 38367, *17 (3d Cir. Dec. 20, 2019). Although that portion of the ruling has been withdrawn, the Third Circuit's original construction of "varies with" remains the preferable construction.

excess of a predetermined minimum. Failure to reach the wRVU target is often a basis for reducing the base salary in succeeding years.

Although the variable in the compensation formula – wRVUs – does not expressly use the term "referral," all parties understand that wRVUs are generated by the physicians performing services that automatically result in a referral to the hospital for the facility component. The physician thus increases his compensation by performing more services that necessarily result in referrals to the hospital. And as a general rule, the more time-consuming and intensive a physician service, the more hospital resources are required, resulting in a higher facility payment. Using wRVUs as a variable thus results in "an increase or decrease in the physician's … compensation that positively correlates with the number or value of the physician's referrals to the entity." Under any common-sense interpretation, the compensation scheme takes referrals into account, since compensation increases as referrals increase, if not in a perfect 1:1 manner.

The commentary accompanying the proposed rule does not sufficiently explain when a wRVU-based compensation scheme will be held to "take into account" referrals. After noting its prior statement that "the fact that corresponding hospital services are billed would not invalidate an employed physician's personally performed work, for which the physician may be paid a productivity bonus (*subject to the fair market value requirement*)," CMS went on to state that

> for 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 physician's referrals *solely* because corresponding hospital services (that is, designated health services) are billed each time the employed physician personally performs a service. We are also clarifying that our guidance extends to compensation arrangements that do not rely on the exception for bona fide employment relationships at § 411.357(c), and under which a physician is paid using a unit-based compensation formula for his or her personally performed services, *provided that the compensation meets the conditions in the special rule at § 411.354(d)(2)*. That is, under a personal service arrangement, an entity may compensate a physician for his or her personally performed services using a unit-based compensation formula—even when the entity bills for designated health services that correspond to such personally performed services—and the compensation will not take into account the volume or value of the physician's referrals *if the compensation meets the conditions of the special rule at § 411.354(d)(2)* (see 69 FR 16067).

84 Fed. Reg. 55766, 55795 (emphasis added).

These comments indicate that whether a compensation scheme "takes into account" referrals turns in part on whether it "meets the conditions of the special rule at § 411.354(d)(2)." This special rule, after the proposed modifications, would read as follows:

> Unit-based compensation (including time-based or per-unit of service-based compensation) is deemed not to take into account "the volume or value of referrals" *if the compensation is fair market value for items or services actually*

> *provided* and does not vary during the course of the compensation arrangement in any manner that takes into account referrals.

42 C.F.R. § 411.354(d)(2) (emphasis added); *see also id*. at (d)(3) (special rule for "other business"). Thus, CMS's commentary indicates that whether a productivity bonus "takes into account" referrals turns in part on whether the compensation is "fair market value for services or items actually provided," and thus satisfies the special rule in (d)(2). Because there is no mention of fair market value in the proposed paragraph (d)(5), however, the proposed rule is confusing as to the interplay between (d)(5) and the special rules in (d)(2) and (d)(3).

CMS should make it clear that any compensation formula that "result[s] in an increase or decrease in the physician's … compensation that positively correlates with the number or value of the physician's referrals to the entity" is properly considered to "take into account" referrals for purposes of paragraph (d)(5), *unless* it is fair market value and otherwise meets the requirements of (d)(2) or (d)(3), in which case it would be excluded from the definition by application of the special rule. To do otherwise would simply allow parties to design compensation arrangements that use proxies for referrals, thus defeating the purpose of the Stark Law. In addition, as discussed below, it would open up new possibilities for abuse in the form of indirect compensation arrangements.

b. A Restrictive Definition of "takes into account" Would Allow Hospitals to Evade Stark Law Scrutiny Altogether by Simply Spinning Off an Affiliate to Employ Referring Physicians

With respect to *direct* financial relationships, the danger of an overly-restrictive definition of "takes into account" is somewhat mitigated by the fact that the arrangement must also satisfy every other element of a Stark Law exception, including the fair market value element. Thus, a direct compensation arrangement under which a physician receives above-FMV compensation may violate the Stark Law even if the compensation is deemed not to take referrals into account.

The situation is different with respect to *indirect* compensation arrangements, where an overly-restrictive definition of "takes into account" may result in arrangements *not being considered financial relationships at all*, even though they result in referring physicians receiving compensation that greatly exceeds fair market value. These arrangements would evade Stark Law scrutiny altogether, even though they present the same potential for abuse as direct compensation arrangements.

To illustrate, consider an ownership structure that is becoming common in the hospital industry. Parent Company owns and operates a number of different hospitals. It also owns a Physician Practice, which employs a number of surgeons, who constitute the hospitals' surgery department. The employment contract requires the physicians to perform surgeries at the Parent Company's hospitals, with rare exceptions. The Parent Company has the right to appoint directors and make all decisions for the hospitals and the Physician Practice, and files consolidated financial statements on behalf of the entire organization, which it describes as an integrated healthcare system. Exercising its control over the Physician Practice, the Parent Company implements a compensation system whereby the surgeons are paid a base salary plus a "productivity bonus" for every wRVU generated over a predetermined number. Because

virtually all of their surgeries are performed at the Parent Company's hospitals, each surgery results in a lucrative referral to the hospital for the facility component of the procedure, while also increasing the surgeon's compensation. Thus, exactly as in the case of a direct compensation arrangement, the compensation system "result[s] in an increase or decrease in the physician's … compensation that positively correlates with the number or value of the physician's referrals to the [hospital]."

If the physicians were employed by the hospital, there would be a *direct* compensation arrangement, and the arrangement would have to comply with a Stark Law exception (including the fair market value requirement), regardless of whether the compensation formula is considered to "take into account" referrals. But because Parent Company has elected to organize its various operations into different subsidiaries, all of them under Parent Company's control, the Stark Law *does not apply at all* unless the arrangement meets the definition of "indirect compensation arrangement" in 42 C.F.R. § 411.354(c)(2).

Currently, the second prong of the indirect compensation arrangement definition requires that the referring physician receive aggregate compensation from the "entity in the chain with which the physician … has a direct financial relationship" [i.e., the Physician Practice] that "varies with, or takes into account, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS [i.e., the hospital], regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under paragraphs (d)(2) or (d)(3) of this section." 42 C.F.R. § 411.354(c)(2)(ii). The proposed rule would delete the words "varies with," leaving "takes into account" as the only basis for finding that an indirect compensation arrangement violates the law.

The Third Circuit has recently interpreted the term "varies with" to mean that "[i]f compensation tends to rise and fall as the volume or value of referrals rises and falls, then the two vary with each other." *Bookwalter*, 938 F.3d at 408.[3] As discussed above, a proper reading of proposed paragraph (d)(5) should yield a similar result. However, if (d)(5) is read to mean that an arrangement does not take referrals into account unless the compensation formula *expressly* uses "referrals" as a variable (as opposed to a proxy for referrals), the elimination of "varies with" from the indirect compensation arrangement definition would open up significant avenues for abuse. A parent company seeking to increase referrals to its hospital could simply spin off a subsidiary physician practice to employ its referring physicians, require them to perform all services at the hospital, and pay them according to a metric that correlates with referrals. Because the arrangement would not constitute an indirect compensation arrangement, the Stark Law would not be implicated at all, even if the compensation was substantially above fair market value. The incentives for overutilization would be enormous and would not be mitigated by the fact that the arrangement is indirect.

The proposed rule and the accompanying commentary do not adequately explain how the proposed changes would affect indirect compensation arrangements. Particularly in the context of integrated healthcare systems that are becoming increasingly prominent in the industry, many

[3] As mentioned above, that discussion was removed in a revised opinion, which skirted the meaning of "varies with" altogether. Nevertheless, the Third Circuit's original construction of that term remains the preferable construction.

indirect compensation arrangements are substantively indistinguishable from direct compensation arrangements and present the same possibilities for knowingly incentivizing overutilization. There is no good reason why indirect arrangements (but not direct arrangements) should be immunized from Stark Law scrutiny, including fair market value concerns, simply because the parties use a proxy for referrals in their compensation formula, rather than referrals themselves.

c. The Proposed Rule is not Clear as to the Interplay Between Paragraph (d)(5) and the "Indirect Compensation Arrangement" Definition in 42 C.F.R. § 411.354(c)(2).

The proposed definition in (d)(5) appears to have no application in determining whether an indirect compensation arrangement exists. As discussed above, where a physician is employed by a physician practice group and makes referrals to an affiliated hospital, there is an indirect compensation arrangement between the physician and the hospital if the physician receives aggregate compensation from the *practice group* that takes into account the volume or value of referrals to the *hospital* (which is the "entity furnishing the DHS"). 42 C.F.R. § 411.354(c)(2)(ii). In the indirect compensation arrangement definition, there is no inquiry as to the compensation from the *entity furnishing the DHS* to the physician, since the physician is not receiving compensation from such entity – indeed, if the physician received compensation from the DHS entity, there would be a *direct* financial relationship.

New paragraph (d)(5), by contrast, is concerned *only* with compensation from the DHS entity to the physician:

> (5)(i) Compensation *from an entity furnishing designated health services to a physician* (or immediate family member of the physician) takes into account the volume or value of referrals only if—
> (A) The formula used to calculate the physician's (or immediate family member's) compensation includes the physician's referrals *to the entity* as a variable, resulting in an increase or decrease in the physician's (or immediate family member's) compensation that positively correlates with the number or value of the physician's referrals *to the entity*; or
> (B) There is a predetermined, direct correlation between the physician's prior referrals *to the entity* and the prospective rate of compensation to be paid over the entire duration of the arrangement for which the compensation is determined.

(Emphasis added).[4]

On its face, therefore, paragraph (d)(5) appears to have no application to the threshold question of whether an indirect compensation arrangement exists between a physician and a hospital. Rather, it is relevant to the question of whether a compensation arrangement can

[4] The same concerns apply to proposed paragraph (d)(5)(ii), which deals with "other business" generated by the physician, and (d)(6), which deals with compensation from the physician to the DHS entity.

satisfy one of the Stark Law exceptions, many of which have elements involving the volume or value standard.

This is consistent with CMS's longstanding approach, in which special rules regarding compensation are considered in the context of exceptions but are not considered in determining whether an indirect compensation arrangement exists. As CMS has explained:

> Our intent is two-fold. First, we intend to include in the definition of "indirect compensation arrangement" any compensation arrangements (including time-based or unit-of-service based compensation arrangements) where the *aggregate* compensation received by the referring physician varies with, or otherwise takes into account, the volume or value of referrals or other business generated between the parties, *regardless of whether the individual unit of compensation qualifies under § 411.354(d)(2) and § 411.354(d)(3)*. Second, we intend to exclude under the indirect compensation arrangement exception at § 411.357(p) that subset of indirect compensation arrangements where the compensation is fair market value and does not reflect the volume or value of referrals or other business generated and the other conditions of the exception are satisfied. Per unit compensation will meet this test if it complies with § 411.354(d)(2) and § 411.354(d)(3). While we agree that the ultimate result may be the same – time, unit-of-service, or other 'per click' based arrangements are generally permitted *if they are at fair market value without reference to referrals* – we believe this construct more closely corresponds to the statutory treatment of direct compensation arrangements.

69 Fed. Reg. 16054, 16059 (emphasis added). CMS has made it clear that, for purposes of determining whether an indirect compensation arrangement exists, "unit-of-service based compensation will always vary with the volume or value of services when considered in the aggregate." *Id*. at 16058-16059.

CMS's historic practice has thus been to recognize that, if *aggregate* compensation tends to rise or fall along with referrals (which is always the case with unit-of-service based compensation), this will satisfy the threshold definition of an indirect compensation arrangement, and the relevant inquiry becomes whether the arrangement meets the requirements of the indirect compensation exception. In considering the applicability of an exception, parties can rely on the special rules set forth in (d)(2) and (d)(3), under which unit-based compensation is deemed not to take into account referrals if it is fair market value and does not vary during the arrangement in a way that takes referrals into account. The effect of this approach has been to place direct and indirect relationships on a similar footing, and CMS has never intended to immunize indirect relationships from fair market value scrutiny (or from compliance with other elements of applicable exceptions) simply because the parties base compensation on a variable that correlates with referrals, rather than on referrals themselves.

Indeed, the proposed rule continues to include an exception for "indirect compensation arrangements" in 42 C.F.R. § 411.357(p) and clarifies that this is the *only* exception applicable to indirect compensation arrangements. This exception requires, among other things, that the compensation received by the physician is "not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the

entity furnishing DHS." But if this is the exact same test for determining whether an indirect compensation arrangement exists in the first place, the exception would be entirely superfluous: If the compensation does not take into account referrals, there is no indirect compensation arrangement, and thus no need to rely on the exception. If the compensation does take referrals into account, then the exception can never be satisfied. The regulatory scheme makes sense only if the "takes into account" test in the indirect compensation arrangement definition, which focuses on *aggregate* compensation, is broader than the "takes into account" test for determining compliance with the exception.

Whether by clarifying that paragraph (d)(5) is a special rule applicable only with respect to Stark Law exceptions, restoring "varies with" to the indirect compensation arrangement definition, or otherwise, CMS should make it clear that, for purposes of determining whether a compensation arrangement exists, an arrangement takes referrals into account if there is a positive correlation between referrals and aggregate compensation. This would reduce any incentive from hospitals to avoid Stark Law scrutiny altogether by simply spinning off a subsidiary to employ referring physicians.

3. Commercial Reasonableness (proposed 42 C.F.R. § 411.351)

The proposed regulations offer two possible definitions of commercial reasonableness:

> (1) the particular arrangement furthers a legitimate business purpose of the parties and is on similar terms and conditions as like arrangements; 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.

84 Fed. Reg. 55766, 55790.

Neither of the proposals as currently written provide clarification or bright line rules, as is CMS's intention. Any definition adopted by CMS must provide that the assessment of commercial reasonableness is an objective, not subjective one.

The first proposal does not offer guidance for determining whether an arrangement furthers a "legitimate business purpose," and will likely lead to even more confusion than no definition at all. If this definition is adopted, significant additional safeguards must be included so that it is clear what is permissible, including additional language that would clarify how parties could determine whether an arrangement is on "similar terms and conditions as like arrangements" and what relevance profit has to the determination of what is commercially reasonable.

With respect to the meaning of "like arrangements" we propose that the rule include additional language:

> Terms and conditions are similar for 'like arrangements' if the key terms are set using a similar methodology and are consistently applied by the entity receiving the Designated Health Services referrals in other arrangements with similar entities, regardless of

provider specialty and regardless of the past, present or expected future value of any referrals from the referring entity.

To the extent that the standard terms vary, due to legitimate business factors such as provider expertise, training, community need or other similar factors, any such variations must be applied consistently to all arrangements, regardless of provider specialty and regardless of the past, present or expected future value of any referrals from the referring entity.

Any variation from the standard methodology based on business factors must be documented, with an objective, evidence-based rationale, at the time of the execution of the agreement.

Thus, a hospital or other provider could decide on the foundational features of its compensation methodology – which dataset to use, which factors to include (e.g., Total Cash Compensation/wRVU), what percentile ranges apply – as well as a set of policies outlining business factors that justify variation. Alternatively, the hospital could address new or unique challenges on a going forward basis, so long as the hospital documents the justification for that variation and applies the variation without respect or reference to the financial value of the expected referrals or downstream revenue.

It is important to ensure that all physician specialties are treated separately. To take a contrary approach would essentially "bake in" the value of referrals for those specialties that are known to generate more lucrative referrals to certain Designated Health Service performing entities.

We recognize that certain industry commentators are likely to contend that this definition would impose an unreasonable regulatory burden. As a practical matter, however, in our experience such "business case" analysis is routinely done in the healthcare industry already. The members of Taxpayers Against Fraud Education Fund have collectively reviewed thousands of physician, hospital and other provider compensation arrangements, and in the vast majority of cases – and certainly for organizations that were operating in an efficient, professional and compliant manner – this sort of analysis was done for the Compensation Committee, the Compliance Committee and/or the Board of Directors as part of the approval process. This is especially true for contracts where significant financial losses were expected.

This approach – providing flexibility in exchange for consistency and documentation – is similar to other flexible government methodologies, such as the way the Federal Acquisition Regulations allow companies to set a methodology for the allocation of overhead costs between and among projects. The key principle there is that the methodology must be applied evenhandedly across projects and from year to year – so that it is not manipulated to inappropriately charge such costs disproportionately to Government contracts.

As to the relevance of financial loss to commercial reasonableness, we propose the following:

> An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties, so long as any material losses expected or regularly sustained are justified by legitimate, documented, objective business factors, and such legitimate business factors are applied similarly to other arrangements regardless of the past, present or expected future value of any referrals from the referring entity.

This would make clear that while losses are not *necessarily* evidence that an arrangement is not commercially reasonable, at the same time, if a hospital only sustains substantial losses on its contracts with high-referring physicians, then such a pattern *may be evidence* that such losses are not commercially unreasonable. The key issue is that the business justification – excluding the financial value of referrals – for expected losses must be documented at the time the contract is executed.

Significantly, while we agree that there may well be a variety of good reasons – such as those identified in the comments to the proposed regulations – why a contract may generate losses for one party or the other, a "commercial reasonableness" definition must address the question of profitability. Depending on the likelihood and magnitude of such losses, they may be commercially reasonable when weighed against other specific, identified, documented business factors. However, that weighing must be done – any legitimate business entity would do as much before agreeing to take on a contract that was expected to generate significant losses.

The second proposed definition is similarly ambiguous, though it at least seems to take into account whether the arrangement is profitable. Language clarifying this point similar to that suggested above would be necessary to allow entities to determine whether a given arrangement is permissible.

Further, neither proposed definition contains the requirement that the arrangement would make commercial sense even if no referrals were made. This should be an integral piece of any definition of commercial reasonableness, as it is the only way to ensure that the purposes of the Stark Law are protected.

4. Value-Based Arrangements and Value-Based Enterprises (proposed 42 C.F.R. § 411.357(aa)

We appreciate that CMS is attempting to create some flexibility in relationships between entities that are, in theory, working towards a value-based model that may not present the potential for abuse. However, we have serious concerns regarding the addition of exceptions for Value-Based Enterprises and Value-Based Arrangements, as it is unclear from the Proposed Rule what specific arrangements these exceptions are intended to protect.

Because the Proposed Rule is not addressing any specific, identifiable beneficial practice, its lack of precision invites bad actors to attempt to conceal a variety of harmful and presently illegal practices under the veneer of VBAs. The Proposed Rule will serve mainly to allow for the creative recharacterization of abusive arrangements as value-based initiatives, which will lead to an increase in the harms the Stark law was intended to prevent.

The Proposed Rule will also impede enforcement of the Stark Law in several ways. First, the government will be forced to find and consider the legality of a wide spectrum of complex arrangements on a case-by-case basis. The sheer variety of arrangements for which healthcare entities will assert protection may render it unlikely that the Government will have the time or resources to ensure that any new VBE/VBA exceptions are working as intended. Second, the Proposed Rule's deference to healthcare entities' intentions and "reasonable beliefs" may preclude the Government from addressing arrangements that the Government believes are abusive, as set forth below. Third, the uncertainty created by the breadth and vagueness of the Proposed Rule may make it prohibitively difficult, as a practical matter, to demonstrate knowledge of wrongdoing under the FCA. As a result, the Proposed Rule could seriously impair the Government's ability to rely upon the assistance of FCA whistleblowers – the Government's most valuable resource in identifying the costliest and most difficult-to-detect schemes – to police misconduct under the Stark Law. It also will create barriers to DOJ's ability to recover under the FCA, the Government's principal civil enforcement tool for redressing fraud.

Finally, the Proposed Rule's VBE and VBA provisions do not satisfy the Stark Law's requirements for new exceptions. The proposed safe harbors exceed the Secretary's discretion under the statute, which allows the Secretary to propose exceptions "[i]n the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse." (42 USC 1395nn(b)(4)). The VBA and VBE exceptions pose a great risk of fraud and abuse because they are so vague with respect to what "value-based" means that many abusive arrangements will now meet the requirements for an exception to the Stark Law.

a. Definitions of "Value-Based Activity" and "Value-Based Arrangement."

The definitions of "value-based activity" and "value-based arrangement" (84 Fed. Reg. 55840-41) are too broad and vague. They would allow healthcare entities to form VBEs for the specific purpose of concealing abusive practices, the true purpose of which is to encourage self-referrals, as long as the participants are able to come up with a "value-based" pretext. Without articulating metrics for measuring specific value-based activities, these provisions would permit participants to mask self-referrals as "value-based activity" and to drive exclusivity to a particular provider or product, whether indirectly or directly.

b. The Proposal Gives Undue Deference to Healthcare Entities' Subjective Beliefs.

The Proposed Rule does not merely protect arrangements that will actually advance the coordination and management of care; it also protects arrangements that are "reasonably designed" to achieve value-based purposes (84 Fed Reg. 55840). Similarly, the Proposed Rule does not require termination of arrangements that do not actually further the coordination and management of care. Instead, CMS has suggested that it include requirements that: (1) The value-based enterprise or the VBE participant providing the remuneration must monitor to determine whether the value-based activities under the arrangement are furthering the value-based purpose(s) of the value-based enterprise; and (2) if the value-based activities will be unable to achieve the value-based purpose(s) of the arrangement, the physician must cease referring designated health services to the entity, either immediately upon the determination that

the value-based purpose(s) will not be achieved through the value-based activities or within 60 days of such determination. (84 Fed. Reg. 55785). Such language is critical to provide accountability within the VBE, but still defers to the parties to the VBA to decide whether a value-based purpose is being achieved.

As a result, the Proposed Rule requires extraordinary deference to the decisions of self-interested VBE participants. To enforce the Stark Law and put an end to an abusive arrangement, it will not be enough for the Government to prove that an arrangement has not in fact improved coordination or management of care or another "value-based purpose." Instead, the Government arguably must prove that the VBA was not "reasonably designed" to achieve a value-based purpose, or that the VBE has not determined that the arrangement furthers or will further the value-based purpose in the future. This would make it substantially more difficult for the Government to identify and root out fraudulent arrangements, even where the Government can demonstrate that the arrangements do not promote patient care or coordination.

This is a significant departure from the statutory structure that Congress enacted and intended. It is important to remember that the Stark exceptions are designed to be just that, exceptions to the general rule that arrangements may not be designed to encourage self-referrals. The Government must consider and formally approve, by regulation, a specific practice before it can be exempted from the reach of the Stark Law. 42 U.S.C. § 1395nn(b)(4). The proposed VBE/VBA safe harbors arguably reverse this presumption. In instances where the Government and a VBE disagree about whether a practice is likely to improve the coordination or management of care, the Government may be unable to prohibit the practice, because the relevant criteria for protection under the new exception is the VBE's intent in designing the VBA, or its reasonable belief in the VBA's efficacy, not the Government's determination to the contrary.

This is likely to impede the Government's ability to respond to abusive practices that clever healthcare entities cloak in "value-based" pretext. Moreover, it is likely to impair the Government's ability to use its most valuable civil enforcement tool, the FCA, because healthcare entities will argue that the existence of any reasonable belief that their arrangement will promote patient care defeats the FCA's scienter element.

The Secretary should not adopt the proposed VBE/VBA exceptions at all given the lack of identification of specific non-abusive circumstances that would provide the basis to adopt a regulatory exception. If it does so, however, it should eliminate the reliance upon the VBE's beliefs. Instead, the relevant provisions should require that if there is any dispute concerning the applicability of this exception, the VBE will bear the burden of proving, based upon objective evidence, that the measurements advance the coordination and management of care of the target patient population. Additionally, the provisions relating to the outcomes of the VBA should state that the parties will terminate the arrangement within 60 days if the objective information available to the VBE's accountable body or responsible person indicates that the value-based arrangement has not furthered the coordination and management of care for the target patient population; has resulted in material deficiencies in quality of care; or has not achieved the evidence-based, valid outcome measure(s). Further, value-based activities should be further clarified and limited to specific practices with verifiable outcomes for specific patient populations

In any dispute concerning the applicability of this exception, the VBE should bear the burden of proving that the information available to the VBE's accountable body or responsible person does not require termination.

c. Records Requirements

The Proposed Rule's VBA/VBE exceptions require that "[r]ecords of the methodology for determining and the actual amount of remuneration paid under the value-based arrangement must be maintained for a period of at least 6 years and made available to the Secretary upon request." 84 Fed. Reg. 55846 (proposed amended 42 C.F.R. § 411.357).

In our experience, entities engaged in abusive self-referral schemes often seek to defend themselves with *post hoc* justifications that have nothing to do with the reasons why they entered into the arrangements in the first place. To guard against such conduct, if the Secretary intends to adopt a VBA/VBE exception, we encourage it to add the following language to these provisions:

> Such documents must include contemporaneous documents certifying/identifying the basis for: (a) the VBE's belief, at the time that the VBA was memorialized in writing, that the VBA is reasonably designed to achieve a value-based purpose; (b) the specific basis for such belief; (c) the VBE's reasonable anticipation, at the time that measures were selected, that particular evidence-based, valid outcome measures will advance the coordination and management of care of the target patient population; and (d) the basis for any determination or decision by the accountable body or responsible person. In any dispute concerning the applicability of this exception, the factfinder shall not consider any arguments in favor of the applicability of the exception not articulated in those contemporaneous documents.

CMS also queried whether it would be appropriate or necessary to include requirements in any final exceptions that the methodology for determining remuneration: (1) Not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity; and (2) is consistent with the fair market value of the value-based activities provided under the arrangement. TAF believes these safeguards are vital to preventing abusive relationships.

d. Excluded Entities

The Proposed Rule's VBA/VBE exceptions define VBE participant as "an individual or entity that engages in at least one value-based activity as part of a value-based enterprise" without additional restrictions or detail as to who can be a party to VBEs. CMS queries in the preamble whether it should exclude "a pharmaceutical manufacturer; a manufacturer, distributor, or supplier of durable medical equipment, prosthetics, orthotics, or supplies (DMEPOS); or a laboratory" from VBE participation.

If the Secretary adopts a VBA/VBE exception, this restriction is necessary. As CMS stated in the preamble, laboratories, pharmaceutical manufacturers, and DMEPOS manufacturers,

distributors and suppliers do not meaningfully provide in-kind services or technology to facilitate the provision or coordination of patient care.

Additionally, we agree with CMS's additional proposal to exclude from the exception pharmaceutical wholesalers, distributors, and suppliers. Pharmaceutical wholesalers, distributors, and suppliers play the same role in the healthcare ecosystem as DME distributors and suppliers, and their ability to engage in fraudulent conduct implicates the same risks of overutilization, increased Government healthcare costs, profit-tainted medical decisions, and unfair competition.

In some circumstances, pharmaceutical wholesalers' incentives also are identical to those of pharmaceutical and DMEPOS manufacturers. Like manufacturers, pharmaceutical wholesalers may profit from the overutilization of drugs, and they may benefit from prescription of expensive, high-margin drugs rather than equally appropriate inexpensive, low-margin drugs. Remuneration schemes involving pharmaceutical and DMEPOS manufacturers are so inherently suspect that they should be excluded from any VBE/VBA exceptions. For the same reasons, pharmaceutical wholesalers, distributors, and suppliers should also be precluded from using the pretext of "value-based arrangements" to steer their customers toward overutilization or higher-priced drugs.

e. Potential Alternative to the VBE/VBA Exceptions

As described above, our principal concern is that the VBE/VBA exception is too broad, too vague, and too deferential to healthcare entities' subjective determinations. It is impossible to determine what arrangements healthcare entities will implement in response to these exceptions, whether they will actually increase the quality of care for government healthcare program beneficiaries, or whether there is any way to prevent those new arrangements from resulting in overutilization and increasing government healthcare costs. As written, the proposed exceptions likely will prevent the government from identifying and redressing abusive arrangements.

At the same time, we recognize CMS's desire to empower healthcare entities to create innovative plans that improve care coordination and management and reduce healthcare costs. One way to achieve that goal without enabling the use of "value" as a pretext for abusive arrangements is to implement an exception for pre-approved arrangements that promote care coordination and management, reduce costs, or facilitate a transition to value-based care.

Much of the work necessary for such an exception has already been accomplished. Rather than leaving to the VBEs the decision regarding whether an arrangement is likely to promote patient care or reduce costs, the exception could grant the government, not the VBEs themselves, the authority to decide whether an arrangement is likely to promote patient care or reduce costs.

This pre-clearance structure would achieve several important goals. First, it would require healthcare entities to justify at the outset (rather than after-the-fact) why their proposed arrangements benefit patients or payors. Second, it would empower the Government to identify and prevent abusive practices, rather than allowing the participants in those practices to veto administrative judgments by adverting to their subjective intent or belief that their practices might later lead to beneficial results. Third, it would eliminate the uncertainty caused by the

vagueness of the proposed VBE/VBA exceptions and enable all parties to know exactly what arrangements are permissible before they commence, rather than forcing parties to enter into those arrangements without knowing whether the Government (or a court) would find them unlawful.

The logistics would not be much more arduous that the current requirements if entities have questions regarding the lawfulness of certain arrangements. Often entities request advisory opinions in order to decide whether arrangements are likely to be found lawful. Those parties who desire to understand how the government would react to their arrangement are familiar with this process and the slight delay at the outset would likely prove beneficial to all parties.

5. Designated Health Services (proposed 42 C.F.R. § 411.351)

TAF is concerned that the proposed changes to the definition of "Designated Health Services" (DHS) will confuse rather than clarify what constitutes a DHS and will leave open large loopholes through which physicians can improperly profit.

Under the current implementation of the Stark Law, financial relationships between physicians and acute-care (inpatient) hospitals are squarely within the definition of Designated Health Services.

The existing regulations**,** at 42 C.F.R. § 411.351, define DHS as follows:

> Designated health services (DHS) means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:
>
> (i) Clinical laboratory services.
> (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.
> (iii) Radiology and certain other imaging services.
> (iv) Radiation therapy services and supplies.
> (v) Durable medical equipment and supplies.
> (vi) Parenteral and enteral nutrients, equipment, and supplies.
> (vii) Prosthetics, orthotics, and prosthetic devices and supplies.
> (viii) Home health services.
> (ix) Outpatient prescription drugs.
> (x) Inpatient and outpatient hospital services.
>
> Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at § 416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for

> example, all services provided as home health services or inpatient and outpatient hospital services are DHS).

The Proposed Rule defines DHS as:

> DHS means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section:
>
> > (i) Clinical laboratory services.
> > (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services.
> > (iii) Radiology and certain other imaging services.
> > (iv) Radiation therapy services and supplies.
> > (v) Durable medical equipment and supplies.
> > (vi) Parenteral and enteral nutrients, equipment, and supplies.
> > (vii) Prosthetics, orthotics, and prosthetic devices and supplies.
> > (viii) Home health services.
> > (ix) Outpatient prescription drugs.
> > (x) Inpatient and outpatient hospital services.
> >
> > Except as otherwise noted in this subpart, the term "designated health services" or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at § 416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS). *For services furnished to inpatients by a hospital, a service is not a designated health service payable, in whole or in part, by Medicare if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Care Hospital Inpatient Prospective Payment System (IPPS).*

(emphasis added).

Thus, the proposed regulations are identical to the existing regulations, except for the removal of DHS paid by Medicare under a Diagnostic Related Group, or "DRG." There are nearly 1,000 DRGs, and it is rare for a Medicare Part A inpatient hospitalization *not* to be covered by one.[5]

[5] The list of DRGs for 2020 appears at https://www.icd10data.com/ICD10CM/DRG (last visited on December 16, 2019).

According to a prominent industry-side law firm:

> CMS proposes to revise the definition of "designated health services" (DHS) to clarify that a service provided by a hospital on an inpatient basis does not constitute a DHS if the furnishing of the service does not affect the amount of Medicare's payment to the hospital under the Acute Hospital Inpatient Prospective Payment System (IPPS). *The rationale here is that physicians have no financial incentive to over-prescribe services that do not affect the rate of payment.*[6]

In fact, however, this rationale is neither stated in the Proposed Rule nor a reasonable prediction of the behavior of either physicians or hospitals should this change be made. CMS asserts that "this proposed rule will have significant, ongoing benefits for the affected physicians and entities and the entire health care system" (84 Fed. Reg. 55837), but neither the agency nor the industry commenters provide significant guidance with respect to arrangements which would be DHS under existing regulations, but would *not* be DHS under the Proposed Rule.

It appears to us that allowing physicians to own ancillary service providers in acute-care facilities poses an outsized risk of intermingling the financial interests of hospitals and physicians. Based on the plain language of the proposal, it appears that physicians could control large swaths of hospital services without Stark Law implications. For example, the group of orthopedic specialists that serves a hospital's inpatient population, including Medicare patients, could own the imaging facilities to which the hospital refers its patients and profit from all imaging referrals made by the hospital. Similarly, the hospital's pathology staff could own and profit from the referral stream generated throughout the hospital. In such a situation, the pathologists might not be referring *directly* to their facility, but the entire treating-physician staff would, and this relationship easily could be managed in a way that generates revenue for the pathologist-owners as a form of compensation for referrals.

On its face, this amendment would legitimize myriad currently-prohibited referral relationships that enrich physicians and risk skewing patient care. For example, a physician who owns a clinical lab could cause a hospital to enter into an agreement to refer its laboratory requirements to his facility, then refer his patients to that hospital, which would directly result in profit to the physician. This change strikes at the heart of the Stark Law, an essential purpose of which is to place physicians in a position where finances do not influence their decisions and thus increase costs or impact patient care.

If the proposed amendments are adopted, lab services, therapy services, radiology and imaging services, DME, and the other very broad service lines identified in the existing regulation (and repeated in the Proposed Rule) will undoubtedly migrate to entities owned by physicians who refer to the hospitals that hire their companies and fail to refer to hospitals which do not.

---

[6] Article, "HHS Proposes Sweeping Changes to AKS and Stark Law, Part 4: Modifications to Key Stark Law Terminology and a New Stark Law Exception," Available online at https://www.mintz.com/insights-center/viewpoints/2146/2019-11-hhs-proposes- sweeping-changes-aks-and-stark-law-part-4 (last viewed December 16, 2019) (emphasis supplied).

The Stark Law is the primary safeguard preventing the intertwining of the financial interests of physicians and hospitals. Eliminating that safeguard by removing all Part A relationships from the Stark Law will likely give rise to a significant risk that patients will be referred for inpatient services when outpatient services might be best for the patient, and that physicians will base their choice of hospitals not on the needs of the patient, but on the hospital's choice of tertiary providers and supplies.

Such a change would also cause entrenchment of relationships between hospitals and physicians depending not on the skills of the doctor, but on the services the doctor provides to the hospital. Doctors would have increased leverage over hospitals to affect their credentialing decisions and hospitals would have strong incentives to favor doctors who own their suppliers.

We also observe that the stated purpose of the elimination of DHS with respect to services and goods covered by Part A DRGs ignores significant purposes underlying Stark. The agency asserts that it has "taken great care to ensure the safeguards against program and patient abuse in our proposed new exceptions impose the minimum burden possible while providing full protection against overutilization and other harms against which the physician self-referral law is designed to protect." (84 Fed. Reg. 55837) In fact, the fundamental purpose of the Stark Law is to eliminate any financial motivation for physicians to send patients for unnecessary services that could raise overall healthcare costs. If the owner of a pathology lab or an imaging apparatus receives remuneration from a hospital each time a patient uses those services, it is unlikely, and certainly not evidenced by any real world examples, that the regulatory change will benefit patients. However, it is patently clear that it would benefit physicians who invest in DHS providers to which hospitals are free to refer Medicare patients.

There is no evidence in the Proposed Rule or otherwise of a groundswell of opposition to the existing definition of DHS. Even the Senate Finance Committee in its Majority Staff Report, *Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models*[7] proposed only changes relevant to alternative payment models. DRG payments are hardly experimental; they have been in effect for decades. And there is nothing about the proposed DHS change that complements the stated purpose of the proposed regulations, which is "To Support Value-Based and Coordinated Care." Physician ownership of DHS providers serves no purpose other than the enrichment of those owners.

In short, neither the proposed regulations, agency commentary, nor the comments of providers and their lawyers suggests any significant problem with the existing definition of DHS. On the other hand, the agency acknowledges that the change has not been studied and its potential effects are unknown. Indeed, the Proposed Rule asserts:

> We do not have data on the number of physicians and entities that furnish designated health services payable by Medicare that have financial relationships, but we believe a substantial fraction of Medicare enrolled physicians, group practices, hospitals, clinical laboratories, and home health agencies are affected

[7] Available online at https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf (last viewed December 16, 2019).

> by the physician self-referral law. We anticipate that this proposed rule will have significant, ongoing benefits for the affected physicians and entities and the entire health care system.

84 Fed. Reg. at 55837.

It is inconsistent with the rule-making process that not even the regulators can anticipate what the real-world impact of this proposed change will be, except that it will likely eliminate inpatient hospitalizations from the reach of the Stark Law. There is no evidence that the proposed changes would bring "benefit to the entire health care system." Instead, the proposed amendment will potentially allow physicians to make huge profits on referrals from hospitals where they refer patients. That result is unsound and is patently inconsistent with the legislative purposes of Stark.

The definition of DHS is not broken. There is no sound policy reason for physicians to be able to own ancillary providers which service facilities to which they refer patients, and whose physicians refer patients to them. The proposed regulation fixes nothing; rather, it opens up new pathways for physicians to improperly profit. The proposed additions to the definition of DHS should be excluded from any final rule.

6. Personal Services Arrangement Exception (proposed 42 C.F.R. § 411.357)

TAF opposes the Proposed Rule with respect to the Personal Services Arrangements exception.

The Personal Service Arrangement Exception (PSAE) to the Stark Law ensures that when hospitals, clinics, hospices, and any other Entity agree to make payments to physicians, those agreements are properly memorialized and, consistent with legal requirements, including fair market value. In order for the PSAE to apply, the arrangement must comply with specific requirements, currently set out at 42 C.F.R. § 411.357(l). The first of these is that "*[t]he arrangement is set out in writing, is signed by the parties, and specifies the services covered by the arrangement.*" (emphasis added). In 2015, the rule was modified to permit an arrangement to be documented by a "collection of documents" under certain circumstances:

> Depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing.

80 Fed. Reg. 70886, 71314.

These requirements are important. As one court recently said:

> This writing requirement is not a mere technicality. The Stark Act 'insist[s] on the transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties which specifies all of the services to be provided by the physician and all of the remuneration to be received for those services.'

United States ex rel. Emanuele v. Medicor Assocs., 242 F. Supp. 3d 409, 419-20 (W.D. Pa. 2017), *quoting United States ex rel. Kosenske v. Carlisle HMA, Inc*., 554 F.3d 88, 96 (3d Cir. 2009).

In 2018, as part of the Bipartisan Budget Act, Congress modified the Stark Law with respect to the writing requirement. It now provides:

> (E) Special rule for signature requirements. In the case of any requirement pursuant to this section for a compensation arrangement to be in writing and signed by the parties, such signature requirement shall be met if—
>
> (i) not later than 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant, the parties obtain the required signatures; and
>
> (ii) the compensation arrangement otherwise complies with all criteria of the applicable exception.

42 U.S.C. § 1395nn(h)(1)(E).

In the experience of TAFEF members, one of the most common ways that providers disguise payments to physicians in order to provide incentives for referrals is "medical director" arrangements, pursuant to which entities (often hospitals, hospices, clinics, or long-term-care facilities) make payments, often amounting to tens of thousands of dollars per year, to physicians in exchange for few or no "services." We recognize that many medical director arrangements result in appropriate oversight and supervision, but many cases demonstrate that medical director contracts are fertile ground for abuse.[8]

The existing regulations are consistent with the 2018 BBA provisions and already allow considerable latitude for the signing of contracts providing for payments to referring physicians for nonreferral "personal services" at 42 C.F.R. § 411.353(g):

> **(g) Special rule for certain arrangements involving temporary noncompliance with signature requirements.**
>
> (1) An entity may submit a claim or bill and payment may be made to an entity that submits a claim or bill for a designated health service if -

---

[8] See e.g. *United States ex rel. Pogue v. Diabetes Treatment Ctrs. of Am*., 565 F. Supp. 2d 153 (D.D.C. 2008) (medical director contracts may violate the Anti-Kickback Statute); *Emanuele*, 242 F.Supp. 3d 409 (medical director contracts found to violate Stark writing requirement); *Renal Physicians Assn v. United States HHS*, 489 F.3d 1267, 1277-78 (medical director contracts implicate Stark).

> (i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in this subpart except with respect to the signature requirement of the exception; and
>
> (ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant and the compensation arrangement otherwise complies with all criteria of the applicable exception.

The Proposed Rule goes much further under the guise of "reconsider[ing] our policy on temporary noncompliance with the signature and writing requirements of various compensation arrangement exceptions." 84 Fed. Reg. at 55813-14. The Proposed Rule would permit the parties to a referral agreement – regardless of whether the failure is intentional and as often as they want – to take up to 90 days to generate (1) a document or (2) a "compilation" of documents; and (3) a final, signed document:

> Under this proposal, the writing requirement or the signature requirement would be deemed to be satisfied if: (1) The compensation arrangement satisfies all requirements of an applicable exception other than the writing or signature requirement(s); and (2) the parties obtain the required writing or signature(s) within 90 consecutive calendar days immediately after the date on which the arrangement failed to satisfy the requirement(s) of the applicable exception. We note that the writing and signature requirements would not be mutually exclusive under the proposal; that is, a party could rely on proposed § 411.354(e)(3) if an arrangement was neither in writing nor signed at the outset, provided both the required writing and signature(s) were obtained within 90 days and the arrangement otherwise satisfied all the requirements of an applicable exception. For arrangements that are 90 days or less, such as short term arrangements as permitted under the exception for fair market value compensation at § 411.357(l), if the parties never obtain the required writing or signature(s), the arrangement could never have complied with an exception in § 411.357 that includes a writing or signature requirement; therefore, the special rule at § 411.354(e)(3) is not available to protect such arrangements. However, depending on the facts and circumstances, the proposed exception for limited remuneration at § 411.357(z), which does not include a writing or signature requirement, if finalized, might be available to protect the short term arrangement.

Thus, parties to these arrangements could routinely intentionally, and repeatedly enter into an oral agreement involving the payment of thousands of dollars to doctors and wait three months before even writing the arrangement down, much less signing it.

TAF does not share the agency's belief that this change does not increase the likelihood of illegal referrals and payments. For example, a physician might be dissatisfied with the amount being paid pursuant to the "grace period" arrangement and leverage an entity to make higher payments by withholding referrals to secure higher-than-agreed-upon payments. Or, perhaps more likely, an entity might conclude after the trial run that it is not getting the referrals it thought it was paying for and decide to leverage the payments downward. In neither case would there be

anything to show that the original agreement was not what the parties eventually signed. These agreements would be virtually impossible to detect and regulate, whether administratively or through litigation under the False Claims Act.

We have no doubt that, as the Proposed Rule asserts, there are many arrangements which would be perfect but for the failure to get a signature. However it is difficult to believe that parties who assiduously comply with all other requirements would not circulate documents for signature, and it does not seem burdensome to require a writing and signature upfront with respect to something as important as a physician's contract. No explanation is given for why the failure to document and execute a valuable contract should be excluded for a single class of government contractor. Rather, it appears that the agency has proposed a carve out for those who want to cut corners or disguise misconduct or fraud.

Most troubling is the proposal allowing protracted noncompliance with both the signature and the writing requirements. The Proposed Rule expressly notes "that the writing and signature requirements would not be mutually exclusive under the proposal; that is, a party could rely on proposed § 411.354(e)(3) if an arrangement was neither in writing nor signed at the outset, provided both the required writing and signature(s) were obtained within 90 days and the arrangement otherwise satisfied all the requirements of an applicable exception."

The elimination of the documentation requirement exceeds the bounds of the 2018 amendment to the Stark Law, which allows a 90-day "grace period" for the signature requirement. The Proposed Rule would allow doctors and entities to enter into oral or informal agreements, which are inconsistent with the "transparency and verifiability that comes from an express agreement reduced to writing and signed by the parties," as the Stark Law requires. By entering into rulemaking that contradicts the purpose and the language of the statute, the agency exceeds its rule making authority.

The Proposed Rule tacitly concedes as much. The stated rationale is that the agency reviewed many arrangements that, but for a signature, would be fully compliant with the law. But in order to be compliant, an arrangement must be properly documented. The Proposed Rule, by implementing an ipse dixit modification to the documentation requirement, allows everything related to the arrangement to be delayed for three months on an annual basis.

Moreover, the Proposed Rule makes no attempt to square the elimination of the writing requirement for the first three months each year of a personal services contract with the plain language of the BBA, enacted little more than a year ago. Congress meant what it said, which was to allow 90 days for the signature requirement alone, but it did not stop there. It said that the 90-day period may be invoked *only when the compensation arrangement otherwise complies with all criteria of the applicable exception* — i.e., when there is a proper writing that needs only to be signed. That is not what is proposed here.

The Proposed Rule could roll back Stark Law requirements regarding the origination and early implementation of personal service agreements. Even if the agency were prepared to actively police compliance on the 91st day–or within some reasonable time thereafter–there would be no excuse for the effective abrogation of the Stark Law for three of every 12 months.

Because the Proposed Rule is unsound and, inconsistent with an Act of Congress, the proposed changes to the writing requirement should be excluded from any final rule.

Conclusion

TAF appreciates your consideration of these comments. If you have any questions or would like any additional information, please do not hesitate to contact us.

Sincerely,

s/ Jacklyn DeMar

Jacklyn DeMar, Director of Legal Education
TAF Education Fund
1220 19th Street NW, Suite 501
Washington, DC 20036
(202) 296-4826, ext. 1300
jdemar@taf.org

/s/ Robert Patten

Robert Patten, President and CEO
Taxpayers Against Fraud
1220 19th Street NW, Suite 501
Washington, DC 20036
(202) 296-4826, ext. 1000
rpatten@taf.org