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VIA EXPRESS MAIL

December 18, 2019

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Regulations to the Physician Self-Referral Law
File Code CMS-1720-P

To the Centers for Medicare & Medicaid Services:

This comment letter is submitted in response to the Proposed Regulations to the Physician Self-Referral Law (also known as the "Stark Law") that were published by CMS in the October 17, 2019 Federal Register and the Preamble thereto (the "Proposed Regulations"). In general, we believe the Proposed Regulations are a significant positive development. In particular, this letter will comment on the Proposed Regulations that address barriers to achieving clinical and financial integration posed by the Physician Self-Referral Law generally and, in particular, the fair market value, commercial reasons and "volume or value" standards set out in the Proposed Regulations.

The law firm of Horty, Springer & Mattern, P.C. devotes its practice exclusively to hospital and health care law. We work with health care providers throughout the country, consulting with hospital boards, hospital management, hospital attorneys and medical staff leaders. Since we represent primarily hospitals, we are intimately familiar with regulatory implications of the financial relationships between physicians and entities that provide designated health services, especially hospital inpatient and outpatient services. We routinely prepare and negotiate hospital-physician arrangements, advise our clients about them, and represent clients in mergers, acquisitions and in False Claims Act litigation when such arrangements may be questioned. We

also represent clients who have made self-disclosures regarding physician-hospital arrangements to CMS's SRDP. In submitting these comments, we are not acting on behalf of any client.

Hospitals and health systems must enter into a wide variety of compensation arrangements with physicians in order to carry on their day-to-day operations. Nonprofit charitable hospitals have additional needs for physician relationships essential to carry out their charitable mission. Rural and inner-city hospitals have additional challenges in meeting the needs of their communities for quality physician services. The Proposed Regulations have addressed many of the difficult situations that confront hospitals when considering compensation arrangements with physicians in a reasonable manner that will further the provision of quality health care.

Prior to the Proposed Regulations, the Stark Law, as it has been implemented by CMS in its regulations and regulatory commentary, applied by the Department of Justice and relators in False Claims Act ("FCA") cases, and interpreted by the courts have presented not only perceived but very real barriers to achieving clinical and financial integration of physicians and hospitals required to reduce costs, coordinate care, and deliver value. The Proposed Regulations do an excellent job of removing many of these barriers. We commend CMS for this and urge CMS to issue the Proposed Regulations in final form without delay.

(1) ESSENTIAL ELEMENTS OF A VIOLATION OF THE STARK LAW

A Stark analysis begins by determining whether the Stark Law applies to a particular transaction. To the extent that the Stark Law applies, then the transaction must be categorized and either a statutory or regulatory exception must be satisfied. 42 U.S.C.A. § 1395nn(a)(1). If a financial relationship between the DHS entity and a physician (or immediate family member) exists and all of the requirements of an exception are not satisfied, then no claim may be submitted to the Medicare program and any amount that was paid to a DHS entity while the prohibited arrangement was in effect must be refunded. 42 U.S.C.A. § 1395nn(a)(1)(A)-(B). The period of time during which referrals are prohibited is referred to as "the period of disallowance," a term that CMS has also clarified. *See* 84 Fed. Reg. 55,766, 55,808-11 (Oct. 17, 2019).

Simply put, a Financial Arrangement does not violate the Stark Law unless the arrangement does not satisfy an exception. 84 Fed. Reg. at 55,767. Therefore, the failure to satisfy an exception is an essential element of a *prima facia* case that a DHS entity has failed to comply with the Stark Law, not an affirmative defense.

Many courts have failed to recognize this fact. For example, in *U.S. ex rel. Bookwalter v. University of Pittsburgh Medical Center*, the Court states that a *prima facia* case "has three elements: (1) a referral for designated health services, (2) a compensation arrangement (or an ownership or investment interest), and (3) a Medicare claim for services." 938 F.3d 397, 406 (3d. Cir. 2019) (citing *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 241 (3d. Cir. 2004)). Therefore, the *Bookwalter* court and other federal courts have failed to recognize that a fourth

element of a *prima facia* case of an alleged violation of the Stark Law is that the Stark Law has not been violated "unless an exception applies." 84 Fed. Reg. at 55,767.

We would recommend that CMS include commentary in the Preamble to the final regulations when discussing the structure of the Stark Law to instruct the federal courts that in FCA cases based on the Stark Law, the plaintiff must plead sufficient facts with the particularity needed to satisfy the heightened pleading standards of Rule 9(b) of the Federal Rules of Civil Procedure that the DHS entity has failed to satisfy an exception to the Stark Law is an essential element of a *prima facia* case of an alleged violation of the Stark Law.

As such, a DHS entity's argument that it has complied with an exception could be considered at the Motion to Dismiss stage of the litigation. A DHS entity should not be required to prove that it satisfied an exception as an affirmative defense that may only be raised following discovery. *See Bookwalter*, 938 F.3d. at 407, 416-17 (citing *U.S. ex rel. Kosenske v. Carlisle HMC, Inc.*, 554 F.3d 88 (3d Cir. 2009). We also urge CMS to continue to remind courts that the courts should be interpreting "the referral and billing prohibitions narrowly and the exceptions broadly...." 84 Fed. Reg. at 55,771.

The Stark Law has, with few exceptions, been enforced through the FCA, almost exclusively by private parties serving as *qui tam* relators. *See, Bookwalter,* 938 F.3d at 406. Requiring defendants to plead exceptions as an affirmative defense forces the defendant to incur unnecessary costs of discovery, and can lead to a DHS entity settling a frivolous claim that it has violated the Stark Law regardless of the parties' good faith efforts to comply with the law.

(2) CMS REGULATORY SPRINT TO THE FINISH

The Stark Law is deceptively simple to summarize. However, in the real world in which hospitals and other DHS entities must operate, the concept that all of a physician's referrals are prohibited unless an exception applies has caused compliance to be difficult and complex, causing one judge to state:

> I write separately to emphasize the troubling picture this case paints: An impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area.
>
> * * *
>
> Despite attempts to establish "bright line" rules so that physicians and healthcare entities could "ensure compliance and minimize costs," 66 Fed. Reg. 856, 860 (Jan. 4, 2001), the Stark Law has proved challenging to understand and comply with. Indeed, "the

> Stark law is infamous among health care lawyers and their clients for being complicated, confusing and counterintuitive; for producing results that defy common sense, and sometimes elevating form over substance. Ironically, the Stark law was actually intended to simplify life by creating 'bright lines' between what would be permitted and what would be disallowed, and creating certainty by removing intent from the equation." Charles B. Oppenheim, the Stark Law: Comprehensive Analysis + Practical Guide 1 (AHLA 5th ed. 2014). Some of the invective used to describe the Stark law even borders on lyrical: "ambiguous, arcane, and very vague;" and "heaps of words in barely decipherable bureaucratese." Steven D. Wales, The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals, 27 Law & Psychol. Rev. 1, 22-23 (2003) (quotation marks and citations omitted).
>
> * * *
>
> In the context of the Stark Law, it is easy to see how even diligent counsel could wind up giving clients incorrect advice.
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> * * *
>
> This case is troubling. It seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act.

U.S. ex rel. Drakeford v. Tuomey, 792 F.3d 364, 393-95 (4th Cir. 2015) (Wynn, J., concurring).

As described in the Preamble to the Proposed Regulations, several federal courts, including the 4th Circuit in the *Tuomey* case cited above, have made compliance with the Stark Law much more complicated than intended by Congress. The Proposed Regulations return the Stark Law to its original intent and also provide much needed guidance for future participation in Value-Based Enterprises.

The Proposed Regulations also have taken a significant step towards removing unnecessary, burdensome and unintended obstacles to care coordination that will allow CMS to complete its planned "Regulatory Sprint to Coordinated Care." In so doing, CMS has also provided much needed guidance to the field and the Proposed Regulations reflect CMS's experience with the SRDP and "insight into thousands of financial relationships – most of which were compensation arrangements – that ran afoul of the physician referral law, but posed no real risk of Medicare

program or patient abuse." 84 Fed. Reg. 55,771. As a result, the federal courts, should defer to CMS's expertise in this matter. *See Kisor v. Wilkie,* No. 18-15, 139 S.Ct. 2400 (2019).

(3) PROPOSED CHANGES TO DEFINITIONS

The Stark Law, like many laws, is definition-driven. The definitional changes CMS has made will improve compliance with the Stark Law and will decrease the cost of compliance by more accurately reflecting the original intent of the Stark Law.

(a) Does Not Violate Anti-Kickback Statute – Part D, Section 1

The Stark Law was intended to provide "bright line" rules, 139 Cong. Rec. E84-01 (January 6, 1993). However, a number of current Stark Regulations[1] require that the arrangement "does not violate the anti-kickback statute."

This term has then been given the vague, circular definition in 42 C.F.R. § 411.351 as an arrangement that satisfies a safe harbor (42 C.F.R. § 1001.952, et seq.), where the parties obtain an advisory opinion from the OIG, or where the arrangement "does not violate the anti-kickback provisions in Section 1128B(b) of the [Social Security] Act."

CMS correctly recognized that the intent-based nature of the AKS creates a level of uncertainty as to whether a particular transaction satisfies the "does not violate the AKS" requirement in a Stark exception any time a transaction is outside of a safe harbor (which are voluntary and often very narrow), or when the parties do not extend the time and cost of obtaining an advisory opinion from the OIG (which is also voluntary).

As such, the definition of "does not violate the AKS" did little to provide the "bright line" guidance required for compliance with the Stark Law any time this term is included in an exception without practical safe harbors that are consistent with the exceptions to the Stark Law. This requirement also ignores the fact that the Stark Law is a "threshold statute" and that a transaction must then comply with the AKS. *See* OIG Supplemental Compliance Guidance for Hospitals, 70 Fed. Reg. 4,858, 4,862-63 (Jan. 31, 2005).

We applaud CMS's proposal to decouple the Stark Law from the Federal Anti-Kickback statute and from federal and state laws governing billing or claims submission by deleting the definition "does not violate the Anti-Kickback Statute" from the definition section of the Proposed Regulations and by deleting this term wherever it was used in the Stark Regulations. We urge CMS to finalize these proposed changes.

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[1] 42 C.F.R. § 411.357(e)(4)(vii); 42 C.F.R. § 411.357(j)(3); 42 C.F.R. § 411.357(k)(1)(iii); 42 C.F.R. § 411.357(l)(5); 42 C.F.R. § 411.357(m)(7); 42 C.F.R. § 411.357(p)(3); 42 C.F.R. § 411.357(r)(2)(x); 42 C.F.R. § 411.357(s)(5); 42 C.F.R. § 411.357(t)(3)(iv); 42 C.F.R. § 411.357(u)(3); 42 C.F.R. § 411.357(w)(12); 42 C.F.R. § 411.357(x)(1)(viii); 42 C.F.R. § 411.357(y)(8).

(b) Commercially Reasonable – Section II, Part B, Fundamental Terminology and Requirements – Section 2

CMS's proposal to add the definition of the term "commercially reasonable" in 42 C.F.R. § 411.351 is a significant contribution to compliance with the Stark Law and is consistent with CMS's prior commentary in which CMS has specifically mentioned "compensation arrangements involving 'mission support payments' and 'similar payments' ('support payments')" in the Preamble to the Phase 4 Rules. 73 Fed. Reg. 48,433, 48,691 (Aug. 19, 2008).

Prior to the Proposed Regulations, CMS has never defined the term "commercially reasonable," let alone describe the interrelation of the Commercial Reasonableness, Fair Market Value, and Volume or Value Standards. The proposed definition of "commercially reasonable" and the analysis of physician compensation in the Preamble of the Proposed Regulations, has presented a thorough and thoughtful discussion of the principles underlying physician compensation. CMS has made it clear that there is no presumption that a hospital or hospital-affiliated entity which compensates a physician an amount in excess of the third party, professional reimbursement that is paid to the employer for that physician's professional services is not "commercially reasonable" or that the DHS entity is compensating the physician in a manner that is based on, or takes into account, the volume or value of the physician's referrals to the hospital.

(c) Fair Market Value's Circular Definition and the Volume or Value Standard – Section II, Part B Fundamental Terminology and Requirements, Section 3

CMS's proposed definitions of "fair market value," "general market value" and its clarification of the "volume or value standard" have addressed a number of significant concerns. The Proposed Regulations correct a circular definition that will make compliance with the Proposed Value-Based Rules discussed below all but impossible.

The current regulations, at 42 C.F.R. § 411.351, define "fair market value" in pertinent part as follows:

> Fair market value means the value in arm's-length transactions, consistent with the general market value. "General market value" means the price that 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. 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**.... (Emphasis added.)

On the other hand, the volume or value standard, while not defined in the body of the current regulations, has been described in CMS commentary as follows:

> A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance **and will result in fair market value compensation**, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated. (Emphasis added.)

66 Fed. Reg. 855, 877-78 (Jan. 4, 2001).

In other words, to comply with the fair market value standard in the current regulations, a compensation arrangement must not take into account the volume or value of referrals, but the compensation arrangement will not take into account the volume or value of referrals only if it results in fair market value compensation. This definition is circular and is not consistent with the statute.

The definitions of "Fair Market Value" and "General Market Value" that have been included in the Proposed Regulations have eliminated this circular definition. The proposed definitions have simplified the definitions of these critical terms, have provided much needed guidance, and are consistent with the statute's definition of "fair market value," which does not mention the volume or value standard. 42 U.S.C. § 1395nn(h)(3). Nor should there be a reference to the volume or value standard, since, as described with great clarity in the Proposed Regulations, these are two separate and independent concepts.

As CMS has repeatedly stated, the requirement that compensation not vary with or take into account the volume or value of physician referrals, which appears in a number of statutory or regulatory exceptions, should be uniformly interpreted wherever it appears. Such uniform interpretation is essential. However, as pointed out in the Preamble to the Proposed Regulation, some courts have interpreted the volume or value standard to consider the subjective intent of the parties, rather than applying an objective "bright line" test as Congress intended, making compliance with the statute much more difficult and uncertain than intended by the statute. In addition, prior CMS commentary has added to this confusion by applying the volume or value

standard to other exception criteria, such as the definition of fair market value, thereby conflating two standards that were intended to stand on their own. CMS should issue further guidance in the Final Regulation to address this confusion.

The proposed definitions of "Fair Market Value," "General Market Value," "Commercial Reasonableness," the amendments to the Volume or Value Standard in 42 C.F.R. § 411.354(d)(5)-(6), and CMS's description of how these terms should be applied have addressed these concerns. We urge CMS to issue these Proposed Regulations in final form.

(d) Definition of Physician and Clarification of Referring Physician

Defining the term "Physician" by referring to Section 1861 of the Act is consistent with the statute and should be finalized. *See* Fed. Reg. at 55,805-06.

We also appreciate CMS recognizing that the statute provides in pertinent part: "the request or establishment of a plan of care by a physician which includes the provision of the designated health services constitutes a 'referral' by a 'referring physician.'" 42 U.S.C. § 1395nn(h)(5)(B). We applaud CMS's analysis in 84 Fed. Reg. at 55,787 and agree with CMS amending 42 C.F.R. § 411.354(c)(2)(ii) to limit the definition of "referring physician" to the physician who actually orders the outpatient hospital service or inpatient hospital admission, and to exclude any other physician who may provide professional services to a patient who has been "referred" for a DHS by another physician.

Without this clarification, some federal courts have permitted *qui tam* relators to attempt to prove unlawful referrals by simply offering into evidence summaries of UB-04 claims forms that identify "attending" or "operating" physicians and which were never intended to identify the "referring physician." This error has caused some to allege that the "tainted" claims include claims where the physician in question is simply listed on the claim form, even if that physician did not "refer" the patient to the DHS Entity. This has resulted in wildly inflated damage awards that were never intended by the statute. This will be addressed through this proposed change.

(e) Definition of Remuneration – Section D: Recalibrating the Scope and Application of the Regulations, Part 2, Definitions Section (d)

The term "remuneration" is defined in a circular manner in the statute as including "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1395nn(h)(1)(B). Thus, CMS has statutory authority to clarify this definition. However, the current definition of remuneration at 42 C.F.R. § 411.351, which includes "any payment or other benefit," is too broad.

We agree with the CMS commentary in the Preamble. *See*, 84 Fed. Reg. at 55,806-07. However, in order to make CMS's position with regard to this criteria term as clear as possible, and consistent

with OIG guidance on the same issue, we recommend amending the definition of remuneration to state that remuneration is limited to items or services with "independent value to the physician" making the "referral" for the DHS.

OIG advisories have stated that the kind of remuneration that could trigger scrutiny of a transaction under the AKS must involve something of "independent value to the physician." *See,* e.g., Off. of Inspector Gen., Dep't. of Health & Human Servs., Special Advisory Bulletin, ["title"] (Aug. 2002); Off. of Inspector Gen., Advisory Opinion 08-05 (Feb. 27, 2008); Ctrs. for Medicare & Medicaid Servs., Advisory Opinion CMS-no-2008-01 (May 2008); 72 Fed. Reg. 51,012, 51,049 (Sept. 5, 2007). This interpretation of the term "remuneration" is also consistent with previous CMS commentary in which CMS has stated that no remuneration is present when an item or service such as a dedicated computer terminal used only for the hospital's patients and services "strikes us as unlikely to involve remuneration to the physician so long as the computer terminal has 'no independent value' to the physician." 69 Fed. Reg. 16,053, 16,114 (Mar. 26, 2004); *see also,* Letter from Kevin G. MacAnaney, Industry Guidance Branch, "Re: Free Computers, Facsimile Machines and Other Goods" (July 3, 1997), https://org.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm.

(f) Other Definitional Changes – Section D Recalibrating the Scope and Application of the Regulations, Part 2, Definitions

In addition to the definitions that are described above, and elsewhere in this comment letter, we appreciate and agree with the proposed changes to the definitions of "Transaction," "Isolated Financial Transaction," "Cyber Security," "Designated Health Services," "Electronic Health Record," and "Interoperable," and urge CMS to finalize these definitions as proposed.

We urge that CMS do the same for the proposed changes to 42 C.F.R. § 411.553(c), 42 C.F.R. § 411.353(g), 42 C.F.R. § 411.354(b)(3), 42 C.F.R. § 411.54(c)(4), 42 C.F.R. § 411.354(d)(4), (5) and (6), and 42 C.F.R. § 411.354(e).

(4) PROPOSED VALUE-BASED RULES

(a) Value-Based Purchasing, Part I Background, Section B, Health Care Delivery and Payment Reform: Transition to Value-Based Care

The Proposed Regulations have added the definitions of "target patient population," "value-based activity," "value-based arrangement," "value-based enterprise," "value-based purpose," and "value-based participant" to 42 C.F.R. § 411.351 and have added a new exception for "arrangements that facilitate value-based health care delivery and payment" as 42 C.F.R. § 411.357(aa)(1)-(3) (collectively, the "Proposed Value-Based Rules"). We urge CMS to publish the Proposed Value-Based Rules in final form without significant change. The Proposed Value-Based Rules have provided hospitals with much needed, immediate guidance concerning

the ability of a hospital to compensate physicians who assist the hospital under Medicare's Value-Based Purchasing Program ("VBP"). They will also assist physicians and permitted DHS entities who are interested in pursuing any type, form or manner of value-based enterprises ("VBE") permitted by the Proposed Value-Based Rules.

Without the Proposed Value-Based Rules, it will be difficult, if not impossible, for a hospital to achieve the desired goals under the VBP and VBE without the type of physician input and cooperation described in the Proposed Value-Based Rules. The Proposed Value-Based Rules have made a significant contribution by recognizing that the fair market value of physician's input and cooperation in a VBP and/or VBE is generally not reflected in the hourly payment rates for the services actually being provided by a physician to a hospital or other DHS entity. Our only suggestion would be to add more examples of permitted value-based activities, arrangements, and enterprises in the Preamble to the final regulations.

Hospitals in particular need the type of assurance described in the Proposed Value-Based Rules that utilizing a payment methodology that is based, in whole or in part, on the amount of the payment that the hospital receives under the VBP or VBE could not be possible without the services provided by the physicians and will be able to satisfy an exception to the Physician Self-Referral Law.

(b) Gainsharing, Part II, Provisions of the Proposed Regulations, Part B: Proposed Exceptions

Since 2001, the Office of Inspector General for HHS has provided Compliance Program and Advisory Opinion Guidance on gainsharing arrangements. *See* OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4,858, 4,869-70 (Jan. 31, 2005); *See also*, OIG Advisory Opinions 01-01 (Jan. 11, 2001); 05-01 (Feb. 4, 2005); 05-02, 05-03, 05-04 (Feb. 17, 2005); 05-05, 05-06 (Feb. 25, 2005); 06-22 (Nov. 16, 2006); 07-21, 07-22 (Jan. 14, 2008); 17-09 (Jan. 5, 2018).

CMS issued a proposed regulation, Incentive Payment and Shared Savings Programs, on July 7, 2008. 73 Fed. Reg. 38,501, 38,604-06 (Proposed July 7, 2008) (to be codified at 42 C.F.R. §.411.357(x)). However, that proposed regulation differed significantly from OIG's gainsharing guidance. Rather than publish a final regulation, CMS asked for public comment on 55 aspects of the proposed regulation. 73 Fed. Reg. 69,725, 69,795-98 (Nov. 19, 2008).

Prior to the issuance of the Proposed Value-Based Rules, CMS has failed to issue any type of formal guidance on gainsharing or other shared savings programs. However, the Proposed Value-Based Rules have provided this much needed guidance on how to analyze a gainsharing arrangement under the Stark Law. *See* 84 Fed. Reg. 55,777-80. As a result, so long as the Proposed Value-Based Rules are published in final form, no specific incentive payment, shared savings, gainsharing or cost sharing rules are necessary.

(5) PHYSICIAN COMPENSATION

(a) Preamble Analysis

The guidance on physician compensation CMS has provided in the Preamble to the Proposed Regulations is invaluable. We urge CMS to repeat the analysis in the final rules. We also request that CMS update the chart set forth at 69 Fed. Reg. 16,053, 16,067-68 (Mar. 26, 2004) in light of its current position on physician compensation.

It was extremely helpful that the Proposed Regulations recognized that hospitals recruit physicians in a national market and will often employ physicians in needed specialties, even if the patient population served by that hospital will not financially support that service. Such professional services are often needed to further the charitable purposes of the hospital regardless of the profitability of that service.

Hospitals that employ physicians often require those physicians to participate in the Medicare and Medicaid programs, which the third circuit court of appeals has described as being "well known as bottom-billers." *Bookwalter,* 938 F.3d at 413. Hospital employed emergency room physicians are required by the Emergency Medical Treatment and Active Labor Act ("EMTALA") to provide care to all patients presenting to the hospital's Emergency Department in an Emergency Medical Condition without regard to the patient's insurance status or ability to pay. Tax-exempt hospitals must also provide charity care and care to patients who qualify for the hospital's Financial Assistance Program that often result in the hospital and its employed physicians providing professional services at a loss. *See*, 26 U.S.C. § 501(r); 26 C.F.R. §§ 1.501(r)-1-1.501(r)-7. In addition, hospitals have little, if any, ability to control the amount that they are paid by various third-party payors for the professional services provided by employed physicians.

As a result, it is not uncommon for a hospital to pay a physician more in compensation than the hospital will be reimbursed for the professional services that are provided by that physician. In many types of VBE and bundled payment models, it is difficult, if not impossible, to even determine if the hospital is losing money on the professional services being provided to the hospital by the physician.

CMS's past failure to define the term "commercially reasonable" has caused a number of courts, most recently the majority opinion in *Bookwalter,* to adopt the incorrect analysis in *Drakeford* that physician compensation in excess of professional reimbursement is a "red flag." *See Bookwalter,* 938 F.3d at 409-11. Rather, the concurring opinion in the *Bookwalter* case is consistent with CMS's analysis of the proper application of the Stark Law to a case involving hospital-physician compensation. *Id.* at 418-25. Uncorrected, the majority opinion in *Bookwalter* misconstrues the intent of the Stark Law and will make almost all RVU-Based compensation formulas unlawful. That is clearly not CMS's intent.

(b) Over-Reliance on Salary Survey Data

All too often, out of an abundance of caution, hospitals have become over-reliant on published salary surveys. CMS's examples at 84 Fed. Reg. at 55,799 describing how over-reliance on survey data could result in the compensation that may be paid to an orthopedic surgeon would be below market value while the compensation paid to a family practice physician would be above market value have provided clear examples that while salary surveys are excellent benchmarks, they are intended to be nothing more than a benchmark.

CMS's position that no salary survey (or any specific percentile within a salary survey) should dictate the fair market value of a physician's services is consistent with the reality in which hospitals and other DHS entities that employ physicians must operate. Furthermore, the amount currently being charged for widely-used published surveys makes it increasingly difficult for small hospitals or independent physician practices to obtain them. We have been informed by clients and by representatives of national salary surveys that some surveys are now being sold for upwards of $30,000. This also raises the question whether such a survey remains a valid benchmark since the new pricing structure makes it difficult to obtain survey data.

CMS's proposed definitions of fair market value, general market value, and commercially reasonable has reinforced CMS's previous guidance that fair market value should reflect the value of the services rendered, should take into account regional factors and the physician's skills, and should not be based solely on national benchmark data. The Proposed Regulations clarify prior CMS comments in the Stark Phase III regulations in which CMS stated that a prior "fair market value safe harbor" that relied on national numbers could mask significant regional differences, stating:

> Ultimately, the appropriate method for determining fair market value for the purposes of the self-referral law will depend on the nature of the transaction, *its location,* and other factors. (Emphasis added.)

71 Fed. Reg. 51,011, 51,015 (Sept. 5, 2007).

(c) Hospital-Employed Physician Bonus Program

Hospitals would also benefit from further clarification from CMS as to what constitutes "remuneration in the form of a productivity bonus based on services performed personally by the physician (or immediate family member of the physician)" when a hospital employs a physician directly. 42 C.F.R. § 411.357(c)(4) (emphasis added).

For example, many physician groups use an incentive compensation model that is based on the group achieving certain goals. The bonus earned is then often divided equally between and among the physicians in the group. What is unclear is whether a hospital that employs physicians directly pursuant to 42 C.F.R. § 411.357(c) is permitted to have a similar incentive compensation model that permits the employed physicians to share in the professional revenue generated by all of the physicians in a particular specialty.

Such group-based specialties are common in physician organizations and encourage common goals. Unfortunately, the Proposed Regulations did not provide guidance as to whether such a group-based incentive compensation model would constitute compensation that is "based on services performed personally by the physician" for purposes of complying with 42 C.F.R. § 411.357(c)(4). We urge CMS to address this issue when final regulations are issued.

(d) Non-Physician Practitioners

Many hospital-physician clinical integration efforts seek to include non-physician practitioners. However, it is unclear as to whether a hospital that directly employs physicians pursuant to § 411.357(c) and bills for the services of non-physician practitioners who are supervised by those employed physicians under the Medicare "Incident to Rules" is permitted to include that revenue in the hospital's compensation of the supervising physician. Such an arrangement is specifically permitted in a physician group that is organized and operated in a manner described in 42 C.F.R. § 411.352. *See* 66 Fed. Reg. 854, 876 (Jan. 4, 2001).

One of the "significant changes in the delivery of health care" (84 Fed. Reg. at 55,768) since the enactment of the Stark Law has been the role played by non-physician practitioners. However, despite the increase in the utilization of non-physician practitioners since 2001, when the Phase 1 rules were published, for all of the excellent commentary that CMS has included in the Proposed Regulations, CMS failed to update the statement in the Preamble to the Phase 1 rules that stated that "incident to" payments are limited to physicians in a group practice organized and operated pursuant to 42 C.F.R. § 411.352 or to physicians in solo practice. *See* 66 Fed. Reg. 856, 891 (Jan. 4, 2001). This leaves the impression that services provided by a non-physician practitioner under Medicare's "incident to" rules would not constitute "services performed personally by the physician" in the incentive compensation model of a hospital-employed physician for purposes of 42 C.F.R. § 411.357(c)(4).

The Proposed Regulations also failed to address how hospital-employed physicians are to be compensated for providing medical direction to non-physician practitioners. It is also unclear how a hospital employer is to audit or to exclude such reimbursement since CMS did not concur with the recommendation included in the OIG's August 2009 report entitled, "Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services" (OEI-09-06-00430), that CMS should identify "incident to" services not personally performed by a physician by using a service code modifier.

As stated on Page 2 of the May 21, 2009 Memorandum from Charlene Frizzera, Acting Administrator of CMS, to Daniel R. Levenson, Inspector General, that was attached to this OIG Report as Appendix F:

> **OIG Recommendation**
>
> Require physicians who bill for services that they do not personally perform to identify the services on their Medicare claims by using a service code modifier. The modifier would allow CMS to monitor claims to ensure that physicians are billing for services performed by nonphysicians with appropriate qualifications.
>
> **CMS Response**
>
> We non-concur with this recommendation as it is currently structured, not because we disagree with its underlying objective of increasing the available data on services provided "incident to," but because incidental services are often shared by physicians and staff, making definition of a service not "personally performed" operationally difficult. CMS will study the operational issues involved in adding code modifiers to services furnished exclusively by staff other than the physician identified as the rendering provider.

This response appears to state that professional services performed by a non-physician practitioner and billed under the physician's provider number using the "incident to" rules are often "shared by physicians." As such, when final rules are issued, CMS should affirmatively state that "incident to" professional revenue (as well as "split/share" revenue for services provided in hospitals) will be considered to be revenue that is "based on services performed personally" by a hospital-employed physician under 42 C.F.R. § 411.357(c)(4) and treated in the same manner as when the same services are provided in a physician group that is organized and operated pursuant to 42 C.F.R. § 411.352.

We have appreciated CMS's decision to add 42 C.F.R. § 411.357(x) to the current regulation that permits a hospital to provide recruitment assistance to a physician group to assist the physician group to recruit a non-physician practitioner. We also agree with the amendments to this section that have been proposed by the Proposed Regulations.

42 C.F.R. § 411.357(x) recognizes that, as a group, non-physician practitioners are easier to locate, less expensive to recruit, and provide many of the same services as a physician. The Medicare Conditions of Participation ("CoPs") provide that in addition to physicians, a hospital's medical staff may include non-physician practitioners. 42 C.F.R. § 482.22. The CoPs also recognize that

many functions that in the past were only performed by physicians, are currently being provided by non-physicians. *See, e.g.*, 42 C.F.R. § 486.344(a)(2). The CoPs also require non-physician practitioners who provide care in a hospital to be credentialed in the same manner as a physician. Medicare Payment rules permit non-physician practitioners to bill Medicare Part B in the same manner as a physician although they are reimbursed at 85% of the Physician Fee Schedule. Therefore, we agree that the regulations should permit a hospital to provide recruitment assistance to a physician organization to recruit a non-physician practitioner.

However, CMS should not arbitrarily limit the definition of non-physician practitioners who may receive recruitment assistance and fit within the exception to the "non-physician practitioners" defined in 42 C.F.R. § 411.357(x)(viii)(3). We also recommend that this section not limit the medical specialties that may utilize this exception to physicians who provide "primary care services or mental health services." 42 C.F.R. § 411.357(x)(vi)(B). Non-physician practitioners who provide surgery, neurology, urology services, and many other specialties are also areas of acute need for many community hospitals and could benefit from this section.

Therefore, we recommend further amending 42 C.F.R. § 411.357(x) to enable a hospital to provide recruitment assistance to a physician organization to recruit any non-physician practitioner to any physician group regardless of specialty with the greatest amount of flexibility as possible.

(e) Volume or Value Standard B Fundamental Terminology and Requirements, Part 3, the Volume or Value Standard and Other Business-Generated Standards

(i) Objective vs. Subjective Interpretation

A number of recent court cases have stated that if a hospital discusses or analyzes the potential referrals, it "takes referrals into account" thereby tainting an otherwise compliant arrangement, even one that pays a fixed fee. This introduces an element of subjective intent into an ostensibly "bright line" statutory and regulatory scheme.

The volume and value standard says that the compensation cannot "take" into account the volume or value of referrals – not "took." This distinction is crucial. What the parties to an arrangement may have intended to achieve is irrelevant for the purposes of the self-referral law. As CMS pointed out in the Phase 1 regulations: "a compensation arrangement does *not* take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary *over the term of the agreement* in any manner that takes into account referrals." 66 Fed. Reg. at 877-78 (emphasis added).

This analysis is also supported by the legislative history of the self-referral law. Congress said that compensation simply could not "fluctuate *during the contract period* based on the volume or value of referrals between the parties to the lease or arrangement." H.R. Rep. No. 103-111, at 545

(1993), *reprinted in* 1993 U.S.C.C.A.N. 378, 779 (emphasis added). What the parties may have wanted to accomplish through the arrangement is not relevant to the legality of the compensation arrangement under the Physician Self-Referral Law. An unlawful intent is to be addressed by the Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b.

(ii) . Correlation of Professional Services to Technical Fees

CMS's guidance on the Volume or Value Standard in 42 C.F.R. § 411.354(d)(5)-(6), which requires a direct correlation between the physician's referrals and the compensation paid to the physician, is also consistent with the Congressional intent cited above. *See* 84 Fed. Reg. 55,793-94.

(iii) Tiered Compensation

The Preamble to the Proposed Regulations at 84 Fed. Reg. 55,794 state that a "tiered" compensation arrangement where physician compensation increases based on increased referrals for DHS would vary based on the volume or value of referrals. However, based on the clarification on the next page that 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, it would be helpful to clarify that the fact that a physician can receive a compensation rate if his or her revenue from professional services increases would not take into account the volume or value of the physician's referrals for the same reason. For example, many health systems have compensation models where a physician might be paid at a higher rate for unit of professional production (e.g., wRVUs) if the production hit certain tier levels. As long as these tiers are based on the physician's personally performed professional services (rather than DHS referrals), the fact that there may be corresponding DHS services should not invalidate such a tiered compensation formula.

CMS has repeatedly stated that a physician's compensation can always be based on personally performed services, 69 Fed. Reg. 16,054, 16,067 (Mar. 26, 2004), even if the payment is "linked to a facility fee." *Id.* at 16,088-89. Unfortunately, at least one court has misinterpreted or ignored this guidance and held that if an employed physician eligible for productivity compensation personally performs a professional service in a hospital and the hospital also bills a technical fee to Medicare, the physician's compensation varies with his or her referrals and thus fails to comply with the volume or value standard. *Bookwalter,* 938 F.3d at 408-11. The vast majority of hospitals and health systems in the country pay doctors on a productivity basis linked to their personally performed professional services performed in the hospital. Without clarification, such as the discussion included in 84 Fed. Reg. 55,818 affirming that an RVU payment formula would not violate the volume or value standard, hospitals and physicians will be faced with grave uncertainty about whether their RVU-based compensation arrangements are compliant with the Stark Law.

CMS is to be commended for addressing the Third Circuit Court of Appeals' incorrect interpretation of "split billing" arrangements in *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88 (3d Cir. 2009) and the incorrect analysis of the Stark Law by the Fourth Circuit in *U.S. ex rel. Drakeford v. Tuomey Healthcare. See* 84 Fed. Reg. 55,795; 80 Fed. Reg. 70,887, 71,321 (Nov. 16, 2015); 80 Fed. Reg. 71,321 (Nov. 16, 2015).

We agree with CMS that a split-bill arrangement does not constitute "remuneration" for purposes of the Physician Self-Referral Law and CMS's interpretation of split-billing arrangements is consistent with the practice in the hospital industry. However, even with this change, as discussed above, the definition of "remuneration" is too vague and could lead to similar results as the one in *Kosenske* in the future.

(f) Group Practice Five-Physician Rule, Section II, Part B, Fundamental Terminology and Requirements, Part C, Section 2(b), Clarifying Provisions

When the employer is a physician group that satisfies the requirements of 42 C.F.R. § 411.352, there is no rational basis or business justification to require an arbitrary minimum number of physicians who must practice within a component of that practice, such as the current five physician minimum found in 42 C.F.R. § 411.352(i)(2).

CMS is to be commended for proposing an amendment to 42 C.F.R. § 411.352(i)(1)(ii) to make clear that this five-physician rule does not apply to a physician group that has fewer than five physicians. However, CMS continues to require the five-physician limit in 42 C.F.R. § 411.352(i) to a group of five or more physicians. As a result, this arbitrary rule would apply even if a group had only six physicians practicing in two or more different specialties. We urge CMS to reconsider the need for this arbitrary number of physicians in a group that includes five or more physicians and allow physician groups the flexibility to create subgroups of their choosing regardless of the number of physicians in any subgroup within that physician group.

(6) OTHER COMPENSATION ARRANGEMENT EXCEPTIONS

(a) Amendments to Other Existing Exceptions

In addition to the comments described above, we agree with, and urge CMS to finalize, the changes in the Proposed Regulations to 42 C.F.R. § 411.357(a)(3), (b)(2), (c)(5), (e)(4), (g)(7), (i)(2), (l), (w) and (x).

(b) New Limited Remuneration to a Physician Exception, Part II, Section E, Providing Flexibility for Non-Abusive Business Arrangements, Section 1

In our experience, the new proposed regulations for limited remuneration to a physician (42 C.F.R. § 411.357(z)) will assist hospitals that require the assistance of a physician that does not clearly

satisfy another exception. We, however, urge CMS to increase the amount of the limited remuneration for $3,500 per calendar year to a more reasonable amount such as $5,000 to $10,000 per calendar year.

Using at least $5,000 per calendar year along with CMS's change to the "writing requirement" in the regulations that went into effect on January 1, 2016 will effectively reverse the unreasonable result, that has played a significant role in many of the submissions to the SRDP that have been found to not be abusive, that have arisen due to the following example of the personal services exception that was included in the Phase 1 Regulations:

> The effect of this statutory scheme is that failure to comply with section 1877 of the Act can have a substantial financial result. For example, if a hospital has a $5,000 consulting contract with a surgeon and the contract does not fit in an exception, every claim submitted by the hospital for Medicare beneficiaries admitted or referred by that surgeon is not payable, since all inpatient and outpatient hospital services are DHS.

66 Fed. Reg. at 860.

(c) New Cyber Security Exception, Part E, Providing Flexibility for Non-Abusive Business Relationships, Section 2, Cybersecurity Technology and Related Services

We also applaud CMS's effort to update the EHR-based exceptions to add an exception that permits the donation of cyber security technology and related services pursuant to 42 C.F.R. § 411.357(w) and for the new cyber security exception at 42 C.F.R. § 411.357(bb). These Proposed Regulations have addressed the vital issue of the security of hospital electronic health records, have furthered the intent of HIPAA and the HITECH Act, and have made these sections of the Proposed Regulations consistent with the regulations that have also been proposed by the Office of Inspector General on October 17, 2019. Again, we urge CMS to finalize these proposed rules in final form without delay.

(7) RULES NOT ADDRESSED IN PROPOSED REGULATION

(a) Retention Payments

CMS is to be commended for the changes to the Stark regulations and for the guidance that was published in the November 16, 2015 Federal Register. 80 Fed. Reg. 70,885, 71,300-35, 71,300. We urge CMS to consider additional changes to its exception for physician retention arrangements, 42 C.F.R. § 411.357(t), that will permit hospitals, regardless of their location, to use this exception and not limit this exception to instances where there is a firm, written recruitment offer.

There is no rational basis or business justification to continue to limit this exception to hospitals that are located in a rural area or HPSA or where the physician's patients reside in a medically underserved area or are members of a medically underserved population, 42 C.F.R. § 411.357(t)(3)(i)(B); *See*, 42 C.F.R. § 411.357(t)(3)(i)(A).

In our experience, hospitals, regardless of their location, would benefit from the ability to assist a physician in an existing independent practice to remain independent. We are aware of a client that was approached by a group of physicians who wanted to remain independent. However, between the charity care they provided, their Medicaid patient population, and the amounts that were being paid to the physicians by Medicaid, Medicare and other third-party payors for their professional services, the group could not generate a sufficient amount of professional reimbursement to allow the group to compensate the physicians at a reasonable fair market rate and precluded the group from expanding the practice even though there was a need for additional physician services.

The hospital could have employed the physicians. However, the physicians preferred to remain independent and the hospital determined that it would lose more money if the hospital employed the physicians than it would if the hospital provided a guarantee-like payment that would allow the physicians to remain independent. While a guarantee-like compensation arrangement could be structured to comply with the Anti-Kickback Statute, because of the hospital's location and the physicians being located in the Geographic Area Served by the Hospital, there is no exception to the Stark Law that would permit this type of retention assistance.

Furthermore, a hospital should not be forced to wait until a physician has a written offer from a third party. *See*, 42 C.F.R. § 411.357(t)(2). By the time a physician has such a firm, written offer, he/she has often decided to leave the area and the permitted retention benefit is of little practical benefit. All hospitals should be permitted to be proactive and have the ability to offer retention assistance to independent practicing physicians as long as the hospital has a good faith belief that the community served by the hospital would benefit from retention assistance, the amount of the financial assistance is reasonable, and the compensation arrangement complies with the other requirements set forth in this exception.

(b) Exceptions That Incorporate AKS Safe Harbors by Reference

The Stark Regulations currently include three exceptions that incorporate compliance with a safe harbor to the AKS by reference: (i) 42 C.F.R. § 411.357(n) "Risk Sharing Arrangements" referencing 42 C.F.R. § 1001.952(l); (ii) 42 C.F.R. § 411.357(q) "Referral Services" referencing 42 C.F.R. § 1001.952(f); and (iii) 42 C.F.R. § 411.357(r) "Obstetrical Malpractice Insurance Subsidiaries" referencing 42 C.F.R. § 1001.952(o).

While we do not recommend that CMS delay finalizing the Proposed Regulations to address the following comments, we strongly recommend that CMS amend each of the above regulations for the reasons described below in the near future.

CMS has discussed the importance of decoupling the Stark Law from the AKS in 84 Fed. Reg. 35,802-04. While both CMS and OIG have discussed the similarities of these two federal statutes, both CMS and OIG have emphasized that the AKS is a threshold statute and DHS entities must also comply with the AKS. *See* OIG Supplemental Compliance Provision Guidance for Hospitals, 70 Fed. Reg. 4,858, 4,862-63 (Jan. 31, 2005).

Also, while the safe harbors under the AKS and the exceptions under the Stark Law may at times be similar, they are very different in their application. AKS safe harbors are voluntary, and often narrow. More importantly, falling outside of a safe harbor does not provide a presumption that a particular transaction violates the AKS citation. However, exceptions under the Stark Law are mandatory and the parties cannot proceed with a transaction "unless an exception applies." 84 Fed. Reg. at 55,767. In addition, the OIG has found in at least two Advisory Opinions that compliance with the Stark Law is irrelevant to their analysis as to whether a particular transaction violates the AKS. *See* OIG Advisory Opinion 08-10 at footnote 1 (Aug. 26, 2008); *See also* OIG Advisory Opinion 04-17 1, 7-8 (Dec. 17, 2004) where the OIG stated "The Stark Law and the anti-kickback statute are independent legal authorities and each must be evaluated separately. (Emphasis added.)

CMS and OIG have recognized this fact and the current best practice is to adopt consistent safe harbors and exceptions that comply with each respective statute. *See* 42 C.F.R. § 411.357(v) and 42 C.F.R. § 1001.952 (Electronic Prescribing Items and Services); 42 C.F.R. § 411.357(w) and 42 C.F.R. § 1001.952(y) (Electronic Health Records Items and Services); Proposed Value-Based Regulation 42 C.F.R. § 411.357(aa) and 42 C.F.R. § 1001.952 (ee)-(hh) (Arrangements That Facilitate Value-Based Health Care Delivery); Proposed Regulation 42 C.F.R. § 411.357(bb) and 42 C.F.R. § 411.1001.952(ii) (Cyber Security Technology and Related Services).

We urge CMS to take a similar approach and adopt separate exceptions for Sections 411.357(n), 411.357(q) and 411.357(r). However, of these sections, we urge CMS to focus first and foremost on 42 C.F.R. § 411.357(r) that limits the application of this section to obstetrical malpractice insurance subsidiaries.

The current exception for obstetrical malpractice insurance subsidy, 42 C.F.R. § 411.357(r), is unnecessarily restrictive, does not allow for malpractice insurance subsidy arrangements that may be provided without a risk of program or patient abuse, and does not permit a hospital to respond in a reasonable and appropriate manner when physicians who are appointed to the medical staff, regardless of specialty, are confronted with precipitous increases in their malpractice insurance premium.

The Stark Law applies to any hospital, regardless of its location, if the hospital's services are paid for in whole or in part by the Medicare program. We fail to find any basis in the Stark Law or in the legislative history to the Stark Law that justifies limiting a safe harbor to a specific medical specialty or to a specific location.

If Congress had intended certain compensation arrangements to be limited to certain medical specialties, to certain populations, to rural areas, to an HPSA or to any other limited geographic area, then Congress would have created such a limited exception similar to the exception that pertains to a physician's ownership or investment interests in rural providers of DHS. *See* 42 U.S.C.A. § 1395nn(d)(2). Having failed to do so provides compelling evidence that Congress did not intend for an exception to be limited to a specific geographic area or to a limited population of beneficiaries.

The fact that the amount of a malpractice insurance subsidy is typically determined by the amount of the increase in a particular physician's insurance premium or by the cost of tail coverage and not on the fair market value of the services provided to a hospital makes it difficult, if not impossible, for a malpractice subsidy arrangement that is outside of the safe harbor protection afforded by 42 C.F.R. § 1001.952(o) to satisfy the personal services safe harbor to the AKS or the personal service exception to the Stark Law.

CMS should adopt a malpractice insurance subsidy exception that will permit any hospital to provide malpractice subsidies to any physician who is appointed to the hospital's medical staff. As such, we recommend that CMS completely revise 42 C.F.R. § 411.357(r). Obstetrical malpractice insurance is of little benefit to Medicare beneficiaries (few, if any, of whom require obstetrical services), ignores the fact that malpractice insurance subsidies may be needed in a variety of geographic settings by any medical specialty, and also ignores the reality that a properly structured malpractice insurance subsidy may be provided without the threat of program abuse. (*See* OIG Advisory Opinion 04-19, OIG Letter on Hospital Corporation's Medical Malpractice Insurance Assistance Program, available at http://oig.hhs.gov/fraud/fraudalerts.html.)

Simply put, if § 411.357(r) is not substantially revised, then it will continue to be impossible for all but a handful of hospitals to provide malpractice assistance to any physician specialty other than obstetrics, even if such assistance is required in order to meet the health care needs of the Medicare population served by the hospital and will further a tax-exempt hospital's charitable mission.

(c) Incentive Compensation for Part-Time Administrative Physicians

Many hospitals and health systems have physician executives who practice part time to maintain their clinical skills. Likewise, many of those hospitals and health systems have executive compensation plans that make some or all of an executive's incentive compensation dependent on hitting pre-determined margin or net earnings targets. However, since the physician executives who practice part time may refer patients to the hospital or health system for designated health services, those referrals could (albeit infinitesimally) increase the net earnings, so their compensation could be said to vary based on the volume or value of their referrals and thus fall outside the exception for remuneration unrelated to the provision of designated health services.

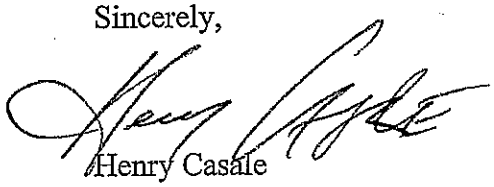
42 C.F.R. § 411.357(g). It would be helpful to clarify that incentive compensation for physicians primarily engaged in providing administrative services would not vary based on the volume or value of their referrals so long as the management incentive payments are based on a specific dollar amount (or percentage of base salary) to be paid only if a net earnings target is achieved.

CONCLUSION

In his introductory remarks to the Comprehensive Physician Ownership and Referral Act of 1993, Congressman Stark stated that "the only way to protect health care consumers from unnecessary referrals is to impose a "bright line rule." 139 Cong. Rec. E84-01 (January 6, 1993). While Representative Stark's intent was to create a bright line rule, the current state of the law is anything but that.

Our comments to CMS's Proposed Regulations are provided in the hope that they will assist to finalize the "bright line" rules that have been described in the Proposed Regulations. In doing so, CMS will: (i) permit hospitals and other DHS entities to operate in a way that will not interfere with legitimate and long-standing relationships with physicians and hospitals; (ii) protect the Medicare program from the type of abuse that the Physician Self-Referral Law has been enacted to prevent; (iii) promote care coordination; (iv) facilitate participation in alternative payment models; (v) provide the flexibility necessary for the development of innovative value-based arrangements; and (vi) make the current regulations less of a "booby trap rigged with strict liability and potentially ruinous exposure."

Sincerely,



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