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VIA EXPRESS MAIL

December 30, 2019

Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Proposed Safe Harbor Regulations
File Code OIG-0936-AA10P

To the Office of Inspector General:

This comment letter is submitted in response to the Proposed Regulations to the Anti-Kickback Statute (the "AKS") and the beneficiary inducement Civil Money Penalty Law ("CMP") that were published in the October 17, 2019 Federal Register and the Preamble thereto (the "Proposed Regulations").[1] In particular, this letter will comment on the Proposed Regulations that address perceived barriers to maintaining and improving the quality of care and to achieving clinical and financial integration posed by the AKS and/or CMP.

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 services that are paid for in whole or in part by a Federal Health Care Program, especially hospital inpatient and outpatient services. We routinely draft and negotiate hospital-physician contracts, 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 to OIG's Self-Disclosure Protocol and to CMS's Voluntary Self-Referral Disclosure Protocol and have previously submitted comments to both CMS and OIG. In submitting these comments, we are not acting on behalf of any client.

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1 84 Fed. Reg. 55,694 (Oct. 17, 2019) (to be codified 42 C.F.R. Pts. 1001 & 1003).

Hospitals and health systems must enter into a wide variety of arrangements with physicians in order to carry on their day-to-day operations. Nonprofit charitable hospitals, regardless of their location, 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. Not all rural hospitals are located in a Health Professional Shortage Area ("HPSA"), Medically Underserved Area ("MUA") or part of a Medically Underserved Population ("MUP").

The Proposed Regulations have addressed many of the difficult situations that confront hospitals when considering financial arrangements with physicians in a reasonable manner that will further provisions of quality health care. The lack of updates to the OIG's compliance guidance to Hospitals since January 31, 2005, a lack of coordination with CMS to align OIG's regulatory guidance with CMS guidance on the Physician Self-Referral Law (also known as the Stark Law), and the manner in which the AKS and CMS have been 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, increase access and improve the quality of health care.

The Proposed Regulations do an excellent job of removing many of these barriers. We commend OIG for this and urge OIG to not only issue the Proposed Regulations in final form without delay, but to also update the OIG's Supplemental Compliance Guidance to Hospitals and to resume issuing fraud alerts that will further describe OIG's position on the issues that have been included in the Proposed Regulations.

(1) RELATIONSHIP TO THE STARK LAW

We appreciate that the AKS and CMP are not limited to the "Designated Health Services" covered by the Stark Law and apply to a wide array of referrals, not just referrals from physicians. Nevertheless, as described in the OIG Supplemental Guidance for Hospitals, "[f]rom a hospital compliance perspective, the physician referral law...should be viewed as a threshold statute."[2]

Accordingly, analysis of any compensation arrangement or investment interest between a physician and a hospital 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. 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.

We appreciate that "[c]ompliance with a Stark Law exception does not immunize an arrangement under the [AKS]."[3] OIG should recognize in the Preamble to the Final Regulations that CMS has also issued Proposed Regulations on October 17, 2019 that will decouple the Stark Law from the AKS by amending the exceptions that are included in the Stark Regulations that require that the

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[2] 70 Fed. Reg. 4,858, 4,862 (Jan. 31, 2005); *See also* 64 Fed. Reg. 63,517, 63,519 (Nov. 19, 1999); 66 Fed. Reg. 856, 863 (Jan. 4, 2001).

[3] 70 Fed. Reg. at 4,863; *See also* OIG Advisory Opinion 08-10 1, 3 n.1 (Aug. 26, 2008); OIG Advisory Opinion 04-17 1, 7-8 (Dec. 17, 2004) (stating that "the Stark Law and the anti-kickback statute are independent legal authorities <u>and each must be evaluated separately</u>") (emphasis added).

arrangement "does not violate the anti-kickback statute"[4] to delete the circular definition of this term for 42 C.F.R. § 411.351 and to delete this requirement from these Stark exceptions. Doing so has removed a level of confusion and difficulty with complying with both laws.

The intent-based nature of the AKS creates a level of uncertainty as to whether a particular transaction satisfies the requirement in the Stark exception as to whether the financial relationship at issue "does not violate the AKS" 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 and CMS is to be commended for these proposed amendments to the Stark Law.

As will be discussed in more detail below, additional uncertainty is created by the need for a definition of "fair market value," as used in the safe harbor regulations, that is consistent with CMS's proposed definition of "fair market value" in 42 C.F.R. § 411.351, by the fact that "fair market value" is key to complying with the AKS, and is an element of almost all Stark exceptions.

(2) RELATIONSHIP TO THE FALSE CLAIMS ACT

Compliance with the AKS and the Stark Law is a condition of payment by Medicare or Medicaid.

Courts have held that a provider can incur liability under the FCA[5] as a result of a failure to comply with the AKS. In 2009, the FCA was amended to provide that any claim for payment submitted in violation of the AKS is false for purposes of the FCA. Recently, the District Court for the Western District of Pennsylvania has held that a violation of the Stark Law and/or AKS could satisfy the materiality standard set forth in *Universal Health Services v. United States ex rel. Escobar*, 136 S.Ct. 1989, 2002 (2016) for purposes of the FCA.[6]

The penalties for violation of the FCA include up to three times the amount of damages suffered by the government, plus (as of February 3, 2017) a civil money penalty of $10,957 to $21,916 per claim[7] and exclusion from federal health care programs. The FCA has a six-year statute of limitations. However, an FCA claim may be brought within ten years of a violation if the claim is brought within three years after the date that facts material to the cause of action are known or reasonably should have been known.[8]

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4 *See* 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).

5 31 U.S.C. §§ 3729-33. *See* footnote 7 of this paper for a list of other cases supporting this conclusion.

6 *U.S. ex rel. Emanuele v. Medicor Assocs.*, 242 F. Supp. 3d 409, 431 (W.D. Pa. 2017). *See also* footnote 10.

7 Each year (no later than January 15), the per claim civil money penalties are to be adjusted to reflect changes in the CPI. It should be noted that the per claim penalty for claims submitted prior to November 2, 2015 will be calculated at the $5,500-$11,000 per claim penalty that was in effect at that time. *See generally* Thomas Sullivan, *Department of Justice Increases FCA Civil Penalties, Again*, Pol'y & Med. (Feb. 6, 2017), http://www.policymed.com/2017/02/department-of-justice-increases-fca-civil-penalties-again.html.

8 31 U.S.C. § 3731(b).

The FCA also permits private parties to prosecute suspected violations of the AKS and/or the Stark Law under the *qui tam* provisions of the FCA.[9] The ability of a private party (a relator) to enforce the AKS and/or the Stark Law by bringing a *qui tam* claim under the FCA is significant because while the Department of Justice actions to enforce the AKS and the Stark Law have occurred, most recent attempts to use the FCA to enforce the AKS and the Stark Law have arisen as a result of a *qui tam* claim that has been brought by a private person on behalf of the government.[10]

This web of these three different but intersecting federal laws has made compliance extremely challenging. As one court has noted in the context of a Stark and FCA claim:

> 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.
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> * * *
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> Despite attempts to establish "bright line" rules so that physicians and healthcare entities could "ensure compliance and minimize costs" ...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".... 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".... (Citations omitted.)
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9 31 U.S.C. § 3730(b). *Qui Tam* is derived from the Latin phrase "qui tam pro domino rege quam pro se ipso in hac parte sequitur" or "he who pursues this action on our Lord the King's behalf as well as his own."

10 *See, e.g., U.S. ex rel. Mohatt v. Kalispell Reg'l Healthcare,* CV 16-125-M-DWM (D. Mont. 2017) (Settled $24 million, Sept. 28, 2018); *U.S. ex rel. Drakeford v. Tuomey,* 792 F.3d 364 (4th Cir. 2015) ($72.4 million settlement); *U.S. ex rel. Schumann v. Astrazeneca Pharm. L.P.*, 769 F.3d 837 (3d Cir. 2014); *U.S. ex rel. Repko v. Guthrie Clinic, P.C.*, 490 F. App'x. 502 (3d Cir. 2012); *U.S. ex rel. Wilkins v. United Health Grp.*, 659 F.3d 295 (3d Cir. 2011); *U.S. ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009) (settlement information undisclosed); *U.S. ex rel. Hefner v. Hackensack Univ. Med. Ctr.*, 495 F.3d 103 (3d Cir. 2007); *U.S. ex rel. Moore v. 21st Century Oncology, L.L.C.*, No. 2:16-cv-99 (M.D. Fla. 2017) ($26 million settlement); *U.S. ex rel. Payne v. Adventist Health Sys./Sun Belt, Inc.* No. 13-217 (W.D.N.C. 2015) ($115 million settlement); *U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654 (S.D. Tex. 2013) ($25 million settlement); *U.S. ex rel. Baklid-Kuntz v. Halifax Hosp. Med. Ctr.,* No. 6:09-cv-1002-Orl-31TBS, (M.D. Fla. Nov. 6, 2012) ($85 million settlement); *U.S. ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602 (W.D. Pa. 2010) ($2.7 million settlement); *U.S. ex rel. Fry v. Health All. of Greater Cincinnati*, No. 1:03-CV-00167 (S.D. Ohio 2008) ($108 million settlement); *U.S. ex rel. Goodstein v. McLaren Reg'l Med. Ctr.*, 202 F. Supp. 2d 671 (E.D. Mich. 2002).

> 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.[11]

The Proposed Regulations show that removing unnecessary governmental obstacles to care coordination is a key priority for OIG and will help OIG to complete the planned "Regulatory Sprint to Coordinated Care." However, OIG should make every effort to issue final safe harbor regulations that will be consistent with the changes to the Stark Law that CMS proposed on October 17, 2019.[12] Whenever possible, OIG and CMS should adopt parallel anti-kickback safe harbors and Stark exceptions, respectively, to address the issues that are described in this comment letter in the same manner that OIG and CMS adopted a consistent safe harbor and exception for providing financial assistance to physicians implementing electronic prescribing and electronic health records.[13] Such a consistent rule-making process is well within the discretion of each regulatory body to implement.

(3) PROPOSED VALUE-BASED SAFE HARBORS

(a) Value-Based Purchasing

The Proposed Regulations have provided hospitals with much needed immediate guidance under both the AKS and the CMP concerning the ability of a hospital to compensate physicians who assist a hospital under Medicare's Value-Based Purchasing Program ("VBP"), with a Value-Based Enterprise, and with a Value-Based Purpose (collectively, "VBE").[14]

We recognize that OIG has taken a different approach in proposing 42 C.F.R. § 1001.951(d)(2)(i)-(ix) and (d)(3)(ii)-(iii) and 42 C.F.R. §§ 1001.952(ee)-(ii) (the "Proposed Value-Based Rules") than has CMS in its proposed Value-Based Rule under the Stark Law, 42 C.F.R. § 411.357(aa).[15] Given these differences, it would be helpful in the Preamble to the final rules for OIG to state that providers who comply with the Stark value-based rule (42 C.F.R. § 411.357(aa)) will satisfy one of these safe harbors. Our only other suggestion would be to add more examples of permitted value-based activities, arrangements and enterprises in the Preamble to the final regulations.

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

12 84 Fed. Reg. 55,766, 55,847 (Oct. 17, 2019).

13 *See* 42 C.F.R. § 411.357(v)-(w); 42 C.F.R. § 1001.952(x)-(y).

14 *See* 84 Fed. Reg. 55,694, 55,700-08 (Oct. 17, 2019).

15 *See* 84 Fed. Reg. at 55,840-41 (Oct. 17, 2019) (to be codified 42 C.F.R. Pt. 411) (proposing amendments to 42 C.F.R. § 411.351, "target patient populations," "value-based activity," "value-based arrangements," "value-based enterprise," "value-based purpose," and "value-based participant"); *Id.* at 55,846-47 (proposing amendment to 42 C.F.R. § 411.357(aa) "arrangements that facilitate value-based health care delivery and payment").

Notwithstanding these questions, we urge OIG to issue the Proposed Value-Based Rules in final form. Without these Proposed Regulations, it is 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 Regulations. The Proposed OIG 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 VBE is generally not reflected in the hourly payment rates for the services being provided by a physician to a hospital or other provider.

Hospitals, in particular, need the type of assurance described in the OIG's 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 ability of the services provided by the physicians and be able to satisfy a safe harbor to the AKS.

(b) New Cyber Security Safe Harbor

We applaud OIG'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. § 1001.952(y) and for the new cyber security exception at 42 C.F.R. § 1001.952(jj). 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 CMS on October 17, 2019.

It would, however, be helpful for OIG to explain its rationale for the differences, slight as they may be, between OIG's proposed safe harbor for Cyber Security and related services (42 C.F.R. § 1001.951(jj)) and the CMS proposed exception for Cyber Security technology and related services (42 C.F.R. § 411.357(bb); 84 Fed. Reg. at 55,847). Notwithstanding this difference between these two regulations, we urge OIG to finalize the cyber security proposed regulations without delay.

(c) Gainsharing and Other Forms of Outcomes-Based Payments

Since 2001, OIG has provided Compliance Program and Advisory Opinion Guidance on gainsharing arrangements.[16] However, as OIG is aware, an Advisory Opinion is only binding on the party that requests the Advisory Opinion, while any provider can take advantage of a safe harbor. Therefore, we appreciate OIG's guidance in the Proposed Regulations that the OIG's proposal to include a definition of "Outcomes-Based Payments" will afford safe harbor protection to "new payment models, such as shared savings, shared losses, episodic payments, gainsharing and pay-for-performance."[17]

OIG is to be commended for making its gainsharing compliance and advisory opinion guidance into a safe harbor. We urge OIG to finalize the Outcomes-Based Payment Safe Harbors without delay. OIG should work then with CMS to have CMS officially take the position that a hospital

16 *E.g.*, Office of Inspector General, Dept. of Health & Human Servs., Advisory Opinion 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); *See also* OIG Supplemental Compliance Program Guidance for Hospitals, 70 Fed. Reg. 4,858, 4,869-70 (Jan. 31, 2005).

17 84 Fed. Reg. at 55,745 (emphasis added).

that complies with the OIG's published guidance on gainsharing will satisfy an exception to the Physician Self-Referral Law.

(d) Amendments to Personal Services and Management Agreement Safe Harbor

We appreciate the careful manner in which OIG has proposed amending 42 C.F.R. § 1001.952(d) (Personal Services and Management Agreements and Outcomes-Based Arrangements). We especially appreciate OIG's proposal to delete the current requirement that safe harbor protection is only available when the requirement that the aggregate amount of compensation to be paid pursuant to the Agreement must be established before the agreement is executed (current regulation 42 C.F.R. § 1001.952(d)(iv)). We also agree with eliminating the terms in this safe harbor that relate to part-time arrangements.

These terms were unduly restrictive, inconsistent with the personal service exception to the Stark Law, and caused many otherwise lawful arrangements to fail to qualify for safe harbor protection. These amendments to the existing safe harbor as well as the above-described outcomes-based payment rules that have been added to this safe harbor as 41 § 1001.952(d)(2) and (3) will provide the clarity needed for gainsharing arrangement and other innovative payment models. We urge OIG to issue these regulations in final form without delay.

(4) LOCAL TRANSPORTATION SAFE HARBOR

The Proposed Regulations have proposed amending the Local Transportation Safe Harbor 42 C.F.R. § 1001.952(bb) to expand the geographic area in which a beneficiary may be transported to 75 miles if the beneficiary resides in a rural area and has included an exception to the mileage limits if the patient is being discharged from an inpatient facility to the patient's residence or another residence of the patient's choice.

We applaud these amendments. We do, however, urge OIG to not limit these exclusions to inpatient facilities. Rather than list certain services such as proposed in 84 Fed. Reg. at 55,751, we urge OIG to make this exclusion available to any individual who has received any hospital inpatient or outpatient service.

We also urge OIG to expand the exclusion from a patient's residence or another residence of the patient's choice to protect "transportation to any location of the patient's choice, including to another health care facility."[18]

Finally, since hospitals exist in thousands of different geographic locations, arbitrary mileage limits do not make sense. We would therefore recommend eliminating mileage limits altogether.

(5) 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 employs or contracts with physicians and bills for the services of non-physician practitioners who are supervised by those physicians under the Medicare "Incident to Rules" is permitted to include that revenue in the hospital's compensation of the supervising physician.

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[18] 84 Fed. Reg. at 55,751.

Neither OIG nor CMS has stated how hospital-contracted physicians are to be compensated for providing medical direction to non-physician practitioners. Furthermore, it is unclear how a hospital is to audit or to exclude such reimbursement since CMS did not concur with OIG's recommendation included in the OIG's August 2009 report entitled, "Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services" (the "OIG Report") that CMS should identify "incident to" services not personally performed by a physician by using a service code modifier.[19]

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 the 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.[20]

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." OIG should address this issue in the Preamble to the Final Regulations and should affirmatively state that "incident to" professional revenue will be considered to be revenue that is based on services performed personally by the supervising physician and address how the fair market value of the physician services is to be measured, especially since the OIG Report recognized that the use of the phrase "incident to" permitted over 200 of the physicians identified in the study to bill more than 24 hours of service in one day, a result that OIG did not claim violated the AKS or the False Claims Act.

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19 Office of Inspector General, Dept. of Health & Human Servs., OEI-09-06-00430, Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services (2009).

20 *Id.* at 31-32.

(6) FAIR MARKET VALUE

OIG has stated that "the general rule of thumb is that any remuneration flowing between hospitals and physicians should be at fair market value for actual and necessary items furnished or services rendered based upon arm's-length transaction and should not take into account, directly or indirectly, the volume or value of any past or future referrals or other business generated between the parties."[21]

Similarly, "Legion courts have held that, absent a few exceptions not at issue here, compliance with the AKS requires that a provider pay fair market value to a physician for his services."[22]

Given the importance of compensation being at "fair market value" and "not take into account the volume or value of referrals" (the "volume or value standard"), in order to achieve compliance with both the AKS and the Stark Law, there should be a clear, consistent definition of these terms. However, the OIG has not included a definition of these essential terms in the Proposed Regulations.

In 1994, OIG published a Special Fraud Alert wherein it addressed the relationship between the AKS and agreements for the provision of clinical lab services. While addressing potential issues that could arise from agreements including remuneration above fair market value, OIG stated that "by 'fair market value' we mean value for general commercial purposes. However, 'fair market value' must reflect an arms-length transaction which has not been adjusted to include the additional value which one or both of the parties has attributed to the referral of business between them."[23]

OIG has also defined "fair market value" as "the value that would be assigned to the item or service in question by individuals or entities who have an arms-length relationship and who have no ability to influence referrals of any health care business to each other."[24]

The following statement in the OIG Hospital Supplemental Compliance Guidance makes it appear that in the context of a hospital-physician compensation arrangement, the OIG uses a facts and circumstances analysis to determine fair market value:

> In particular, hospitals should review their physician compensation arrangements and carefully assess the risk of fraud and abuse using the following factors, among others:
>
> - Does the compensation represent fair market value in an arm's length transaction for the items and services?

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21 70 Fed. Reg. at 4,866 (Jan. 31, 2005).

22 *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of America*, 565 F. Supp. 2d 153, 162 (D.D.C. 2008) (citing *U.S. v. Rogan*, 459 F. Supp. 2d 692, 722-23 (N.D. Ill. 2006)).

23 Office of Inspector General, Dept. of Health & Human Servs., Special Fraud Report (Dec. 19, 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

24 Office of Inspector General Dept. of Health & Human Servs., Recommended Preliminary Questions and Supplementary Information for Addressing Requests for OIG Advisory Opinions In Accordance With Section 1128D of the Social Security Act and 42 C.F.R. Part 1008. https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm.

- Could the hospital obtain the services from a non-referral source at a cheaper rate or under more favorable terms?
- Does the remuneration take into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the parties?
- Is the compensation tied, directly or indirectly, to Federal health care program reimbursement?
- Is the determination of fair market value based on a reasonable methodology that is uniformly applied and properly documented?[25]

It is also important to note that 42 C.F.R. § 1001.952 (b) and (c), the safe harbors for space rentals and equipment rentals, include a definition for fair market value within the safe harbor. Under these safe harbors, fair market value "means the value of the rental property for general commercial purposes [and equipment], but shall not be adjusted to reflect the additional value that one party…would attribute to the property as a result of its proximity or convenience to sources of referrals or business otherwise generated for which payment may be made in whole or in part under Medicare, Medicaid and all other federal health care programs."[26]

While we appreciate the description of Fair Market Value that has been included in the Preamble to the Proposed Regulations,[27] we request that OIG promulgate definitions of fair market value and general market value as part of the final regulations that are consistent with the manner in which CMS has proposed to define these key terms in 42 C.F.R. § 411.351.[28]

(7) VOLUME OR VALUE STANDARD

The requirement that compensation must not take into account the volume or value of referrals between the parties appears in a number of safe harbors (i.e., 42 C.F.R. § 1001.952(d)(5)). Again, we appreciate OIG's description of the Volume or Volume Standard in the Preamble to the Proposed Regulations.[29] However, the Proposed Regulations should describe this vital term in the regulations in the same manner as CMS has proposed in 42 C.F.R. § 411.354(d)(5) and (d)(6), 84 Fed. Reg. 55,842-55,843 so that this term that is essential to compliance with both the Stark Law and the AKS will be uniformly interpreted by OIG and CMS wherever it appears. Such uniform interpretation is essential.

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.

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[25] 70 Fed. Reg. at 4,867.
[26] 42 C.F.R. § 1001.952(b)(6); *See also* § 1001.952(c)(6).
[27] *See* 84 Fed. Reg. at 55,714, 55,747.
[28] *See* 84 Fed. Reg. at 55,840.
[29] *See, e.g.*, 84 Fed. Reg. 55,711, 65,714-16, 55,747.

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."[30]

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."[31] OIG should make it clear that the AKS will be interpreted in the same manner.

This definition is circular and is not consistent with either the Stark Law or AKS.

(a) Correlation of Professional Services to Technical Fees

OIG should also recognize that a physician's compensation can always be based on personally performed services – even if the payment is linked to a facility fee. Unfortunately, at least one court has held that if a 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.[32]

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 further clarification from both OIG and CMS affirming that this would not violate the volume or value standard, hospitals and physicians will be faced with grave uncertainty about whether their compensation arrangements are compliant.

(b) Tiered Compensation

OIG should also address "tiered compensation" in a manner that is consistent with CMS's discussion. The Preamble to the Stark Proposed Regulations at 84 Fed. Reg. 55,794 states 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 per 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 referrals for items and

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30 66 Fed. Reg. at 877-78 (emphasis added).

31 H.R. Rep. No. 103-111, at 545 (1993), *reprinted in* 1993 U.S.C.C.A.N. 378, 779 (emphasis added).

32 *U.S. ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009).

services paid by a federal health care program), the fact that there may be corresponding technical services should not invalidate such a tiered compensation formula.

OIG should also issue guidance under the AKS similar to the guidance issued by CMS[33] that a split-bill arrangement does not constitute "remuneration" for purposes of the AKS and that split billing arrangements are a common practice in the hospital industry.

(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 items or services paid by a federal health care program, 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 items or services paid for in whole or in part by a federal healthcare program. 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.

(d) Definition of Referring Provider

CMS has recognized that the Stark Law 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.'"[34] We urge OIG to adopt CMS's analysis in 84 Fed. Reg. at 55,787 and make it clear that the definition of "referring provider" applies to the provider who actually orders the item or service, and to exclude any other physician who may provide professional services to a patient who has been "referred" for an item or service that is paid in whole or in part by a federal health care program.

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 for items or services. This has resulted in wildly inflated damage awards that were never intended by the statute. This will be addressed through this proposed change.

(8) UPDATE OIG GUIDANCE

OIG has not issued formal compliance guidance since its September 30, 2008 Supplemental Compliance Guidance for Nursing Homes.[35] While the OIG's Supplemental Compliance Guidance for Hospitals has proven to be very valuable, that Guidance was issued on January 31,

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33 *See* 80 Fed. Reg. 70,885, 71,321 (Nov. 16, 2015).

34 42 U.S.C. § 1395nn(h)(5)(B).

35 73 Fed. Reg. 56,832 (Sept. 30, 2008).

2005 and is dated. We urge OIG to update that guidance, whether formally through safe harbor regulations, by updating the 2005 Supplemental Compliance Guidance for Hospitals, or through fraud alerts.

Similarly, the OIG's Compliance Guidance for Individuals and Small Group Physician Practices and the appendices that were attached to that guidance were excellent when they were published. However, that guidance was published on October 5, 2000 and also needs to be updated.[36] As the name suggests, this Compliance Guidance is also limited to individual and small group physician practices. OIG should also issue compliance advice for multi-specialty physician groups and for physicians who are employed by hospitals or hospital-affiliated entities.

(9) RETENTION ARRANGEMENTS

While not addressed in the Proposed Regulations, we urge OIG to consider that 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. OIG should issue a safe harbor that would permit such a compensation arrangement to qualify for safe harbor protection and to work with CMS to develop an exception to the Stark law to permit a hospital, regardless of its location, to provide retention assistance to a physician or group of physicians.

(10) DEFINITION OF REMUNERATION

We would suggest that the OIG issue clear guidance consistent with judicial decisions that if fair market value is paid for a particular good or service, no "remuneration" changes hands because of the even exchange.[37] In such cases, there is no inducement or remuneration necessary to establish a violation of the AKS.

Furthermore, we suggest that the OIG formally adopt the position in OIG informal guidance that has stated that the kind of remuneration that could trigger scrutiny of a transaction must involve something of "independent value to the provider." For example, in informal guidance, OIG has determined that an item or service with no monetary value to the physician, such as a dedicated

[36] *See* 65 Fed. Reg. 59,434 (Oct. 5, 2000).

[37] *U.S. ex rel. Jamison v. McKesson Corp.*, 900 F. Supp. 2d 683, 698 (N.D. Miss. 2012). *See also Bingham v. BayCare Health Sys.*, 2016 WL 8739056, at *6 (M.D. Fla. 2016): ("To constitute remuneration, the parking services provided to physicians working in the Heart Center MOB must have been provided 'for free or for other than fair market value'"); *U.S. ex rel. Gale v. Omnicare, Inc.*, 2013 WL 3822152, at *6 (N.D. Ohio 2013) (concluding that if one party charges the same price for services regardless of whether the other party refers patients, then nothing of value has been given in exchange for referrals).

fax machine or 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."[38]

Since fax machines and dedicated computer lines are antiquated technology, OIG should also update this guidance to address computer interfaces and the type of computer systems typically seen in a modern hospital.

(11) MALPRACTICE INSURANCE SUBSIDIES

The current safe harbor for obstetrical malpractice insurance subsidy, 42 C.F.R. § 1001.952(o), 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 OIG's restrictions are all the more onerous because of the terms that have been included in the Stark Law malpractice insurance subsidy exception. 42 C.F.R. § 411.357(r). As the title of this exception states, this exception is limited to "obstetrical" malpractice insurance subsidies and the first element in this exception states that the "remuneration that meets all of the conditions set forth in § 1001.952(o) of this title."[39] The fact that OIG limits this exception geographically to practitioners who reside in an HPSA or MUA or are part of an MUP further restricts the ability of a number of hospitals to qualify for safe harbor protection.

OIG should adopt a malpractice insurance subsidy exception that will permit <u>any</u> hospital to provide malpractice subsidies to <u>any</u> physician who is appointed to the hospital's medical staff. As such, we recommend that OIG completely revise 42 C.F.R. § 1001.952(o).

The AKS 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 AKS or in the legislative history to the AKS 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.[40] Having

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38 *See, e.g.*, Office of Inspector General, Dept. of Health & Human Servs., Special Advisory Bulletin, Offering Gifts and Other Inducements to Program Beneficiaries (Aug. 2002); Office of Inspector General, Dept. of Health & Human Servs., Advisory Opinion 08-05 (Feb. 22, 2008); *see also* Letter from Kevin G. MacAnaney, Chief Industry Branch "Re: Free Computers, Facsimile Machines and Other Goods" (July 3, 1997).
<u>https://org.hhs.gov/fraud/docs/safeharborregulations/freecomputers.htm</u>; Centers for Medicare & Medicaid Servs., Dept. of Health & Human Servs., CMS Advisory Opinion CMS-AO-2008-01 (May, 2008); 72 Fed. Reg. 51,012, 51,049 (Sept. 5, 2007); 69 Fed. Reg. 16,053, 16,114 (Mar. 26, 2004).

39 42 C.F.R. § 411.357(r)(1).

40 *See* 42 U.S.C.A. § 1395nn(d)(2).

failed to do so provides compelling evidence that Congress did not intend for safe harbor protection to be limited to a specific geographic area or to a limited population of beneficiaries.

As currently drafted, 42 C.F.R. § 1001.952(o) does not permit a hospital that is not located in the limited geographic areas described in the Regulation to enter into the type of arrangements that may be necessary to further the charitable mission of the hospital and to provide services to the Medicare beneficiaries who reside within the geographic area served by the hospital.

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.

For example, two similarly situated physicians who will perform the same service may receive a different amount of subsidy since again the value of the subsidy is based on the physician's premium cost, not the value of the service to the hospital. As a result, contrary to the position stated in the OIG's Supplemental Compliance Guidance for Hospitals, a malpractice assistance arrangement outside of the limits permitted by 42 C.F.R. § 1001.952(o) will not qualify for safe harbor protection under any of the existing safe harbors. As such, the current safe harbor is unreasonably restrictive, especially given the terms of the Stark obstetrical malpractice subsidy exception.

We request that OIG revise its safe harbor to permit a hospital such as the one described in OIG Advisory Opinion 04-19 to be able to qualify for safe harbor protection. Since the physicians described in the Advisory Opinion were neurosurgeons who were not located in a rural area, neither 42 C.F.R. § 1001.952(o) nor 42 C.F.R. § 411.357(r) would apply even though it is much more likely that a Medicare beneficiary would require the services of a neurosurgeon than an obstetrician.[41]

Similarly, CMS has also repeatedly recognized that a hospital may be interested in providing malpractice assistance to physicians who are appointed to its medical staff.[42] But because the Stark malpractice assistance exception incorporates by reference the OIG obstetrical malpractice insurance subsidy safe harbor,[43] CMS has failed to provide a reasonable, practical exception that is available to <u>all</u> hospitals, regardless of their location, to provide the type of malpractice insurance assistance that the OIG's Supplemental Compliance Guidance for Hospitals has stated is consistent with the AKS to <u>any</u> physician regardless of specialty. 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.[44]

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41 *See also* OIG Letter on Hospital Corporation's Medical Malpractice Insurance Assistance Program, available at <u>http://oig.hhs.gov/fraud/fraudalerts.html</u>.

42 *See* 63 Fed. Reg. 1,659, 1,702-03 (Jan. 9, 1998); 66 Fed. Reg. 855, 907, 920 (Jan. 4. 2001); 69 Fed. Reg. 16,053, 16,093-94, 16,115, 16,121 (March 26, 2004)) and again in 72 Fed. Reg. 38,182.

43 *See* 42 C.F.R. § 411.357(r)(1).

44 *See* OIG Advisory Opinion 04-19; *see also* OIG Letter on Hospital Corporation's Medical Malpractice Insurance Assistance Program, available at <u>http://oig.hhs.gov/fraud/fraudalerts.html</u>.

Simply put, if § 1001.952(o) 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, further a tax-exempt hospital's charitable mission, and not violate the AKS or the Stark Law.

(12) RECRUITMENT ARRANGEMENTS

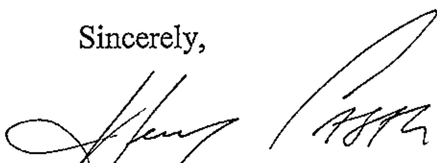
Similarly, all hospitals, regardless of location, should be permitted to be proactive and have the ability to offer recruitment assistance to independent practicing physicians as long as the hospital has a good faith belief that the community served by the hospital would benefit from retention assistance, the amount of the financial assistance is reasonable, and the compensation arrangement complies with the other requirements set forth in the Stark recruitment exception, 42 C.F.R. § 411.357(e).

The OIG's Supplemental Guidance recognizes that "many hospitals provide incentives to recruit a physician or other health care professional to join the hospital's medical staff and provide medical services to the surrounding community."[45] As such, there is no valid policy justification for limiting safe harbor protection for recruitment arrangements to a practitioner who locates his or her practice in an HPSA as currently required by 42 C.F.R. § 1001.952(n) or to have a safe harbor that differs so significantly from the Stark recruitment exception.

CONCLUSION

Our comments to OIG's Proposed Regulations are provided in the hope that they will assist to finalize the excellent guidance that has been described in the Proposed Regulations. In doing so, OIG will: (i) permit hospitals and other providers 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 AKS and CMP have 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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45 70 Fed. Reg. at 4,868 (Jan. 31, 2005).