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July 28, 2008

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1390-P
P.O. Box 8011
Baltimore, MD 21244-1850

Attn: Don Romano

Re: Comments on the Treatment of Physician-Owned Implant and Other Device Companies Under the Physician Self-Referral Law (Filecode: CMS-1390-P)

Dear Mr. Romano:

The Washington Legal Foundation (WLF) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services on the above-referenced Solicitation of Comments (73 Fed. Reg. 23694 (April 30, 2008)) regarding physician self-referrals rules in the context of physician-owned implant and other medical device companies ("POCs").

WLF supports rigorous enforcement of the Physician Self-Referral Law (the "Stark Law") as a means of ensuring that Medicare beneficiaries receive the highest standards of medical care while simultaneously protecting the integrity of the Medicare program. WLF is concerned by reports regarding the proliferation of physician-owned implant and other medical device companies (POCs). By most accounts, POCs provide few if any added medical benefits, yet drive up costs and pose a threat of reduced quality in medical care.

WLF urges CMS to amend its Stark Law regulations to address POCs more specifically, and to make clear that in most instances POCs will be deemed DHS "entities" subject to the Stark Law's prohibitions against self-referral. While many of the current arrangements among physicians, POCs, and hospitals may violate the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), WLF does not believe that that statute provides an adequate mechanism for preventing abuse.

WLF does not have extensive first-hand knowledge of the reported abuses in this area; accordingly, WLF is not in a position to comment on just how widespread those abuse are. Rather, WLF is submitting these comments to emphasize two points: (1) new regulations providing explicitly that the Stark Law applies to POCs fall well within CMS's statutory authority; and (2) clarifying the self-referral laws is the most appropriate means of addressing concerns surrounding POCs and similar physician-owned companies.

I. Interests of the Washington Legal Foundation

WLF is a non-profit public interest law and policy center based in Washington, D.C., with supporters in all 50 States. Since its founding in 1977, WLF has engaged in litigation and advocacy to defend and promote individual rights and a limited and accountable government. In particular, WLF devotes a substantial portion of its resources to promoting patients' rights and improved health care. For example, WLF has worked to improve patient access to developmental drugs. *See, e.g., Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (*en banc*), *cert. denied*, 128 S. Ct. 1069 (2008). WLF successfully challenged FDA restrictions on patient access to speech regarding off-label uses of FDA-approved products. *Washington Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir. 2000). WLF is currently involved in litigation with CMS over CMS's restrictions on patient access to truthful information about insurance benefits available to under Medicare Part D. *Fox v. Leavitt*, No. 06-1490(RMC) (D.D.C.). WLF regularly submits formal comments to CMS in regulatory proceedings, in support of increased patient access to medical care. For example, WLF submitted comments to CMS on February 10, 2004, and June 25, 2004, concerning Medicare coverage of off-label uses of FDA-approved cancer drugs under Part B, Part D, and the Section 641 demonstration program. WLF also submitted comments to CMS on June 6, 2005, concerning the agency's draft guidance entitled, "Factors CMS considers in Making a Determination of Coverage with Evidence Development." On June 13, 2007, WLF submitted comments to CMS concerning the agency's "Proposed Decision Memorandum for Erythropoiesis Stimulating Agents (ESAs) for Non-Renal Disease Indications."

II. Background

In connection with its recent proposed 2009 Inpatient Prospective Payment System regulation, 73 Fed. Reg. 23528 (Apr. 30, 2008), CMS noted that it is concerned with a recent "increase in physician investment in implant and other medical device manufacturing, distribution, and purchasing companies" and the possible program and patient abuse that this could cause. 73 Fed. Reg. at 23694. As a result, CMS requested public comments regarding "whether our physician self-referral rules should address POCs and similar physician owned companies more specifically." *Id.* at 23695.

CMS's concern revolves around the likelihood that "[t]he financial incentives paid to the physicians [with an ownership stake in a POC] may foster an anti-competitive climate, raise quality of care concerns, and lead to over-utilization of the device or other product to which the physician is linked." *Id.* at 23694. This concern arises because physicians tend to order more medical services and supplies when they have a financial interest in an entity providing those services and supplies. CMS also expressed concern that because physicians are responsible for recommending the devices ordered for a hospital's patients and have a natural tendency to

recommend devices sold by POCs in which they have a financial interest, there is a serious danger that "medical device or implant companies without physician investment will have difficulty finding referral sources in areas where many physicians are invested in a POC that offers competing products." *Id.* Thus, CMS solicited comments regarding whether "physician self-referral rules should address POCs and similar physician owned companies more specifically, or whether the concerns surrounding POCs and similar organizations . . . are better addressed through enforcement of the False Claims Act, the anti-kickback statute and similar fraud and abuse laws." *Id.*

III. CMS is Authorized to Modify Its Self-referral Rules to Apply Them Specifically to POCs and Similar Physician-Owned Companies.

CMS is charged with administering the Social Security Act (SSA), which includes the Stark Law. Its responsibilities include promulgating and revising regulations designed to implement and further the purposes of the SSA. CMS would be acting well within its statutory authority were it to revise those regulations to provide explicitly that the Stark Law in most instances prohibits a POC from supplying implants or other medical devices in connection with the services of a physician with a financial interest in the POC.

WLF notes initially that CMS itself recognizes that "many POCs" are already subject to the Stark Law's restrictions by virtue of existing regulations related to indirect compensation arrangements. 73 Fed. Reg. at 23695. As CMS acknowledges:

> In some problematic circumstances, an unbroken chain of financial relationships will connect the physician owner of a POC to a DHS entity to which the physician makes referrals, and the other elements of an indirect compensation arrangement contained in [42 C.F.R.] § 411.354(c)(2) will also be present, including the requisite knowledge by the DHS entity of the physician's interest in the POC. In many instances the arrangement would not satisfy the requirements of the exception for indirect compensation arrangements in § 411.357(p), and would, therefore, run afoul of the physician self-referral statute.

Id. Thus, CMS recognizes that the Stark Law authorizes CMS to broadly prohibit self-referral even when the entity in which the physician holds a financial interest does not itself present any Medicare claims. The principal difficulty with the current state of affairs, however, is (as stated above) that the indirect compensation regulations require evidence that the hospital (the DHS entity) knows of the physician's financial interest in the POC from which it purchases medical devices. While it is wholly reasonable to assume that a hospital knows that a physician would not be recommending that it purchase product from a new, boutique device company in the absence of such a financial interest, proving such knowledge can be difficult and has led to underenforcement of the Stark Law. Yet, even in the absence of evidence of such knowledge, it

is fair to characterize the relationship between a doctor, his/her POC, and the hospital to which the doctor recommends the POC's product (and which undoubtedly recognizes that abiding by the doctor's recommendation greatly serves its financial self-interests) as constituting "an unbroken chain of financial relationships." *Id.*

The Stark Law contains very broad statutory language that can comfortably be interpreted as authorizing CMS to take actions to ensure that the self-referral rules specifically address POCs and similar physician-owned companies. The Stark Law provides that if a physician has a financial relationship with an entity in which he has an ownership, investment, or compensation interest, then: (A) the physician may not make a referral to the related entity for the furnishing of "designated health services" (DHS) for which payment otherwise may be made under the Medicare laws; and (B) the entity may not present "or cause to be presented" a claim for Medicare payment for DHS provided pursuant to a referral from the physician. 42 U.S.C. § 1395nn(a)(1).[1] Although POCs do not normally themselves present claims for Medicare payment, CMS could reasonably determine that a POC "cause[s]" a claim "to be presented" whenever a hospital purchases an implant from the POC for the purpose of permitting the physician-owner to use that device in his practice at the hospital. Physicians are in a position to insist that hospitals buy through their POCs, of course, because they can take their surgical business elsewhere if the hospital balks. That power to insist on purchases from their POCs exists regardless whether they reveal their ownership interest to the hospital.

Moreover, § 1395nn(a)(1)(B) can reasonably be interpreted by CMS to attribute the actions of the POC to the physician – *i.e.,* if the POC has caused a claim to be presented to Medicare, then so has the physician. Just as CMS has deemed physicians to "stand in the shoes" of their group practices, so too should it deem physicians to "stand in the shoes" of their POCs, particularly given that most POCs do not offer any real services but rather serve as a device by which physicians can funnel additional funds to themselves. Accordingly, WLF supports both of the principal regulatory changes proposed by the Quality Implant Coalition – revising 42 C.F.R. § 411.351 to clarify the circumstances under which an entity "causes a claim to be presented" and revising 42 C.F.R. § 411.354(d) to clarify when payments by a hospital to a POC should be deemed a "direct compensation arrangement" with the referring physician. WLF respectfully submits that regulations clarifying the Stark Law in this manner would be well within the statutory authority of CMS under the Stark Law.

The history and purpose of the Stark Law amply support the notion that CMS is authorized to extend the rules to address POCs explicitly. Prior to the enactment of the Stark Law, there were a number of studies that gave rise to concern over the referral patterns of

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[1] The term "designated health services" encompasses a wide range of medical supplies, services, and equipment, which incorporates implants and virtually all other medical devices. *See* 42 U.S.C. 1395nn(h)(6).

physicians who make referrals to entities with which they have some financial relationship. For example, one study conducted by the Office of Inspector General (OIG) of the Department of Health and Human Services reported that patients of physicians who owned or invested in independent clinical laboratories received forty-five percent more laboratory services than all Medicare patients in general. 63 Fed. Reg. 1659 (Jan. 9, 1998). Other studies consistently found that physicians who had ownership or investment interests in entities to which they referred ordered more services than physicians without those financial relationships. This created concerns of over-utilization and other problems, such as anti-competitive behavior. 66 Fed. Reg. 856, 860 (Jan. 4, 2001). Thus, the Stark Law was enacted for the purpose of broadly "addressing over-utilization, anti-competitive behavior, and other program abuses that occur when physicians have financial relationships with certain entitles to which they refer Medicare or Medicaid patients." 72 Fed. Reg. 51012, 51078 (Sept. 5, 2007).

The Stark Law was enacted in 1989 by Section 6204 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239, which added Section 1877 to the Social Security Act. In general, the law provided that, if a physician had any financial relationship with a clinical laboratory, that physician could not make a referral to the laboratory entity for the furnishing of clinical laboratory services for which Medicare might otherwise pay. Since 1989, the Stark Law has been revised and clarified by Congress and CMS a number of times, but the focus of the law remains broadly combating physician referral arrangements that cause over-utilization and create an anti-competitive climate. CMS recently determined that referrals to certain "under arrangements" service providers (e.g., physician-owned staffing, leasing, and similar entities) were "contrary to the plain intent" of the Stark Law due to the likelihood of over-utilization and negative effects on the market, and thus that it was authorized to enact regulations providing that such referrals are barred under the Stark Law. 72 Fed Reg 38122, 38187 (July 12, 2007). That rationale supports a similar determination with respect to POCs.

Self-referral arrangements have changed in recent years. At the time the Stark Law was enacted, the main focus was on physician investment in independent laboratories. Today, on the other hand, there has been a large increase in physician investment in implant and other medical device companies, which are not now specifically addressed by regulations implementing the Stark Law. These arrangements, like those with independent laboratories, threaten the very purpose for which the Stark Law was originally enacted. CMS recently noted its concern that the increase in self-referral to implant and other medical device companies could "foster an anti-competitive climate, raise quality of care concerns, and lead to over-utilization of the device or other product to which the physician is linked." 73 Fed. Reg. at 23694. Because physician-owned implant and other medical device companies threaten the very purpose of the Stark Law, CMS would be well within its authority to take action to ensure that such arrangements are covered under the Stark Law.

IV. Clarifying the Self-Referral Law is the Most Appropriate Means of Addressing Concerns Surrounding POCs and Similar Physician Owned Companies.

The Stark Law is the most appropriate means of addressing concerns associated with POCs. As noted earlier, the purpose of the Stark Law is to address concerns regarding over-utilization and anti-competitive behavior that occur when physicians have an economic interest with entitles to which they refer Medicare and Medicaid patients. 72 Fed. Reg. 51012, 51078. There are no laws better equipped to address concerns surrounding POCs. Because proving violations of the anti-kickback statute and the False Claims Act entails meeting significantly higher evidentiary standards, particularly with respect to intent, those statutes are not up to the task of halting POC abuses.

Both the anti-kickback statute and the Stark Law address Congress's concern that when physicians have a financial incentive to refer patients to facilities or recommend certain procedures and products, the medical marketplace suffers. 63 Fed. Reg. 1659, 1662. Although generally similar in purpose, the two laws are different in structure and approach. The anti-kickback statute prohibits, *inter alia*, knowingly and willfully soliciting or receiving any remuneration in return for referring a patient, or recommending or purchasing any facility, good, or service that is paid for in part under a federal health care program. *See* 42 U.S.C. § 1320a-7b(b).

The False Claims Act (FCA) was enacted to prevent fraud against the government. The FCA imposes liability on any person who submits a false claim to the federal. Therefore, a physician would be liable under the FCA for submitting a falsified bill to Medicare, or causing others to do so. Like the anti-kickback statute, the FCA requires that a litigant prove that the wrongdoer acted "knowingly" with respect to his fraudulent conduct. 31 U.S.C. § 3729.

The Stark Law is much broader in scope than the anti-kickback statute and the FCA. First, unlike its counterparts, the Stark Law does not contain an intent, or *mens rea*, requirement. Prior to enacting the Stark Law, Congress recognized the problem of self-referral and realized that it could not be adequately addressed under a statute that required litigants to show intentional or willful wrongdoing. Congress realized that the most serious shortcoming of the prior law was "the enormous difficulty involved in proving to the satisfaction of a judge that a particular arrangement is deliberately structured to induce referrals." 135 Cong. Rec. H240-01 (1989). Thus, Congress enacted the Stark Law as a ban on self-referral "that is effective regardless of intent." 63 Fed. Reg. 1659, 1662. The lack of an intent requirement makes the Stark Law a much more effective means of combating the POC self-referral issue, because, unlike the situation faced in litigation under the anti-kickback statute or the FCA, the government does not have the often insurmountable burden of proving that a commonplace, seemingly legitimate business arrangement was knowingly organized to defraud the federal government.

Also, the Stark Law has comparatively narrow exceptions. The anti-kickback statute, for example, includes very broad "safe harbor" exceptions which provide absolute immunity for those entitles that can establish their eligibility for those safe harbors. 42 U.S.C. § 1320a-7b(b). Under the Stark Law, however, a questionable referral is presumptively prohibited, unless the physician can show that it fits into one of the narrow exceptions enumerated in the Stark Law itself. It is entirely possible that a physician that could not meet a safe harbor exception would be liable under the Stark Law but not liable under the anti-kickback statute. 63 Fed. Reg. 1659, 1662-63. Therefore, although a physician could potentially be held liable for recommending or referring a patient to a POC under the anti-kickback statute, the False Claims Act, and similar fraud and abuse laws, the Stark Law is a more appropriate means of addressing the POC self-referral problem. In light of evidence that POCs give rise to all the problems that led to adoption of the Stark Law – an anti-competitive climate, concerns over quality-of-care issues, and over-utilization of devices – there is every reason to conclude that Congress intended the Stark Law to apply to POCs.

Conclusion

For the foregoing reasons and those provided in other comments, the Washington Legal Foundation respectfully requests that CMS clarify the physician self-referral rules to more specifically address POCs. The Stark Law is better suited to address the issues regarding POCs than are other enforcement mechanisms. Moreover, the Stark Law undoubtedly authorizes expanding the regulations in this manner, given that doing so directly serves the very purposes of the statute.

Sincerely,

/s/ Daniel J. Popeo
Daniel J. Popeo
Chairman and General Counsel

/s/ Richard A. Samp
Richard A. Samp
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/s/ Britton D. Douglas
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Judge K.K. Legett Academic Fellow