Physician's Guide to the Anti-Kickback Statute – Part I

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Date: October 15, 2016

As we noted in our recent articles concerning the Stark law (the Physician's Guide to the Stark Law – Part I and Part II), physicians are under increasing scrutiny by federal and state enforcement agencies with respect to their financial relationships both within their medical practices and outside their medical practices. As such, these relationships often need to be evaluated, not only to ensure compliance with the Stark law, but also to ensure compliance with what is referred to colloquially as the "Anti-Kickback Statute" (the "**AKS**"). Stated otherwise, compliance with the Stark Law does not automatically equate to compliance with the AKS and vice-versa. This article provides a cursory summary of the AKS, which is a criminal statute that prohibits exchanging, or offering to exchange, anything of value in return for referring, or inducing another to refer, Federal health care program business. While the original intent of the AKS was to prohibit only what is commonly understood as cash kickbacks or bribes in the context of providing or seeking certain referrals, the reach of the AKS prohibition has expanded exponentially over time to also proscribe many non-cash arrangements where even a single purpose of the arrangement is to induce referrals of Federal health care program business. This article is not intended to provide an exhaustive treatment of the AKS, but rather, to serve as a general reference and educational guide. Physicians and medical practices are encouraged to seek advice from their own counsel to address specific legal issues that arise in their individual practices.

This initial AKS article will address the AKS prohibition in detail and then generally discuss the exceptions and safe harbors thereto. In a follow up article, we will address in greater detail certain exceptions and safe harbors often relied on by physicians in an effort to avoid violating the AKS.

The Anti-Kickback Statute Prohibition.

The AKS, as amended, prohibits *anyone* from knowingly and willfully soliciting or receiving, or offering or paying, any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring, or to induce a person to refer, an individual for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. § 1320a-7b(b)(1) and (2). The AKS, as amended, also contains a similar prohibition forbidding the exchange of remuneration in return for the, or to induce a person to, purchase, lease, or order (or for arranging for or recommending the purchase, lease or order of) any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program. *Id*. Again, even non-cash arrangements, such as a hospital renting a physician office space below fair market value or providing a physician with free support staff, may violate the AKS if even one purpose of the arrangement is to induce referrals. Moreover, the penalties for violating the AKS may be severe.

Unlike the Stark law, the AKS is a criminal statute and, as a result, conviction thereunder is a felony that may result in a fine up to $25,000 and imprisonment up to five years for a single violation. *Id.* Conviction also results in mandatory exclusion from participation in Federal health care programs. 42 U.S.C. § 1320a-7(a). Even if conviction is avoided, a violation of the AKS may still result in mandatory exclusion from participation in Federal health care programs at the discretion of the Secretary of the United States Department of Health and Human Services ("**HHS**") as well as civil monetary penalties (including possible treble, i.e., triple, damages plus $50,000 for each violation). 42 U.S.C. § 1320a-7(b) and 42 U.S.C. § 1320a-7(a)(7). Finally, as clarified in the 2010 Patient Protection and Affordable Care Act ("**PPACA**"), any claim submitted in violation of the AKS may also constitute a false or fraudulent

claim in violation of the False Claims Act, 31 U.S.C. §§ 3729–3733 ("**FCA**"). Pursuant to the FCA, a civil enforcement statute that will be discussed in greater detail in a subsequent article, penalties may include treble damages and an additional penalty of $5,500 to $11,000 for each "false claim" filed (many FCA cases involve numerous false claims that have been submitted over the span of several years, which can often lead to ruinous exposure). Moreover, individuals may be found liable, perhaps even criminally in extreme cases, if they are found to have acted willfully, recklessly, or with deliberate ignorance in making or causing the submission of false claims. 31 U.S.C. § 3729. In an effort to avoid these substantial dangers, let's take a closer look at each element of the AKS prohibition.

The AKS prohibits:

i. anyone

Comment: The AKS applies to physicians and non-physicians alike. As the HHS has specifically stated: "one does not have to be a 'provider'… to be covered by the anti-kickback statute" and "[t]he statute covers any persons who offer, pay, solicit, or receive any unlawful remuneration." 42 C.F.R. § 1001.951.

ii. from knowingly and willfully

Comment: Violation of the AKS requires that some degree of scienter, i.e., criminal intent, exists. Specifically, an individual cannot be prosecuted under the AKS unless he or she "knowingly and willfully" engages in the conduct proscribed by the statute. While courts have long disagreed on whether violation of the AKS required an individual to have actual knowledge of what the AKS proscribed and/or specific intent to violate the statute, PPACA amended the AKS to explicitly clarify that an individual need have neither (actual knowledge, or a specific intent to commit a violation, of the AKS) in order to violate the statute. *See* 42 U.S.C. § 1320a-7b(h). Rather, an individual can violate the AKS if he or she knew that his or her conduct was generally unlawful, i.e., was intended to induce referrals with, or make referrals for, anything of value, even if the individual did not know that the conduct was explicitly proscribed by the AKS. Although room still exists for interpretation of the AKS intent standard as clarified by PPACA, there is little doubt that an AKS violation is now much easier for the government to prove. Moreover, many courts still adhere to the "one purpose" rule first espoused in *United States v. Gerber*, 760 F.2d 68 (3d. Cir. 1985). This rule holds that if even one purpose of a payment is to induce referrals of Federal health care program business, the payment violates the AKS regardless of the existence of other legitimate purposes for the payment. Accordingly, as the AKS intent standard is presently defined and interpreted, neither ignorance of the AKS prohibition nor the existence of legitimate business reasons for making or receiving a payment insulates an individual from the reach of the statute if even one purpose of the payment is to induce (or to reward) the referral of Federal health care program business.

iii. soliciting or receiving, or offering or paying,

Comment: The AKS prohibition applies to both sides of a referral relationship. That is, it covers those who solicit or receive payment in return for making referrals of Federal health care program business as well as those who offer to pay or pay for such referrals. Of course, if payment is solicited for such referrals but the solicitation is denied, or if an offer to pay for such referrals is made but the offer is denied, then only the individual who engaged in the proscribed conduct is liable under the AKS. However, such scenarios are rare, and in the more typical scenario where both sides of the referral relationship are the subject of the government's investigation, the government often plays one side against the other in an effort to bolster its position. Also, as the

statute makes clear, an AKS violation can exist even if the improper payment is merely solicited or offered—it need not be exchanged.

iv. any remuneration, directly or indirectly, overtly or covertly, in cash or in kind

Comment: The AKS specifically provides that remuneration includes any "kickback, bribe, or rebate." However, the AKS further provides that remuneration can be direct or indirect, overt or covert, in cash or in kind. While direct cash payments in return for referrals (or the offer of such payments) clearly constitute remuneration for purposes of the AKS, it is less clear what qualifies as indirect, covert or in kind remuneration subject to the AKS. As a starting point, the United States Department of Justice (the "**DOJ**") recently implied that "remuneration" for purposes of the AKS includes those practices described in the definition of "remuneration" contained in the civil monetary penalties ("**CMP**") statute. *See* DOJ's January 21, 2015 Amicus Curiae brief filed in *Ameritox, Ltd. v. Millennium Laboratories, Inc.*, 803 F.3d 518 (11th Cir. 2015) (citing the CMP "remuneration" definition found at 42 U.S.C. § 1320a-7a(i)(6) for the proposition that "the AKS broadly defines the term 'remuneration' to include 'transfers of items or services for free or for other than fair market value.'"). Accordingly, it is reasonable to conclude that the DOJ believes, and courts have specifically held, that those practices detailed in the CMP "remuneration" definition, including "the waiver of coinsurance and deductible amounts (or any part thereof)," as well as "transfers of items or services for free or for other than fair market value," are practices that qualify as "remuneration" for purposes of the AKS, except in those limited circumstances also outlined in the CMP "remuneration" definition. *See, e.g., U.S. v. Narco Freedom, Inc.*, 95 F.Supp.3d 747, 757 (S.D.N.Y. 2015) (citing numerous cases that have cited the CMP "remuneration" definition when interpreting what constitutes "remuneration" under the AKS). Conversely, however, the HHS Office of Inspector General (the "**OIG**") has intimated that those practices specifically excluded from the CMP "remuneration" definition are not necessarily excluded from the ambit of "remuneration" for purposes of the AKS. *See* Medicare and State Health Programs, 79 Fed. Reg. at 59,724 (asserting that the exceptions to the CMP "remuneration" definition apply only to the definition of "remuneration" in the CMP statute). In short, then, unless a proposed practice falls within the narrow definition of "remuneration" set forth in the CMP "remuneration" definition or is the specific subject of an OIG advisory opinion or court decision, which is highly unlikely, whether the practice represents "remuneration" under the AKS will fall in a gray area. In such instances, it is critical to understand that "remuneration" for purposes of the AKS has typically been broadly defined, by both the OIG and courts, as anything of value whether tangible or intangible, including, by way of example, an "opportunity to generate fees" and even the "opportunity to bill" for patient services. *See* OIG Advisory Opinion 08-10 (August 26, 2008) and *United States ex rel. Fry v. The Health Alliance of Greater Cincinnati, et al.* (Christ Hospital of Cincinnati), No. C-1-03-167 (S.D. Ohio Feb. 2, 2010).

v. in return for referring, or to induce a person to refer, an individual to a person for the furnishing or arranging for the furnishing of any item or service (or in return for the, or to induce a person to, purchase, lease, order, or for arranging for or recommending the purchase, lease or order of, any good, facility, service or item)

Comment: As the statute also makes clear, an AKS violation can exist even if the improper referral is not made or accepted (or the improper purchase, lease or order is not made or offered) – simply intending to induce such an improper referral (or improper purchase, lease or order) can constitute an AKS violation.

vi. for which payment may be made in whole or in part under a Federal health care program

Comment: For purposes of the AKS, a "Federal health care program" is not limited to the Medicare and Medicaid programs, but rather is defined to include "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part by the United States Government (other than the [Federal employee health benefits program]); or (2) any State health care program…" 42 U.S.C. § 1320a-7b(f). While the AKS specifically limits its application to "Federal health care programs," the OIG has repeatedly voiced its concern that referral arrangements that purport to concern only "private pay" referrals may, in fact, improperly induce parties to refer other business which is funded under a Federal health care program. *See*, *e.g.*, OIG Advisory Opinion No. 13-03 (June 7, 2013) (stating in part that "…we are concerned that the financial incentives offered through the private pay clinical laboratory business under the Proposed Arrangement are likely to affect a physician's decision-making with respect to all of his or her patients, including Federal health care program beneficiaries, potentially resulting in the overutilization of laboratory services generally and increased costs to the Federal health care programs.").

The AKS Exceptions and Safe Harbors.

Perhaps recognizing the breadth of the AKS and the uncertainty that it has created among health care providers, Congress has to date created ten (10) separate exceptions to the application of the AKS, including an exception that permits the HHS to promulgate regulations outlining certain practices that will not be prosecuted under the AKS or result in exclusion from participation in Federal health care programs. In turn, the OIG (on behalf of the HHS) has to date promulgated over twenty-five (25) separate regulatory "safe harbors." Each safe harbor has very specific requirements, often including that the proposed arrangement be commercially reasonable and the remuneration contemplated by the proposed arrangement be consistent with fair market value. However, because the AKS is not a strict liability statute, an arrangement that implicates the AKS may still be permissible even if it does not fully satisfy an applicable safe harbor. Even so, under any circumstance, a proposed arrangement should be structured to comply as closely as possible with a safe harbor, precisely because the reach of the AKS is so expansive and many proposed arrangements are neither clearly permitted under, nor prohibited by, the AKS. The AKS exceptions and safe harbors, including the often-employed safe harbors for space and equipment rental and personal services and management contracts, will be the focus of our next article.
