Healthcare Whistleblower Claims Based on Self-Referral Arrangements

Two federal laws regulate referrals and financial arrangements between healthcare providers and facilities – Stark Law and the Anti-Kickback Statute.[1] These laws have recently been at the center of important **healthcare whistleblower fraud cases**. While both serve the same essential purpose – to eliminate improper financial incentives that interfere with independent medical judgment and good patient care – they do so in slightly different ways and contexts.

Stark Law (also known as the "Ethics in Patient Referrals Act") prohibits physician referrals of specified or "designated health services" for Medicare and Medicaid patients, where the physician or her immediate family member has a financial relationship with the referred entity.[2] A financial relationship can include ownership, investment interest, and direct or indirect compensation arrangements.[3] A "referral" is broadly defined to include "the request by a physician for the item or service" (Medicare Part B services) and "the request or establishment of a plan of care by a physician which includes the provision of the designated health service" (all other services).[4] Designated health services (DHS) include laboratory services, physical therapy and occupational services, radiology (including MRI, ultrasound, and computer tomography scan) services, radiation therapy services and supplies, durable medical equipment and supplies, prosthetics, orthotics, and prosthetic devices, home health services and supplies, outpatient prescription drugs, and inpatient and outpatient hospital services.[5]

Many types of contractual arrangements involving physicians and health providers may be implicated by Stark Law, including employment and compensation agreements, personal services agreements, physician incentive plans, practice group hospital contracts, physician payments, and equipment and other leases, to name a few. If a referral of DHS is covered by Stark, then, unless one of Stark's enumerated exceptions applies, the entity providing the DHS may not bill the patient, Medicare or Medicaid, or any other entity, and must refund any payments collected for DHS services provided. The law has several exclusions, including certain physician services and in-office ancillary services, ownership in publicly traded securities and mutual funds, fair market rental of office space and equipment, and bona fide employment relationships.[6] Penalties of up to $15,000 may be imposed for each non-compliant bill or failure to make a refund, and up to $100,000 for any "circumvention scheme."[7]

The Anti-Kickback Statute (AKS) is a criminal statute that prohibits the exchange (or offer to exchange) of anything of value, in order to induce (or reward) the referral of federal health care program business.[8] The law is broadly drafted, and creates civil and criminal penalties for all individuals and entities involved in prohibited transactions. A person convicted of a single

[1] 18 U.S.C. §1395nn (Stark Law); 42 U.S.C. §1320a-7b(b) (Anti-Kickback Statute).
[2] 42 U.S.C. §1395nn.
[3] 42 U.S.C. §1395nn(a)(2).
[4] 42 U.S.C. §1395nn(h)(5)(a).
[5] 42 U.S.C. §1395nn(h)(6).
[6] 42 U.S.C. §1395nn(b)-(e).
[7] 42 U.S.C. § 1395nn(g)(3)-(4).
[8] 42 U.S.C. § 1320a-7b.

violation of the AKS may be fined up to $25,000 and be sentenced up to five years in prison.[9] A conviction also results in a provider's mandatory exclusion from participation in federal health care programs (including Medicare and Medicaid).[10] Even individuals not convicted of a violation may still be excluded from federal programs at the discretion of the Secretary of Health and Human Services.[11] Under the AKS, the government may also assess civil monetary penalties, including treble damages, and $50,000 for each violation.[12]

Like the Stark Act, the AKS excludes certain transactions and payment arrangements.[13] The U.S. Department of Health & Human Services Office of Inspector General (OIG) has also adopted safe harbors excluding certain business and financial practices from criminal and civil prosecution, provided that they are within parameters defined to minimize the risk of possible corruption.[14] Transactions which are not specifically excluded or granted safe harbor protection are evaluated by the OIG on a case-by-case basis,[15] and parties facing uncertainty over specific arrangements can seek an advisory opinion from the OIG.

While neither the Stark Act nor AKS provides a private right of action, courts have held that violations of these laws can provide a basis under the False Claims Act[16] for individuals to bring private qui tam actions.[17] Under the **False Claims Act**, a private citizen who discovers or knows about **false claims** or fraud against the federal government may sue on behalf of the government to recover damages. If successful, the whistleblower or "relator" may receive a percentage of the ultimate recovery for their efforts, typically between 15 and 25 percent. More and more, federal whistleblower cases are being successfully pursed in the context of healthcare fraud, including for unlawful referral fees and financial arrangements in violation of Stark Act and the AKS. From 2009 through 2013, the federal government obtained over $19 billion in healthcare fraud recoveries.[18]

A recent example of a successful **healthcare whistleblower lawsuit** involving alleged Stark Law violations is the case of *U.S. ex rel. Baklid-Kunz v. Halifax Hospital Medical Center and Halifax Staffing, Inc.*[19] In the suit, filed in 2009 by Halifax Hospital's former director of physician services, the hospital was accused of improperly compensating medical oncologists and neurosurgeons for referring patients to the hospital for procedures. The government intervened and sought to recover over $34 million in fraudulent Medicare claims it contended were the result of an unlawful compensation plan that paid doctors bonuses based on the net

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[9] 42 U.S.C. § 1320a-7b(b).
[10] 42 U.S.C. § 1320a-7(a).
[11] 42 U.S.C. § 1320a-7(b).
[12] 42 U.S.C § 1320a-7a(a)(7).
[13] 42 U.S.C. § 1320a-7b(b)(3).
[14] 42 C.F.R. § 1001.952.
[15] *See* Office of Public Affairs, Office of Inspector General Department of Health & Human Services, Fact Sheet November 1999, Federal Anti-Kickback Laws and Regulatory Safeharbors.
[16] 31 U.S.C. §§ 3729–3733.
[17] *See U.S. ex rel. Pogue v. American Heatlhcorp., 914* F.Supp. 1507 (M.D. Tenn. 1996); *U.S. ex rel. Pogue v. Diabetes Treatment Centers of America, Inc.*, 238 F.Supp.2d 258 (D.D.C. 2002); *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corporation*, 125 F.3d 899 (5th Cir. 1997).
[18] http://www.hhs.gov/news/press/2014pres/02/20140226a.html
[19] Case No. 6:09-cv-1002-Orl-31TBS, United States District Court for the Middle District of Florida.

operating margin of the hospital's medical oncology program. With treble damages and civil penalties under Stark Law, the hospital faced a possible damage award exceeding $1 billion. In March 2014, on the eve of trial, the hospital agreed to pay $85 million to settle the government's claims.

In the current era of managed healthcare and accountable care organizations, physicians and other providers can sometimes be subjected to severe economic pressure by healthcare organizations or facilities where they are employed or have practice relationships to engage in conduct that involves direct or indirect financial incentives that may potentially violate Stark Law, AKS, or both. Such actions could expose the provider to substantial civil and possible criminal liability[20] and possible exclusion from Medicare and Medicaid programs, putting the provider's license and career at risk. CMS provides a Voluntary Self-Referral Disclosure Protocol pursuant to which potential Stark violations can be reported in an effort to minimize potential liability.[21]

Given the serious consequences, physicians, healthcare providers or their employees who have questions about the legality of a contractual or other arrangement regarding medical services should seek qualified legal counsel to review the contract and circumstances and provide guidance on the potential serious legal issues and obligations she faces regarding with the same.

Disclaimer: thoughts shared here do not constitute legal advice. Please consult with an attorney to discuss your legal issue.

About the authors
Jay Brownstein and Kevin Little are experienced litigators who often represent parties in complex disputes pending in state and federal courts and before administrative agencies, including whistleblower matters. To learn about the authors, please visit their websites at www.bnlawatlanta.com and www.ksllawfirm.com, or email them at jdb@bnlawga.com or kevin@ksllawfirm.com.

[20] For example, fines under Stark Law are up to $15,000 for *each instance* of a prohibited referral and $100,000 for each prohibited referral arrangement. 42 U.S.C. 1395nn(g)(4).
[21] *See CMS Voluntary Self-Referral Disclosure Protocol*, OMB Control No. 0938-1106.