The Stark Law and Anti-Kickback Statute: What Are They and Why Do Health Care Industry Participants Need to Know?

by Rachel V. Rose

Rachel V. Rose, J.D., MBA, is the chair of the FBA's Corporate and Association Counsel Division and is on the FBA Government Relations Committee. Rose is co-author of What Are International HIPAA Considerations? *and* The ABCs of ACOs. *She can be reached at* rvrose@rvrose.com.

Relationships with providers raise a number of potential issues under a variety of federal fraud and abuse laws. Specifically, the Department of Health and Human Services Office of the Inspector General (HHS-OIG) identified the five most crucial federal fraud and abuse laws that apply to physicians and, in turn, industry participants who have relationships with them. The five laws include: the federal Anti-Kickback Statute (AKS), the Physician Self-Referral Law (Stark Law), the False Claims Act (FCA), the Civil Monetary Penalties Law, and the federal statutory authorities under which a physician may be excluded from federal health care programs.[1] There are two laws that every person involved in or interacting with the health care industry needs to know—Stark Law[2] and the AKS.[3] The primary goal of the Stark Law is to mitigate the influence of financial considerations on physician referrals.[4] The AKS extends beyond referrals and impacts a multitude of physician business relationships. Moreover, both of these laws can be used as the basis for FCA violations when government programs are impacted.[5] Therefore, the potential damages, both economic and reputational, increase exponentially for all parties involved.

Given the importance of these two laws and the recent changes to the Stark Law, this article provides an overview of the law, the recent changes, and ways to avoid violations.

Analysis

The goal of this analysis is not to cover every aspect of these laws; rather, it is to provide the reader with a "flavor" for their importance. One of the reasons is that in 2015, the U.S. Department of Justice resolved a $237 million FCA judgment involving illegal payments made to referring physicians.[6] *United States ex rel. Drakeford v. Tuomey Healthcare System Inc*. Case No. 3:05-cv-02858 (MBS) (D.S.C.) became one of the most noted cases in the health law sector. "The type of abusive compensation arrangements at issue in this case is precisely what the physician self-referral law was designed to prevent," said HHS Inspector General Dan Levinson. "Patients need and deserve to know that the hospital services they receive are the product of sound medical judgment, rather than motivated by the physician's financial interests. The extensive litigation and settlement in this case should send a signal to the hospital industry that these tainted financial relationships simply will not be tolerated."[7] This statement again underscores that Stark and AKS violations can be used as the basis for FCA violations.

It is important to note that if the compensation arrangement is between a hospital and physician group that qualified as an Accountable Care Organization (ACO), then compliance with both the federal Stark Law and federal AKS may be waived.[8] Therefore, it is important to identify the corporate structure/relationship before considering what laws may or may not apply.

Stark Law

As set forth in the Nov. 16, 2015, *Federal Register*, the creation, inception, and evolution of the Stark Law is long and convoluted:

> Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payer) for those referred services. The statute establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Section 13624

of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66) (OBRA 1993), entitled "Application of Medicare Rules Limiting Certain Physician Referrals," added a new paragraph (s) to § 1903 of the act to extend aspects of the physician self-referral prohibitions to Medicaid. For additional information about § 1903(s) of the act, see 66 FR 857–858.

Several more recent statutory changes have also affected the physician self-referral law. Section 6001 of the Affordable Care Act amended § 1877 of the act to impose additional requirements for physician-owned hospitals to qualify for the rural provider and hospital ownership exceptions. Section 6409 of the Affordable Care Act required the Secretary, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral law.[9]

The Stark Law applies to a multitude of scenarios and has been implemented in three phases (e.g., Stark I,[10] Stark II,[11] and Stark III[12]). Further, numerous exceptions apply (e.g., office space and equipment rental exceptions, risk-sharing arrangements exception, and physician recruitment exception).[13] After the Stark Law was referred to by a judge for the U.S. Court of Appeals for the Fourth Circuit as "even for well-intentioned health care providers, […] a booby trap rigged with strict liability and potentially ruinous exposure,"[14] CMS revealed its final changes in the CY 2016 Medicare Physician Fee Schedule final rule.[15] Some key areas to evaluate closely in the final rule relate to recruitment and retention (§§ 411.357(e) and 411.357(t)), physician-owned hospitals, and disclosure of ownership requirements. In sum, Stark remains a complex law, which should not be overlooked by physicians, hospitals, or suppliers.

Anti-Kickback Law

Like Stark Laws, the AKS applies to a plethora of physician business relationship scenarios, which typically involve the procurement of goods and/or services, which are paid for by a federal health care program. "The Anti-Kickback Statute prohibits the knowing and willful solicitation, receipt, offer, or payment of any remuneration in return for: referring an individual for any items or services covered by a federal health care program; or purchasing, leasing, or ordering or arranging for, or recommending or arranging for the purchase, lease, or ordering of any item or service paid for (in whole or in part) by a federal health care program."[16] Like Stark, the AKS also has "safe harbors" that exempt certain business arrangements from falling under the purview of the AKS. Some of the safe harbors include: payments to bona fide physician employees, certain investment interests, and waivers of coinsurance for Medicare services for select individuals.[17] Because of the potential civil and criminal penalties, close care should be taken to ensure compliance.

Conclusion

The easiest way to avoid potential violations of the Stark Law and AKS, as well as the FCA, is to make sure that the arrangement fits into the safe harbors of each law. Just because the Stark Law safe harbors are met does not mean the AKS safe harbors are satisfied and vice-versa. The first step is to look at the structure of the hospital-physician relationship. The second step is to identify the type of transaction (i.e., pharmaceutical company contract with physician for services, investment in a laboratory, or the development of an ACO). Third, see if the item fits into the safe harbors of each law or waiver program, if an ACO. Finally, in some instances, it may be prudent to request an opinion from the OIG. In sum, there is a lot at stake for violating these laws and it is important for all of the participants in these transactions to appreciate the consequences. ⊙

Endnotes

[1]American Bar Association, Physician Law—Evolving Trends & Hot Topics 2014, at 1 (2014).

[2]The Physician Self-Referral Law, § 1877 of the Social Security Act, 42 U.S.C. § 1395nn (1989).

[3]Anti-Kickback Statute, § 1128B(b) of the Social Security Act, 42 U.S.C. § 1320a-7b(b).

[4]American Health Lawyers Assoc., Public Policy Discussion: Taking Measure of the Stark Law (2009), *available at* www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf (last visited Feb. 29, 2016).

[5]*See* United States ex. rel. Moilan v. McAllen Hosps. L.P., No. M-05-cv-263 (S.D. Tex. Oct. 30, 2009); R. Grier, S. Frazier, J. Androphy, *False Claims Act Damages in Anti-Kickback and Self-Referral Cases,* ABA eSource (June 2011), *available at* www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1106_grier.html (last visited Feb. 29, 2016).

[6]U.S. Department of Justice, *United States Resolves $237 Million False Claims Act Judgment against South Carolina Hospital that Made Illegal Payments to Referring Physicians* (Oct. 16, 2015), *available at* https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital.

[7]*Id.*

[8]Raymund King, et al., *The ABCs of ACOs 32-33,* n. 7 (2014).

[9]80 Fed. Reg. 70855, 71300 (Nov. 16, 2015).

[10]Omnibus Budget Reconciliation Act of 1989 Pub. L. No. 101-239, 103 Stat. 2395 (1989).

[11] Omnibus Budget Reconciliation Act of 1993 Pub. L. No. 103-66, 107 Stat. 312 (1993).

[12] 72 Fed. Reg. 51012 (Sept. 5, 2007).

[13] *Id.*

[14] *U.S. ex rel. Drakeford v. Tuomey,* 792 F.3d 364, 395 (4th Cir. 2015) (Wynn, J., concurring).

[15] U.S. Dep't of Health and Human Servs., Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016, 80 Fed. Reg. 70885, 71300-71341 (Nov. 16, 2015). A pre-publication version of the Final Rule was released by CMS on Oct. 30, 2015.

[16] *Supra* n. 1.

[17] See 42 U.S.C § 1320a-7b(b)(3); 42 C.F.R. § 1001.952(a).