NEW YORK STATE BAR ASSOCIATION

HEALTH LAW SECTION

October 26, 2018

Gregory R. Smith, Esq.
Garfunkel Wild, P.C.
111 Great Neck Road
6th Floor
Great Neck, NY 11021
gsmith@garfunkelwild.com

I. ANTI-REFERRAL LAWS

The anti-referral laws were designed, in part, to ensure that referrals for health care services are based on medical necessity and the best interests of the patient, rather than on the financial motives of the referring provider.

A. Anti-Kickback Laws. There are both Federal (*42 U.SC. § 1320a-7b[b])* and New York State Anti-kickback laws (*e.g., Social Services Law § 366-d*).

1. The Federal Anti-Kickback Statute (AKS). In general, the Federal AKS makes it a criminal offense to knowingly and willfully solicit, receive, offer or pay any remuneration to induce or reward referrals of items or services payable by a Federal health care program.

(a) What is Remuneration? The Federal AKS broadly defines "remuneration" to include virtually anything of value, including kickbacks, bribes or rebates solicited or given directly or indirectly, overtly or covertly, in cash or in kind. *See 42 U.S.C. §1320a-7b(b).*

EXAMPLE:

- *See e.g., U.S. v. Borrasi, 639 F.3d 774 (7th Circ. 2011)* (Affirming AKS conviction where, in return for past patient referrals or to induce future referrals, a physician and other members of his group were placed on an inpatient psychiatric hospital's payroll, given false titles and faux job descriptions and asked to submit false time sheets. They were not expected to perform any services. The hospital also paid the salary for the group's secretary and lease payments on one of its offices).

- *See e.g., U.S.A. v Narco Freedom, Inc., 95 F.Supp3d 747 (S.D.N.Y. 2015)* (granting government's motion for preliminary injunction against operator of Medicaid subsidized drug treatment programs upon finding that the operator provided "remuneration" to clients in the form of below-market housing conditioned on client enrollment in its outpatient programs, for which it received payments from Medicaid).[1]

(b) <u>What is a Federal health care program</u>? For purposes of the AKS, a "Federal health care program" is defined to mean: "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 . . . ." The definition also includes certain State health care programs. *See 42 U.S.C. §1320a-7b(f).* Examples include: Medicare, Medicaid, Veterans' programs and the State Children's Health Insurance Programs.

(c) "<u>One Purpose</u>." Courts have found that the AKS applies to any arrangement in which *one* purpose of the remuneration is to obtain money for the referral of services or to induce further referrals, even if there are other, wholly legitimate purposes for the arrangement. The purpose of the payment of remuneration to induce referrals need not be the primary or substantial purpose of the payment.

[1] Narco Freedom eventually entered into a settlement agreement with the U.S. Attorney's Office for the Southern District of N.Y. regarding three alleged separate fraud schemes, including the one described above. As part of the settlement, Narco Freedom, which at the time was in Chapter 7 bankruptcy, agreed (through the Chapter 7 Trustee) that the U.S. had a general unsecured claim for damages in the amount of $50,509,440 to be paid through the bankruptcy proceeding. Moreover, Narco Freedom was also excluded from participating in Federal health care programs for 50 years. *See Department of Justice Press Release*, dated July 14, 2017, issued by the U.S. Attorney's Officer for the Southern District of New York available at https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-settles-civil-fraud-lawsuit-against-narco-freedom-joining.

EXAMPLE:

- *See U.S. v Nagelvoort, 856 F.3d 1117, 1130 (7th Circ. 2017), certiorari denied by 138 S.Ct. 556 (2017)* confirming the Court's prior holding in *U.S. v Borrasi, 639 F.3rd 774, 781-82 [7th Circ. 2011]* that this interpretation of the AKS is not unconstitutionally vague as there is nothing in the AKS that implies that only the primary motivation of remuneration is to be considered in assessing the conduct at issue).

- *See e.g., U.S.A. v Narco Freedom, Inc., 95 F.Supp3d 747 (S.D.N.Y. 2015)* (one purpose of houses owned by Medicaid subsidized drug treatment provider was to induce Medicaid beneficiaries to enroll in operator's treatment programs. A resident faced eviction if he or she failed to attend the operator's programs).

(d) <u>Consequences</u>. A violation of the AKS is a felony, punishable by a fine of up to $100,000, imprisonment of up to ten years, or both. *See 42 U.S.C. § 1320a-7b(b).*[2] Among other potential consequences, administrative proceedings to impose civil monetary penalties (under 42 U.S.C. § 1320a-7a) and/or exclusion from participation in Federal health care programs under (under 42 U.S.C. § 1320a-7) are possible for AKS violations.

- *See, e.g., U.S. v. Babaria, 775 F.3d 593 (3rd Circ. 2014), Certiorari Denied by 135 S.Ct. 2066 (2015)* (affirming 48 month sentence of imprisonment and $25,000 fine imposed on radiologist who abused his

[2] These maximum penalties for violations of the AKS went into effect on February 9, 2018, as part of a revamping of both criminal and civil penalties for Federal health care program fraud and abuse enacted under the Bipartisan Budget Act of 2018 (Public Law No. 115-123). Prior to February 9, 2018, the maximum penalty for violating the AKS was a fine of up to $25,000, imprisonment of up to five years, or both.

position of trust vis-à-vis Medicare and Medicaid as the medical director and manager of an authorized MRI provider. On behalf of the provider, he certified compliance with the AKS, but nevertheless utilized his position as medical director/manager to supervise and conceal the payment of kickbacks. Babaria acknowledged when entering his guilty plea that he had paid physicians to refer their patients to the MRI provider for diagnostic testing, and that he billed Medicare and Medicaid for diagnostic testing that was tainted by these corrupt referrals.

EXAMPLE:

- *See, e.g., Anderson v. Thompson, 311 F. Supp.2d 1121 (D. Kan. 2004)* (Fifteen-year mandatory exclusion from participation in Medicare, Medicaid, and other Federal health care programs – three times the minimum exclusion period – was reasonable for hospital executive who was incarcerated for his convictions on conspiracy to commit kickback violations and offering and paying illegal remunerations, where conduct leading to convictions occurred over more than 10 year period and caused over a certain amount of loss to the Medicare program).

(e) <u>False Claims Act Exposure</u>. In addition to the above cited consequences, any claims submitted for items or services resulting from a violation of the AKS constitute a "false claim" under the Federal False Claims Act. *See 42 U.S.C. § 1320a-7b(g).* See discussion of the Federal and NY State False Claims Acts below in Section II.

(f) "<u>Knowledge or Intent</u>." A person need not have actual knowledge or specific intent to violate the statute in order to have violated the AKS. *See 42 U.S.C. § 1320a-7b(h).* However, the government must prove an intent to induce or reward referrals for the AKS to be violated.

(g) "<u>Safe Harbors</u>." Given the expansive nature of the AKS statute, Congress enacted exceptions for certain payment and business arrangements. *See 42 U.S.C. § 1320a-7b(b)(3).* In addition, the United States Department of Health and Human Services' Office of Inspector General (the "OIG") has promulgated regulations detailing a number of "safe harbors" that are not treated as violations of the law. *See 42 C.F.R. § 1001.952*. Safe harbor protection is only afforded to arrangements that precisely meet *all* of the conditions of the applicable safe harbor(s). That an arrangement is not in safe harbor, however, does not mean that it is illegal *per se*. *See MedPricer.com, Inc. v. Becton, Dixon and Company, 240 F.Supp.3d 263 (D. Conn. 2017), citing U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F.Supp.2d 39, 47 (D. Mass. 2011) ("To receive protection, a business arrangement must fit squarely within a safe harbor; substantial compliance is not enough, although compliance is voluntary and failure to comply is not a per se violation of the statute." (other citations omitted).* Rather, government agencies will typically look at the totality of the facts and circumstances in assessing whether there may be a violation of the law. In so doing, there are certain areas of particular concern that will usually be considered. These include, for example, whether the proposed transaction would result in: (a) a distortion in medical decision-making; (b) overutilization of Federal health care

program items or services; (c) increased Federal health care program costs; and/or (d) unfair competition. The government, of course, also looks at whether the arrangement reflects the parties' intention to induce improper referrals.

i. **Common Safe Harbor Provisions**. The more commonly encountered safe harbors (*i.e.*, those for space rentals, equipment rentals and personal services and management contracts) have certain similar provisions. These safe harbors all require that:

- the agreement be set out in writing and signed by the parties;
- the term of the agreement be for not less than one year;
- the aggregate rental or services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the rental or services;
- If the agreement is intended to provide the lessee with use of the equipment or space for periodic intervals of time, or for the services of the agent to be provided on a sporadic or part-time basis, rather than on a full-time basis, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact rent or charge for such interval.
- the aggregate rental charge or compensation be set in advance, be consistent with fair market value in arms-length transactions and not be determined in a manner that takes into account the volume or value of

any referrals of business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs; and

- the aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

- Note: for the space and equipment rental safe harbors, the term "fair market value" means the value of the rental property for general commercial purposes or the value of the equipment when obtained from a manufacturer or professional distributor, as applicable, and cannot be adjusted to reflect the additional value one party would attribute to the space or equipment 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 or other Federal health care programs.

- Note: for the personal services and management contracts safe harbor, there is the additional requirement that services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.

The current safe harbors are listed in Appendix A to this document.

- *See e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Circ. 2017), certiorari denied by 138 S.Ct. 556 (2017)* (Evidence was sufficient for jury to conclude that hospital's leases, personal service contracts, and teaching agreements with physicians took into account physicians' potential referrals, thereby placing them outside Anti-Kickback Statute's safe harbor, where, among other things, physicians testified that they had understanding that they were required only to bring patients to hospital and were not actually required to perform work outlined and chief operating officer was recorded stating that lease arrangement with physician was "a quid pro quo. We expect admissions to be sent to Sacred Heart Hospital, otherwise it doesn't make financial sense for us.")

EXAMPLE:

- *See e.g., U.S. ex rel. Banigan v. Organon USA Inc., et al., 883 F.Supp.2d 277 (D.Mass. 2012), reconsideration denied, 2012 WL 3929822* (alleged discounts and rebates in purchasing agreements between pharmaceutical manufacturer and long-term care pharmacy provider were not protected by the "discount" safe harbor to the AKS; relators alleged that contracts did not disclose the complete terms and conditions of the discount or rebate, and that the full terms and amounts of the discounts were allegedly concealed in various sham collateral contracts).

(h) <u>Advisory Opinions</u>. The OIG is authorized to issue advisory opinions addressing certain aspects of the AKS in relation to an existing arrangement, or

one which the requestor in good faith plans to undertake.[3] The OIG may opine on what constitutes prohibited remuneration; whether an arrangement or proposed arrangement satisfies the criteria set forth in an applicable "safe harbor," what constitutes an inducement to reduce or limit services to Medicare or Medicaid beneficiaries, and whether any activity or proposed activity constitutes grounds for the imposition of sanctions. *See 42 U.S.C. 1320a-7d(b); 42 C.F.R. §§ 1008.5, 1008.15.*

All of the OIG's Advisory Opinions are available on its website at: https://oig.hhs.gov/compliance/advisory-opinions/index.asp#advisory.

2. **The New York State Kickback Prohibition**. New York State also makes it a crime to offer, agree to give or give, or to solicit, receive, accept or agree to receive or accept, any payment or other consideration in any form to or from another person to the extent such payment or other consideration is given: (i) for the referral of services for which payment is made under the Medicaid Program; or (ii) to purchase, lease or order any good, facility, service or item for which payment is made under the Medicaid Program. Those who violate this statute may be found guilty of a misdemeanor crime punishable by fines of up to $10,000, imprisonment for up to one year or both; except that those who violate the statute and obtain money or property having a value in excess of $7,500 may be found guilty of a class E felony. However, if an activity meets a Federal exception or "safe harbor" under the Federal AKS, the

[3] The OIG may also issue advisory opinions as to the application of the following laws: exclusion authorities under 42 U.S.C. § 1320a–7, civil monetary penalty authorities under 42 U.S.C. §1320a–7a, and criminal penalties for acts involving Federal health care programs under 42 U.S.C. § 1320a–7b.

activity will also be deemed to have not violated New York's law. *See NY Social Services Law § 366-d.*

B. Physician Self-Referral Laws

1. The "Stark Laws." Federal and State law also prohibit certain referrals to an entity when the referring physician (or, in New York, certain health care practitioners) or his or her immediate family member has a financial relationship with the entity, unless an exception is met. Both the Federal and New York Stark laws are strict liability laws. In other words, the intent of the parties is irrelevant.

(a) The Federal Stark Law. The Federal Stark Law prohibits "referrals" by a physician (as defined below) for designated health services ("DHS," defined below) covered by Medicare (and possibly Medicaid) that are furnished by an entity with which the referring physician (or an "immediate family member" of the referring physician, defined below) has a direct or indirect "financial relationship" (as defined below), unless a specific statutory or regulatory exception is met. *See 42 U.S.C. § 1395nn (a)(1)(A).*

The Federal Stark Law also prohibits any entity from presenting or causing to be presented a claim or bill to Medicare (and possibly Medicaid) for DHS furnished pursuant to a prohibited referral. *See 42 U.S.C. § 1395nn (a)(1)(B*). Violating the Federal Stark Law can result in monetary penalties of up to $15,000 for each service billed. Entering into a scheme for the principal purpose of circumventing

the Federal Stark Law can result in a penalty of up to $100,000. *See 42 U.S.C. § 1395nn (g).*[4]

i. **Designated Health Services:** The Federal Stark Law and associated regulations enumerate the following list of DHS that are subject to the Law's referral prohibitions:

- Clinical Laboratory Services;
- Physical Therapy, Occupational Therapy and Outpatient Speech-language Pathology Services;
- Radiology and certain other imaging services;
- Radiation Therapy Services and Supplies;
- Durable Medical Equipment and Supplies;
- Parenteral and Enteral Nutrients, Equipment and Supplies;
- Prosthetics, Orthotics, and Prosthetic Devices and Supplies;
- Home Health Services;
- Outpatient Prescription Drugs;
- Inpatient and Outpatient Hospital Services.

See 42 U.S.C. § 1395nn (h)(6); 42 C.F.R. § 411.351.

[4] The above amounts are the amounts listed in the statute. They are subject to annual inflation-related adjustments. Currently, the adjusted amounts are $24,253 and $161,692, respectively, for penalties assessed after February 3, 2017, whose associated violations occurred after November 2, 2015. *See 45 C.F.R § 102.3.*

The Centers for Medicare and Medicaid Services (CMS) publishes lists of Current Procedural Terminology (CPT)/Healthcare Common Procedure Coding System (HCPCS) Codes that define the scope of the following DHS: clinical laboratory services; physical therapy services; outpatient speech-language pathology services; occupational therapy services; radiology and certain other imaging services; and radiation therapy services and supplies. The list is updated yearly.[5] The remaining categories of DHS are defined in the regulations.

ii. **Entity Furnishing DHS:** Generally speaking, an "entity" is considered to be furnishing DHS if it (i) is the person or entity that has performed services that are billed as DHS; or (ii) is the person or entity that has presented a claim to Medicare (and possibly Medicaid) for the DHS, including the person or entity to which the right to payment for the DHS has been reassigned (to an employer or under a contractual arrangement). *See 42 C.F.R. § 411.351.*

iii. **Fair Market Value:** "Fair market value" is the value that would be ascribed to the item or service in an arm's-length transaction, as the result of bona-fide bargaining between well-informed parties who are not otherwise in a position to generate business for each other. *See 42 C.F.R. § 411.351.*

[5] The list of codes for DHS is available through the Physician's Self- Referral Section of CMS's Web site at http://www.cms.gov/PhysicianSelfReferral/01_overview.asp

EXAMPLE:

➢ October 2015: A protracted prosecution involving violations of the Federal Stark Law came to a close when a settlement was reached allowing the defendant hospital system to pay $72.4 million to the U.S. government and approximately $18.1 million to the *qui tam* relator who had alleged that the hospital system, fearing that it could lose lucrative outpatient procedure referrals to a new freestanding surgery center, entered into contracts with 19 specialist physicians that required the physicians to refer their outpatient procedures to the system and, in exchange, paid them compensation that far exceeded fair market value. A jury had previously found that the health system violated the Stark Law and a $237 million judgment against the system had been entered. The government had also argued that the health system ignored and suppressed warnings from one of its attorneys that the physician contracts were "risky" and raised "red flags." *See* *https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital*.

iv. Financial Relationship: Unless specifically excepted, a "financial relationship" includes a referring physician's (or immediate family member's) (i) direct or indirect ownership or investment interest (which may be via equity, debt or otherwise and includes an option or nonvested interest) in the entity rendering the DHS or in an entity that holds an ownership or investment interest in the entity rendering the DHS; or (ii) direct or indirect compensation arrangement with the entity rendering the DHS, which means an arrangement involving any "remuneration (directly

or indirectly, overtly or covertly, in cash or in kind)" between a physician (or immediate family member of the physician) and a DHS entity. *See 42 C.F.R. §411.354*.

v. **Immediate Family Member:** The Federal Stark Law considers an "immediate family member" to be a husband or wife; natural or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild. *See 42 C.F.R. § 411.351*.

vi. **Referral and Referring Physician:** A "referral" is a request by a physician for, or the ordering of, or the certifying or recertifying the need for, any DHS for which payment may be made under Medicare Part B (and possibly Medicaid). In addition, the request or establishment by a physician of a plan of care that includes the provision of DHS is a referral by a referring physician. A referral does not include DHS personally performed or provided by the referring physician.

Under certain conditions, a referral under the Stark law does not include: (i) a request by a pathologist for clinical diagnostic laboratory tests and pathological examinations; (ii) a request by a radiologist for diagnostic radiology services; or (iii) a request by a radiation oncologist for radiation therapy. In general, these requests are excluded from the definition of referral when the request results from a consultation initiated by a

physician other than the one performing the tests, and tests or services are furnished by or under the supervision of the pathologist, radiologist or radiation oncologist. *See 42 C.F.R. § 411.351.*

vii. Exceptions. The Federal Stark Law contains a number of statutory and regulatory exceptions that are similar (although not identical) to the "safe harbor" regulations under the Federal AKS. *See 42 C.F.R. §§ 411.355 - 411.357.* which can be categorized as follows:

- exceptions applicable to ownership interests and compensation arrangements;
- exceptions applicable only to compensation arrangements; and
- exceptions applicable only to ownership interests

The current exceptions are listed in Appendix B to this document.

viii. Advisory Opinions. Any individual or entity may request a written advisory opinion from CMS concerning whether a physician's referral relating to DHS (other than clinical laboratory services) is prohibited under the Stark Law. *See 42 C.F.R. § 411.370.* CMS's advisory opinions are posted at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html.

(b) The New York State Stark Law. In New York, a health care practitioner may not make a referral to a health care provider for clinical laboratory services,

pharmacy services, radiation therapy services, x-ray or imaging services or physical therapy services if the practitioner or a member of his immediate family has a financial relationship (including an ownership interest, an investment interest or a compensation arrangement) with that provider, unless a statutory or regulatory exception is met (and again, there are a number of varied exceptions that exist). *See NY Public Health Law § 238 et seq.;10 N.Y.C.R.R. § 34-1.1 et seq.*

Unlike its Federal counterpart, the New York State Stark law covers all payors. If the referral is prohibited, so too is any demand for payment. The New York State Stark law also covers any cross-referral scheme designed to make referrals indirectly that could not be made directly. A provider or practitioner that collects any amount under a prohibited referral is jointly and severally liable to the payor. In addition, disciplinary action (including license revocation) by the appropriate State licensing authority is also a possibility. As with the Federal Stark Law, if the New York State self-referral law is implicated, applicable exception(s) must be met, or the law will have been violated (*i.e.*, the intent of the parties is irrelevant).

Note that there are differences between the scope and breadth of the Federal and State laws and exceptions. In other words, compliance with the Federal Law does *not* automatically mean that the arrangement complies with New York State's Law. Notably, the Federal law contains exceptions that do not appear in the State counterpart.

II. FALSE CLAIMS LAWS

As noted above, any claims submitted for items or services resulting from a violation of the AKS constitute a "false claim" under the Federal False Claims Act. *See 42 U.S.C. § 1320a-7b(g).* Although the Stark Law does not contain a similar provision, there are many examples of False Claims Act prosecutions and settlements based on referral arrangements that violated the Stark Law. *See e.g., U.S. ex rel. Drakeford v. Tuomey, 792 F.3d 364 (4th Circ. 2015).*

A. <u>The Federal False Claims Act</u>. The Federal False Claims Act ("FCA") is a broad statute that the government often utilizes in fighting fraud and abuse in the health care arena. Among other things, the FCA is violated by any person who:

- knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- conspires to commit the above (or other specified) violations; or
- knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the U.S. Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the U.S. Government. *See 31 U.S.C. § 3729.*

1. **Definitions**. In order to understand the FCA, and how it may be violated, there are certain key terms that must be understood. Some of the more significant ones are as follows:

(a) The term **"claim"** means any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that: (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(b) The term **"obligation"** means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

(c) The term **"material"** means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(d) The FCA broadly defines the terms **"knowing"** and **"knowingly."** Specifically, "knowingly" means a person: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. Moreover, under

the FCA, a specific intent to defraud is not required in order to prove that the law has been violated. *See 31 U.S.C. § 3729(b*). The purpose of the FCA's scienter requirement is to avoid punishing honest mistakes or incorrect claims submitted through mere negligence. *See United States ex rel. Drakeford v. Tuomey, 792 F3d 364 (4th Circ. 2015), citing United States ex rel. Owens v. First Kuwaiti Gen. Trading & Contracting Co., 612 F.3d 724, 728 (4th Cir.2010) (internal quotation marks omitted).*

2. **Qui Tam Relators**. The FCA provides that private parties may bring an action on behalf of (and in the name of) the United States. These private parties (known as "*qui tam* relators") may share in a percentage of the proceeds from a FCA action or settlement. *See 31 U.S.C. § 3730.*

3. **Penalties**. Under the statute, a person found to have violated the FCA may be held liable for a per claim civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages sustained by the U.S. Government.[6] *See 31 U.S.C. § 3729(a)(1).* Other consequences may also flow from a violation of the FCA, *e.g.*, exclusion from participating in Federal health care programs.

EXAMPLE:

- August 2018: Detroit area hospital system agreed to pay $84.5 million to resolve its False Claims Act liability based on allegations that it violated the AKS over an eight-year period by providing physicians with

[6] These penalty amounts are subject to annual inflation-related adjustments. Currently, they have been increased to a minimum of $11,181 and not more than $22,363 for penalties assessed after January 29, 2018, whose associated violations occurred after November 2, 2015. *See 28 C.F.R. § 85.5.*

compensation substantially in excess of fair market value and free or below market value office space and employees to secure patient referrals and then submitted claims to Medicare, Medicaid and Tricare programs for services provided pursuant to these illegally referred patients. *See Department of Justice Press Release*, dated August 2, 2018, available at: https://www.justice.gov/opa/pr/detroit-area-hospital-system-pay-845-million-settle-false-claims-act-allegations-arising

- March 2018: A Pennsylvania hospital and a cardiology group agreed to pay $20.75 million to settle a False Claims Act lawsuit alleging that they knowingly submitted claims to the Medicare and Medicaid programs that violated the AKS and Physician Self-Referral Law. The settlement resolved allegations brought in a whistleblower action filed under the False Claims Act alleging that, from 1999 to 2010, the hospital paid the cardiology group up to $2 million per year under twelve physician and administrative services arrangements which were created to secure patient referrals for the hospital. The hospital allegedly had no legitimate need for the services contracted for, and in some instances the services either were duplicative or were not performed. *See Department of Justice Press Release*, dated March 7, 2018, available at: https://www.justice.gov/opa/pr/pennsylvania-hospital-and-cardiology-group-agree-pay-2075-million-settle-allegations.

B. The New York False Claims Act. New York State has its own False Claims Act ("NYFCA") that is similar to the Federal FCA. Courts have held that the NYSFCA "follows"

the federal FCA, and it is "appropriate" to look to the FCA when interpreting the NYSFCA. *See United States v. Mount Sinai Hospital, 256 F.Supp.3d 443 (S.D.N.Y. 2017) citing State ex rel. Willcox v. Credit Suisse Sec. (USA) LLC, 140 A.D.3d 622 (1st Dept. 2016).* Among other things, the NYFCA prohibits any person from:

- knowingly presenting or causing to be presented to any employee, officer or agent of the State or a local government a false or fraudulent claim for payment or approval;

- knowingly making, using or causing to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State or a local government;

- conspiring to defraud the State or a local government by getting a false or fraudulent claim allowed or paid; or

- knowingly making, using or causing to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the State or a local government. *See NY State Finance Law § 187 et seq.*

2. **Penalties**. Like the Federal FCA, liability under the NYFCA includes treble (three times) the amount of the damages the State or the local government sustains. Civil

penalties to the State of $6,000 to $12,000 per claim may also result from a violation of the NYFCA.[7] *See NY State Finance Law § 189.*

3. **Qui Tam Relators**. Also like the Federal FCA, the NYFCA allows "*qui tam*" actions to be brought by a private party on behalf of New York State or a local government. The *qui tam* relator may recover a percentage of the proceeds recovered in the action or in settlement of the action. *See NY State Finance Law § 190.*

[7] Effective September 30, 2018, these penalty amounts are to be adjusted to be equal to the penalties allowed under the Federal FCA.

APPENDIX A

The current safe harbors to the Federal Anti-kickback Statute relate to the following types of arrangements:

Investment Interests	Obstetrical malpractice insurance subsidies
Space Rental	Investments in group practices
Equipment rental	Cooperative hospital service organizations
Personal services and management contracts	Ambulatory surgical centers
Sale of practice	Referral arrangements for specialty services
Referral services	Price reductions offered to eligible managed care organizations
Warranties	Price reductions offered by contractors with substantial financial risk to managed care organizations
Discounts	Ambulance replenishing
Employees	Health centers
Group purchasing organizations	Electronic prescribing items and services
Waiver of beneficiary copayment, coinsurance and deductible amounts	Electronic health records items and services
Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans	Federally Qualified Health Centers and Medicare Advantage Organizations.
Price reductions offered to health plans	Medicare Coverage Gap Discount Program
Practitioner recruitment	Local Transportation

APPENDIX B

The current exceptions to the Federal Stark Law are:

General Exceptions Related to Both Ownership/Investment and Compensation (42 C.F.R. § 411.355)	
Physician services	Erythropoietin (EPO) and other dialysis-related outpatient prescription drugs furnished in or by an ESRD facility
In-office ancillary services	
Services furnished by an organization (or its contractors or subcontractors) to enrollees	Preventive screening tests, immunizations and vaccines
Academic medical centers	Eyeglasses and contact lenses following cataract surgery
Implants furnished by an ambulatory surgical center	Intra-family rural referrals
Exceptions Related to Ownership or Investment Interests (42 C.F.R. § 411.356)	
Publicly traded securities	Specific providers
Mutual funds	
Exceptions Related to Compensation Arrangements (42 C.F.R. § 411.357)	
Rental of office space	Risk-sharing arrangements
Rental of equipment	Compliance training
Bona fide employment relationships	Indirect compensation arrangements
Personal service arrangements	Referral services
Physician recruitment	Obstetrical malpractice insurance subsidies
Isolated transactions	Professional courtesy
Certain arrangements with hospitals	Retention payments in underserved areas
Group practice arrangements with a hospital	Community-wide health information systems
Payments by a physician	Electronic prescribing items and services
Charitable donations by a physician	Electronic health records items and services
Non-monetary compensation	Assistance to compensate a nonphysician practitioner
Fair market value compensation	Timeshare arrangements
Medical staff incidental benefits	