ANTI-KICKBACK STATUTE ENFORCEMENT TRENDS

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Following two large settlements in the latter part of 2014 involving almost $500 million, the pace of Anti-Kickback Statute (“AKS”) cases remained high in 2015. These cases are, in large part, a result of the government’s focus in bringing fraud and abuse cases in the healthcare space. A combination of three additional factors, however, makes it even more likely that government enforcement of the AKS will remain steady for the foreseeable future, if not increase.

• First, the Patient Protection and Affordable Care Act (“PPACA”) clarified that each violation of the AKS was also a violation of the False Claims Act (“FCA”) and lowered the government’s burden in proving criminal AKS violations.

• Second, the Sunshine Act and its state counterparts have not only increased public awareness of the money flowing from the pharmaceutical, biotechnology, and medical device industry (“industry”) to physicians and teaching hospitals, but have also increased the government’s and relators’ bar’s access to data documenting the flow of money.

• Third, the government and relators’ bar are facing headwinds in off-label cases, a historically lucrative area of FCA litigation, and investigative resources may be shifted to bringing cases with less legal uncertainty.

Settlements in 2015 have also demonstrated that AKS enforcement is evolving and cases are becoming more complex. While cases involving cash payments and travel in exchange for patient referrals that don’t even pretend to fall under a safe harbor still exist, they are primarily last decade’s problem. The current AKS battleground — especially for institutional providers — are payments that arguably fall within a safe harbor but which the government may view as a funnel for patient referrals. Current cases involve remuneration in the form of speaker programs, management services agreements, processing and handling fees, and consulting agreements. There were also a number of significant legal developments in 2015, including a case that arguably expanded the AKS’s reach with a broad definition of “referral” and a number of cases illustrating courts’ willingness to dismiss AKS cases early.

This article summarizes the AKS, details the three reasons AKS enforcement will likely increase, and discusses significant AKS actions and legal developments that occurred in 2015.

AKS Overview

The AKS prohibits knowingly and willfully paying or receiving remuneration in exchange for patient referrals from which payment may be made by a federally funded healthcare program, including Medicare, Medicaid, and Tricare. Congress passed the AKS in 1972 to combat fraud and abuse in federal health benefit programs. AKS violations in their original form constituted a misdemeanor that applied only to “kickbacks” and “bribes.” In 1977, however, Congress made a violation of the AKS a felony and also expanded the scope of the statute to include “any remuneration,” including a kickback, bribe, or rebate in return for referring a patient to a provider of covered services, directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

A) to refer an individual to a person 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, or

B) to purchase, lease, order, or arrange for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program...

Because of the AKS’s broad reach and potential to chill beneficial arrangements in healthcare, there are a number of AKS safe harbors. Some of the safe harbors are statutory and others are regulatory. Any individual or entity asserting a safe harbor bears the burden of proof.

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Whether conduct falls within a safe harbor must be analyzed on a case-by-case basis accounting for the language of the safe harbor, subsequent interpretations of that language in case law and the facts of each case. Many of the safe harbors are complex and include multiple elements embedded with numerous terms of art. There are six statutory safe harbors:

• discounts;
• bona fide employees;
• authorized purchasing agents;
• waivers of coinsurance for individuals who qualify for subsidized services;
• risk-sharing arrangements; and
• drug discounts for certain beneficiaries.5

Congress also provided the Secretary of HHS with authority to promulgate safe harbor regulations. Since the late 1980s, the HHS Secretary delegated that authority to the OIG.6 Regulatory safe harbors include:7

• investment interests;
• fair market space rental;
• fair market equipment rental;
• personal services and management contracts;
• sale of practice;
• referral services unrelated to volume or value of referrals;
• warranties;
• discounts;8
• bona fide employees;
• group purchasing organizations;
• waiver of beneficiary coinsurance and deductibles;
• increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans;
• price reductions offered to health plans;
• practitioner recruitment;
• obstetrical malpractice insurance subsidies;
• investments in group practices;
• cooperative hospital service organizations;
• ambulatory surgical centers;
• referral arrangements for specialty services;
• price reductions offered to managed care organizations;
• price reductions offered by contractors with substantial financial risk to managed care organizations;
• ambulance replenishing;
• transfers to health centers;
• certain electronic prescribing and services; and
• electronic health records items and services.

In addition to the current safe harbors, the OIG considers proposals for new safe harbors annually.9 Current safe harbors under consideration include:

• certain cost-sharing waivers, such as (1) pharmacy waivers of cost-sharing for financially needy Medicare Part D beneficiaries, and (2) waivers of cost-sharing for emergency ambulance services furnished by state- or municipality-owned ambulance services;
• remuneration between Medicare Advantage organizations and federally qualified health centers;
• discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program;10 and
• free or discounted local transportation services that meet specified criteria.11

Each conviction for an AKS violation can result in a five-year term of incarceration and a $25,000 fine. Additionally, AKS violations can result in large penalties under the FCA as well as administrative exclusion from federal health benefit programs.

Drivers of AKS Enforcement Growth

While she was the United States Attorney for the Eastern District of New York, now U.S. Attorney General Loretta E. Lynch made clear that “fighting healthcare fraud” is one of the Department of Justice’s top priorities.12 As one of the statutory tools to fight healthcare fraud, the AKS is being applied as part of this prioritization. The Department of Justice (“DOJ”) has entered into large AKS settlements with providers in the past few years, which will very likely result in an increased focus on AKS enforcement by prosecutors nationwide. Further, the federal government’s high and increasing return on investment in healthcare enforcement — approximately eight dollars recovered for every dollar invested — makes continued investment in healthcare enforcement almost certain.13 In addition to the focus on healthcare and large AKS settlements, there are three other factors that are driving the increased use of the AKS as an enforcement tool:

PPACA

PPACA clarified two legal aspects of the AKS that have made the AKS a more appealing statute to pursue both civilly and criminally. First, prior to enactment of PPACA, many courts held that violations of the AKS did not automatically constitute a false claim and required plaintiffs to prove additional facts to assert a valid FCA violation.14 PPACA clarified that no additional facts were required to prove a FCA violation. “[A] claim [submitted to a federal health benefit program] that includes items or services resulting from a violation of [AKS] constitutes a false or fraudulent claim for purposes of [the FCA].”15

Second, in criminal cases, there was a split of authority regarding the meaning of the phrase “knowingly and willfully” in the AKS. Some courts
held that a defendant had to have a specific intent to violate the law, while other courts interpreted “willfully” to require only that the defendant did something purposefully that the law forbids. PPACA resolved the split of authority with the addition of subsection (h) of the AKS, which provides: “With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.” Thus, while the government still must prove intent to establish an AKS violation, PPACA made intent easier to prove.

Physician Payments
Sunshine Act

The Sunshine Act, another provision in PPACA, mandated that industry — including pharmaceutical and medical device companies — report to CMS most payments to physicians and academic medical centers. CMS collects this data through a program it calls “Open Payments.” Payments that must be reported include consulting fees, honoraria, gifts, travel and lodging, research, educational contributions, grants, and speaking fees. Congress passed the law to address concerns regarding the financial relationships between industry and medical professionals and the possibility that payments could impact what drugs and devices physicians prescribed. CMS first released the Sunshine Data to the public in September 2014. According to the CMS Open Payments website, industry paid medical professionals $3.43 billion in 2013 and $6.49 billion in 2014. Each of those years, over 1,300 companies made payments to over 470,000 physicians. A search tool that accesses the CMS data enables anybody to search almost all payments from any medical device manufacturer or pharmaceutical company to any physician. Searches may also be done by physician.

The Sunshine Act data will implicate the AKS in a number of ways. First, the large amount of money flowing from industry to physicians has generated significant negative publicity, such as articles titled “Latest Sunshine Act Bombshell: $6.5B in doc-and-hospital payments last year,” and “What Pharma Wants to Hide.” These types of headlines frequently result in increased government scrutiny. Second, investigative journalists and reporters have used the data to criticize a company for its payments to doctors.

Like the journalists, whistleblowers, federal prosecutors, patients, and even competitors will be able to use the data to their own ends. The relators’ bar and prosecutors can use the data to search for targets, corroborate allegations, or look for other anomalies. A company that believes its competitor is violating the AKS can do the same and report wrongdoing to the government.

Off-Label Cases

The laws relating to off-label promotion and misbranding — which traditionally produced huge settlements under the FCA — are under attack, and there are real questions about which off-label and misbranding theories remain viable. A line of cases culminating with the Second Circuit’s 2012 decision in United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), have made the Food and Drug Administration’s ("FDA") efforts to allege and ultimately win off-label cases more difficult. In Caronia, the Second Circuit held that the First Amendment protected truthful speech regarding an industry product, even if the speech promoted an off-label use.

Caronia’s impact continues to be debated, as the FDA’s choice not to appeal it limited its holding to the Second Circuit. Further, the FDA has interpreted Caronia to be limited to the unique facts of the case, and believes that under Caronia, it could “bring a misbranding action against a manufacturer or its representative where the conduct at issue consists solely of truthful and non-misleading speech promoting an off-label use of an approved drug.” A number of post-Caronia cases have been settled under the misbranding theory. A more recent case, Amarin Pharma, Inc. v. FDA, however, held that the FDA cannot pursue a misbranding theory based on truthful statements and has put some of the government’s misbranding theories in question.

Relying on Caronia and Amarin, other companies are proactively filing lawsuits against the FDA seeking declaratory and injunctive relief against FDA enforcement of off-label provisions.

Developments in 2015

The DOJ’s increasing reliance on the AKS as an enforcement tool is evident from a number of important developments over the past year. For example, 2015 witnessed several more large settlements under the AKS, individual convictions on AKS charges, federal case law interpreting important provisions of the AKS, and OIG Advisory Opinions clarifying the government’s position on whether conduct falls within particular safe harbors.

Settlements

Several hospitals and pharmaceutical companies settled AKS allegations with the DOJ over the course of the past year. The following discussion highlights the most significant of these settlements from 2015.

Daiichi Sankyo, Inc.

On January 9, 2015, Daiichi Sankyo, Inc. (“Daiichi”), a large global pharmaceutical company, agreed to pay the United States and state Medicaid programs $39 million to resolve allegations that it violated the FCA by paying kickbacks to induce physicians to prescribe Daiichi drugs. The DOJ had alleged that Daiichi paid physicians improper kickbacks in the form of speaker fees as part of Daiichi’s Physician Organization and Discussion programs (“PODs”), which it ran from...
January 1, 2005, through March 31, 2011, in addition to other speaker programs that ran from January 1, 2004 through February 4, 2011. These improper payments were allegedly made to physicians even when the physician participants in the PODs took turns “speaking” on duplicative topics over Daichi-paid dinners, the recipient spoke only to members of his or her own staff in his or her own office, or the cost of the lavish associated dinner exceeded Daichi’s internal cost limitation of $140 per person.

Health Diagnostics Laboratory Inc. and Singulex Inc.

In April 2015, two cardiovascular testing laboratories — Health Diagnostics Laboratory (“HDL”) of Richmond, Virginia, and Singulex Inc. (“Singulex”) of Alameda, California — collectively paid $48.5 million to settle allegations that they violated the AKS by paying remuneration to physicians in exchange for patient referrals and billing federal healthcare programs for medically unnecessary testing. According to the charges, HDL, Singulex, and a third laboratory induced physicians to refer patients to them for blood tests by paying them processing and handling fees of between $10 and $17 per referral and by waiving patient copayments and deductibles. As a result, physicians referred patients to HDL and Singulex for medically unnecessary tests, which were then billed to federal healthcare programs, including Medicare.

Westchester Medical Center

On May 14, 2015, New York-based Westchester Medical Center (“WMC”) agreed to pay $18.8 million to settle civil fraud claims under the FCA related to WMC’s alleged violations of the AKS and other charges. The DOJ alleged that between 2000 and 2007 WMC maintained a financial relationship with Cardiology Consultants of Westchester, P.C. (“CCW”) — a cardiology practice formerly operating on WMC’s Valhalla campus — that violated the AKS. According to the settlement, WMC advanced funds to CCW to open a practice for the express purpose of generating referrals to the hospital. When CCW began making payments to WMC purportedly to repay the advances, WMC entered into retroactive, no-work consulting agreements under which it paid CCW tens of thousands of dollars.

Hebrew Homes Health Network

On June 16, 2015, a skilled nursing facility in Miami called Hebrew Homes Health Network Inc. (“Hebrew Homes”), along with its operating subsidiaries and affiliates and William Zubkoff, its former president and executive director, agreed to pay $17 million to settle allegations that Hebrew Homes violated the AKS by improperly paying doctors for referrals of Medicare patients requiring skilled nursing care. According to the DOJ’s allegations, from 2006 through 2013 Hebrew Homes operated a sophisticated kickback scheme that included hiring numerous physicians ostensibly as medical directors pursuant to contracts that specified job duties and hourly requirements. Hebrew Homes’ facilities had several of these medical directors under contract at any given time, paying each of them thousands of dollars monthly. The DOJ alleged that these were actually “ghost positions,” and that most of the medical directors were required to perform few, if any, of their contracted job duties. Instead, they were allegedly paid for their patient referrals to the Hebrew Homes facilities, which increased significantly once the medical directors were put on the payroll.

New York Hospitals and Management Company

In August 2015, three New York hospitals (Benedictine Hospital, Columbia Memorial Hospital, and St. Joseph’s Medical Center), a health management company called SpecialCare Hospital Management Corporation (“SpecialCare”), and SpecialCare’s chief executive officer, Robert McNutt, agreed to pay over $8 million to resolve claims that they defrauded the Medicare and Medicaid programs in connection with detoxification treatment provided to patients at the hospitals. The allegations, which were brought jointly by the United States and the New York State Attorney General’s Medicaid Fraud Control Unit, focused primarily on fraud charges related to unlicensed drug and alcohol detoxification programs, but the government also alleged that two of the hospitals — Columbia Memorial and St. Joseph’s — paid SpecialCare for patient referrals in violation of both federal and state anti-kickback laws.

Millennium Health

On October 19, 2015, Millennium Health (“Millennium”), a large San Diego-based urine testing laboratory, agreed to pay $256 million to settle charges under the FCA and allegations that it provided free items to physicians who agreed to refer expensive laboratory testing business to Millennium. The government alleged that Millennium violated the AKS and the Stark Law by providing free point of care testing (“POCT”) cups for urine drug testing to physicians on the condition that the physicians agree to return the urine specimens to Millennium for additional tests costing hundreds of dollars.

Focus on Physicians

While many of the most significant settlements from 2015 involved hospitals, pharmaceutical companies, and health laboratories, a special fraud alert issued by the OIG on June 9, 2015 suggests that the government may begin to focus more on physicians’ roles in kickback schemes. In the alert, the
OIG warned that [p]hysicians who enter into compensation arrangements such as medical directorships must ensure that those arrangements reflect fair market value for bona fide services the physicians actually provide.40 Citing recent settlements with twelve individual physicians in 2014 for violations of the AKS, the alert makes clear that the government will prosecute not only the hospitals involved in these improper compensation arrangements, but the individual physicians, as well.41 This heightened focus may result in additional AKS settlements with physicians in the coming year. It may also incentivize physicians to become more involved in hospital compliance efforts.

**Convictions**

In addition to this AKS settlement activity, there were a number of criminal convictions during 2015 under the AKS. One example involving multiple convictions on AKS violations centered on the now-closed Sacred Heart Hospital in Chicago.42 On March 19, 2015, the former owner and chief executive officer (Edward Novak), the chief operating officer (Clarence Nagelvoort), and the chief financial officer (Roy Paywall) of Sacred Heart were convicted by a jury after a nearly two-month trial of collectively paying hundreds of thousands of dollars in illegal kickbacks in exchange for the referral of hospital patients who were insured by Medicare and Medicaid.

The jury found that between 2001 and April 2013, all three of these Sacred Heart officers paid physicians concealed bribes and kickbacks to induce patient referrals and to increase the patient census, which boosted hospital revenue. Consequently, all three defendants were convicted of one count of conspiring to violate the AKS by offering and paying kickbacks and bribes, directly and indirectly, to physicians in order to induce them to refer patients to the hospital for services that would be reimbursed by Medicare and Medicaid. Each of the defendants was also convicted of numerous counts of paying kickbacks for patient referrals.

**Legal Developments**

As government enforcement of the AKS has continued to rise, courts have begun to provide additional clarity on how certain provisions of the statute should be interpreted post-PPACA. Over the past year, several courts have issued opinions with the potential to have a significant impact on AKS enforcement going forward.

**United States v. Patel**

In February 2015, the Seventh Circuit issued an important ruling in United States v. Patel regarding the meaning of the term “refer.”43 Although prior courts to consider this issue (including an earlier Seventh Circuit panel) have largely agreed that a “referral” means sending patients to a certain provider,44 the court in Patel adopted a broader interpretation, holding that a physician makes a “referral” for purposes of the AKS when he or she makes a “certification and recertification” that care is necessary, even if the physician never steered patients to the particular provider.45 By expanding the definition of the term “referral,” Patel creates greater potential for AKS liability in circumstances when doctors authorize the use of medical service providers.

A closer examination of the facts in Patel helps to illustrate the scope of its holding. Defendant Dr. Kamal Patel was an internist from Chicago whose elderly patients were frequently in need of home health care.46 Rather than discussing with these patients which providers to use, however, a member of Dr. Patel’s staff would provide them with ten to twenty home healthcare company brochures, and the patients would choose one of those providers on their own.47 The defendant would then “certify[y]” the patient for sixty days of home care — and “recertif[y]” if longer care was needed — by signing a Form 485 (“a standardized Medicare form that certifies that home care is medically necessary and outlines a patient’s diagnosis, medications, treatment plans, and goals”) for each patient.48 According to the charges, Grand Home Health Care (“Grand”) — one of the ten to twenty providers that Dr. Patel’s staff had provided to patients — would provide Dr. Patel with $400 in cash per certification and $300 per recertification every time a new patient was admitted at Grand.49

Based on these established facts, the district court held that the defendant “referred” patients to Grand under the AKS when “he certified or recertified that the patient needed care, that the care would be provided by Grand, and that Grand could be reimbursed by Medicare for services provided.”50 On appeal, Dr. Patel argued that this “certification and recertification” process did not constitute a “referral” under the AKS because to “refer” means to personally recommend that a patient use a particular provider.51 By contrast, the government argued that “refer” should include a doctor’s authorization of care, which would include the certification and recertification process.

In adopting the government’s interpretation, the court relied on the definition of “referral” under certain state laws, the Stark law, and in the way that Dr. Patel himself had used the term on one occasion. Moreover, the court found it significant that on at least one occasion Dr. Patel had withheld certification forms from Grand until he received his payment. This was important because if Dr. Patel refused to sign these forms, Grand could not bill Medicare for the services it provided to his patients.52 Ultimately, the Seventh Circuit found that what mattered in this analysis was whether Dr. Patel authorized the service, even if he did not personally recommend it: “Patel is correct that it does not matter who first identifies the care provider; what matters is whether the doctor facilitates or authorizes that choice. . . .

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Patel acted as a gatekeeper to federally-reimbursed care. Without his permission, his patients’ independent choices were meaningless.53

Cooper v. Pottstown Hospital Co

While Patel creates the potential for broader liability under the AKS, recent district court decisions suggest a trend toward requiring a more demanding standard in establishing the intent requirement under the AKS. In Cooper v. Pottstown Hospital Co., for example, the Eastern District of Pennsylvania dismissed with prejudice AKS claims predicated on a physician-relator’s theory that the defendant hospital entered into on-call contracts with him that were actually “covert means of inducing referrals to the hospital.”54 Noting that the relator was concededly unaware of the defendant until after the agreement had been in place for several months, the court rejected this theory as “implausible,” emphasizing: “Any practicable scheme to induce referrals would not have left him ignorant of its true purpose.” The court’s decision in Cooper to dismiss these claims (with prejudice) at the motion to dismiss stage based on the typically fact-intensive inquiry of illicit intent may reflect a growing distrust by courts of the relators’ bar in AKS actions.56

OIG Advisory Opinions

The OIG also issued two Advisory Opinions in 2015 providing guidance on the AKS. First, in Advisory Opinion 15-03, the OIG addressed a Medigap insurer’s proposed arrangement allowing discounts on deductibles at certain network hospitals through a preferred provider organization, with a portion of the resulting savings going to the insurer’s policyholders.57 Although the OIG reasoned that this arrangement would not be covered by any existing safe harbors, it nevertheless concluded that the arrangement would not result in penalties under either the AKS or the Civil Monetary Penalties Law’s prohibition on inducements to beneficiaries because the likelihood of fraud and abuse under the proposal was minimal. This conclusion is consistent with the OIG’s previous advisory opinions from recent years approving discounts to Medigap insurers by preferred hospitals and credits to Medigap policyholders who use preferred hospitals.58

Second, in Advisory Opinion 15-04, the OIG warned in a negative advisory opinion that a multi-regional laboratory’s waiver of fees for certain patients of its physician-practice clients could be considered prohibited remuneration under the AKS and could even lead to permissive exclusion for violation of the “substantially in excess” provision of the Social Security Act.59 Under the proposed arrangement, a multi-regional laboratory would enter into agreements with physician practices under which the physicians would send all of their patients, including patients who were beneficiaries of federal healthcare programs, to the requesting laboratory as a means of enhancing ease of communication and consistency in test-result reporting. The requesting laboratory would provide a limited-use interface to participating physicians for transmitting test results, and it would refrain from billing the physicians’ patients when the services were “out-of-network” for that patient’s health plan.60 In concluding that this arrangement raised risks of improper remuneration under the AKS, the OIG reasoned that:

- Participating referring physicians may derive benefit from the convenience and efficiency of working with a single laboratory and receiving all results in a uniform format from a single interface;
- The arrangement could result in expense relief to referring physicians from receiving the free limited-use interface from the laboratory, as this would replace the various interfaces for which physicians would otherwise have to pay due to monthly maintenance fees charged by some vendors; and
- There was no “discernable quality or safety improvements that would be gained by reducing these burdens” or other safeguards that could make this remuneration low risk under the AKS; to the contrary, the OIG stated that the proposed actions could result in the inappropriate steering of patients.

This negative Advisory Opinion reflects the critical view that the OIG has adopted toward relationships between laboratories and physician practices, as evidenced by a 2014 Special Fraud Alert and recent enforcement activity addressing payments to physicians by laboratories.61 It is also significant as a rare opinion concerning the OIG’s permissive exclusionary authority under the “substantially in excess” provision of the Social Security Act.

Similarly, in October 2015, the OIG issued an alert providing guidance on the AKS safe harbor for donations of electronic health record (“EHR”) technology items and services to potential referral sources.62 In the alert, the OIG made clear that if a donor — or an individual on the donor's behalf — takes any action to limit or restrict the use, compatibility, or interoperability of the donated items or services with other electronic prescribing or EHR systems, the donation arrangement would not receive safe harbor protection. This alert serves as a reminder to providers of the risks of practices such as information blocking that are associated with donations of EHR technology to potential referral sources.
DOJ's Amicus Brief in Ameritox

The government also provided guidance on the AKS in an unusual manner this year: by filing an amicus brief in a civil lawsuit. The case centered on a dispute between Ameritox LTD (“Ameritox”) and Millennium involving Millennium’s practice of providing free POCT cups to doctors on the condition that the doctors agreed not to bill an insurer for the cups and to return the specimen samples in each cup to Millennium for additional (and expensive) lab testing. Ameritox sued Millennium for unfair competition (in addition to other claims), arguing that Millennium’s practices violated the Stark Law and AKS and thus constituted “unfair, deceptive, or unconscionable business practices” in violation of the unfair competition statute. After a jury awarded Ameritox a multimillion-dollar verdict, Millennium appealed to the Eleventh Circuit Court of Appeals.

On appeal, Millennium argued that the district court had misapplied the Stark Law and AKS in finding that the provision of the free POCT cups in exchange for confirmatory testing referrals constituted prohibited remuneration. Millennium’s argument that provision of the POCT cups did not constitute remuneration because the physicians did not bill for them was rejected. POCT cups, however, “confer significant benefits on physicians” outside Millennium’s testing services. As for Millennium’s argument that the POCT cups could only constitute remuneration if a physician billed for them, the DOJ stated that whenever a provider “offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business.”

While the DOJ’s amicus brief did not advance an interpretation of the AKS that it had not previously asserted, its decision to intervene in a civil case underscores the importance to the DOJ of establishing its broad interpretation of remuneration under the Stark Law and AKS. Accordingly, the DOJ’s positions in the Ameritox amicus brief may serve as a helpful warning to scrutinize carefully whether any benefits provided in a healthcare arrangement qualify as “remuneration” under the Stark Law and AKS.

AKS Compliance and the Yates Memo

AKS developments in 2015 counsel in favor of continued diligence when it comes to AKS compliance. There is also another reason to refocus compliance efforts now: the Yates Memo. On September 9, 2015, Deputy Attorney General Sally Quillian Yates published a memo to the DOJ emphasizing individual accountability for corporate wrongdoing. Although the implications of the Yates memo are beyond the scope of this article, the Yates memo will likely result in a number of changes in how companies conduct internal investigations and interact with the government in resolving AKS enforcement actions. Among them, companies seeking cooperation credit will have to allocate resources to investigating individual knowledge and provide all relevant facts to the government regarding individuals involved in misconduct. As a result, it is expected that AKS enforcement actions will be accompanied by an increasing number of parallel criminal actions against individuals. This focus on individuals could also result in an increasing number of cases where companies and employees have conflicting interests.

Conclusion

These 2015 enforcement actions, coupled with the DOJ’s focus on healthcare, PPACA, the Sunshine laws, and issues surrounding off-label marketing cases make clear that AKS enforcement will remain a government priority. The DOJ has also demonstrated that it will be proactive in litigating issues that could result in a narrowing of its broad interpretation of what constitutes remuneration. Categorizing payments under a safe harbor will not be enough to avoid AKS scrutiny. Companies need to focus on the substance of the exchange of any remuneration to determine whether the remuneration legitimately falls within a safe harbor or whether the safe harbor is simply being used to hide payments for patient referrals.

The opinions expressed in this article do not necessarily reflect the views of O’Melveny or its clients, and should not be relied upon as legal advice.

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Endnotes

1. See Social Security Amendments Act, Pub. L. No. 92–603, §§ 242(b) (Medicare) and (c) (Medicaid), 86 Stat. 1419 (1972).
5. 42 U.S.C. § 1320a–7b(3).
7. 42 C.F.R. § 1001.952.
8. Some safe harbors, such as discounts, are included in both the statute and regulations. The provisions of the regulatory and statutory safe harbors, however, may be different, and the regulations frequently set forth the requirements of the particular safe harbor in greater detail. Compare 42 U.S.C. § 1320a–7b(3a) (generally defining discount), with 42 C.F.R. § 1001.952(b) (defining discount with more precision).
10. The Medicare Coverage Gap Discount Program is a program run by the Centers for Medicare & Medicaid Services (“CMS”) for pharmaceutical companies that “makes manufacturer discounts available to eligible Medicare beneficiaries receiving applicable, covered Part D drugs, while in the coverage gap.” Centers for Medicare & Medicaid Servs., PART D INFORMATION FOR PHARMACEUTICAL MANUFACTURERS, https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Pharma.html (last visited Oct. 29, 2015). To participate in the program, manufacturers are required to sign an agreement with CMS to provide the discount on all of its applicable drugs.
11. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59717 (Oct. 3, 2014). This OIG proposed rule is still pending. There has been no agency action since the proposed rule posted. The comment period for public comments ended on December 2, 2014, and there were a total of 109 public comments filed on this rule. See Medicare and State Health Care Programs: Fraud and Abuse; Safe Harbors under the Anti–Kickback Statute, Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing; Revisions, http://www.regulations.gov/#/docketDetail?D=HHSIG-2014-0005 (last visited Oct. 30, 2015).
15. 42 U.S.C. § 1320a–7b(g) (as amended by § 6402 of PPACA).
16. Compare United States v. Baystate Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20, 33 (1st Cir. 1989) (defining “willfully” to mean doing something purposely with the intent to violate the law, or doing something purposely knowing that the law forbids), with Hanlerst Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (“We construe ‘knowingly and willfully’ in § 1128B(b)(2) of the anti-kickback statute as requiring appellants to (1) know that § 1128B prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law.”).


Formerly Millennium Laboratories.


778 F.3d 607 (7th Cir. 2015).


Id. at 612–18.

Id. at 608–09.

Id. at 610–11.

Id. at 610.

Id. at 611.

Id. at 609.

Id. at 612.

Id. at 617.

Id. at 614–16.


Id. at *4.

See also United States ex rel. Rascher v. Omnicare, Inc., No. 04-08-cv-3396, 2015 U.S. Dist. LEXIS 117900 (S.D. Tex. Sept. 3, 2015) (holding that to overcome summary judgment in an AKS action, relators must produce non-ambiguous evidence of illegal intent). The FCA contains a qui tam provision that enables people who are unaffiliated with the government — “relators” — to file actions on behalf of the government for violations of the FCA. See 31 U.S.C. § 3730. A relator who succeeds in recovering damages for the government is entitled to a portion (up to 30 percent) of the recovery. Id. § 3730(d)(2); United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225–26 (1st Cir. 2004). Because of the opportunity to recover proceeds, the majority of FCA lawsuits are brought by relators.


Id. at 22.

Id. at 22–23.

Id. at 23 (quoting OIG Special Fraud Alert: Laboratory Payments To Referring Physicians (June 25, 2014), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf.


Id. at *8.

Id. at *2. “Stark defines ‘remuneration’ as ‘any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.’ The AKS definition is materially indistinguishable and includes ‘any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.’” Id. (quoting 42 U.S.C. §§ 1320a–7b(b), 1319(b)(1)(A)).


The proposed arrangement involved only patients with federal healthcare program coverage as their secondary, rather than primary, insurance.


Id. at *8.

Id. at *2. “Stark defines ‘remuneration’ as ‘any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.’ The AKS definition is materially indistinguishable and includes ‘any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.’” Id. (quoting 42 U.S.C. §§ 1320a–7b(b), 1319(b)(1)(A)).