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The 2021 Anti-Kickback Statute Year in Review and 2022 Outlook: What's Old Is New

By Miranda Hooker and Allison DeLaurentis*

This article analyzes the key developments in Anti-Kickback Statute enforcement in 2021 and areas to watch in 2022.

In a year consumed with vaccinations (or lack thereof) and the continued odyssey of the global pandemic, the health care fraud enforcement landscape felt like a bit of a retreat to years past. The U.S. Department of Justice ("DOJ") recorded the largest False Claims Act ("FCA") recovery since 2014: a whopping $5.6 billion—more than $5 billion of which came from the health care industry.

But this significant recovery should not be interpreted as signaling any major uptick in enforcement. Approximately $3.2 billion of the total can be attributed to settlements from opioid manufacturers, including the $2.8 billion resolution with Purdue Pharma. Excluding these opioid cases, the 2021 recovery is in line with FCA enforcement recoveries in recent years, demonstrating that DOJ continues to scrutinize the health care industry, and specifically, resolutions stemming from alleged violations of the Anti-Kickback Statute ("AKS") continue to be a revenue generator for the United States.

As expected, AKS enforcement actions in 2021 centered on theories and areas of scrutiny that we have seen before, including copay support, price fixing, electronic health records, telehealth, and (DOJ's favorite) speaker programs and meals/travel/entertainment. As always, companies operating in the health care industry should take note of these continued enforcement trends, and be proactive in conducting risk assessments and implementing appropriate auditing and monitoring of its sales and marketing programs.

This article analyzes the key developments in AKS enforcement in 2021 and areas to watch in 2022.

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THE AKS "MEANS WHAT IT SAYS"

In a highly watched case relating to the ability of pharmaceutical manufacturers to support patient copay assistance, in October 2021, the U.S. District Court for the Southern District of New York denied a pharmaceutical manufacturer's request for a declaratory judgment that two proposed patient assistance programs would not violate the AKS. In doing so, the court analyzed the AKS's intent requirement, ultimately concluding that the AKS "means what it says," and declining to read any "corrupt" intent into the language of the statute.[1]

By way of background, the manufacturer argued that its direct copay assistance program did not violate the AKS because the remuneration (copay support) was not paid with "corrupt" intent, and did not constitute a quid pro quo capable of influencing a physician's decision to prescribe because the payments were made to patients after physicians had already prescribed the drug (for which there was no other therapeutic alternative, in this instance).

In addressing the manufacturer's arguments, the court engaged in a statutory construction analysis of the text of the AKS. Specifically, the court interpreted the plain meaning of "remuneration" as "payment" or "compensation," and did not read any "corrupt" intent into the term. It further interpreted the plain meaning of "induce" as "enticing," "persuading," or "influencing" another to take a course of action.

Consequently, the court concluded that because the AKS "prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of medical treatments or services," the manufacturer's proposed program to provide remuneration to patients to entice ongoing purchases of the product violated the plain meaning of the statute.

KEY ISSUES IN 2021 SETTLEMENTS AND RESOLUTIONS

Electronic Health Records

DOJ's seemingly new-found enforcement focus on electronic health records ("EHR") manufacturers in 2020 continued in 2021.

In January 2021, a health care technology company paid $18.25 million to resolve allegations out of the District of Massachusetts that it paid kickbacks to generate sales of its EHR product.[2] The government alleged that the company paid kickbacks through three different marketing schemes.

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[1] *See* https://www.nysd.uscourts.gov/sites/default/files/2021-10/20cv4920 Opinion on Summary Judgment Motions.pdf.

[2] *See* https://www.justice.gov/usao-ma/pr/athenahealth-agrees-pay-1825-million-resolve-allegations-it-paid-illegal-kickbacks.

First, the company allegedly invited customers to entertainment events, such as the Kentucky Derby and the Masters Tournament, and provided accommodations, meals, and alcohol.

The second alleged scheme involved payments of up to $3,000 to physicians who signed up for its services.

Lastly, DOJ alleged that the company entered into "conversion deals" where it paid EHR competitors that ceased offering EHR products to refer their customers to the company.

The government claimed that these kickbacks caused health care providers to submit false claims to the government for incentive payments for achieving Meaningful Use.

In April 2021, an EHR software developer[3] resolved allegations from the U.S. District Court for the Southern District of Florida that its marketing referral program—known as the "Champions Program"—violated the FCA and AKS. Through this program, the software developer provided participating clients cash equivalent credits, cash bonuses, and percentage success payments to recommend its EHR products to prospective clients. The software developer's contracts with clients in the Champions Program also prohibited clients from providing negative information about the software developer's products to prospective clients. Both the remuneration and the prohibition on sharing negative information were unknown to the software developer's prospective clients.

These resolutions come on the heels of other recent AKS enforcement actions in the her space. While the theories of liability have varied, and are all indirect, a clear takeaway is that this industry is an area of focus for DOJ. As such, providers of EHR technology, its purchasers and users, and pharmaceutical manufacturers that have arrangements with EHR providers should be evaluating the structure of financial relationships and related compliance controls to protect against regulatory scrutiny.

Telehealth

Telehealth fraud enforcement continued to be a significant focus of DOJ enforcement actions in 2021. Indeed, DOJ's 2021 health care fraud "takedown" boasted charges in fraud schemes that resulted in $1.4 billion in alleged losses, of which $1.1 billion stemmed from telehealth fraud schemes. Many of these schemes were alleged kickback schemes in which telemedicine companies or

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[3] *See* https://www.justice.gov/usao-sdfl/pr/miami-based-carecloud-health-inc-agrees-pay-38-million-resolve-allegations-it-paid.

executives paid kickbacks to physicians to order or prescribe medically unnecessary durable medical equipment ("DME"), genetic or other laboratory testing, and pain medication with limited or no patient interaction.

Telehealth fraud cases based on alleged kickback schemes have been front and center of DOJ's enforcement efforts in recent years: Operation Brace Yourself (2019) focused on alleged kickbacks schemes relating to prescriptions for DME;[4] Operation Double Helix (2019) focused on alleged kickback schemes where physicians were paid to order genetic testing without any patient interaction or after limited consultation;[5] and Operation Rubber Stamp (2020) charged companies and individuals with alleged kickback schemes relating to both improper DME prescriptions and orders for medically unnecessary genetic testing.[6]

Similarly, DOJ's September 2021 health care fraud takedown announced substantial charges alleging fraudulent claims that stemmed from medically unnecessary orders for DME and genetic tests that were induced by kickbacks.[7] While many of these charges focused on purported shell companies and the individuals perpetuating those schemes, DOJ also charged four health care providers for their participation in signing prescriptions or orders for equipment or tests for the purported benefit of patients they had never met or files they had never reviewed.[8]

These types of telehealth fraud schemes will continue to be an enforcement priority for DOJ. But, what remains to be seen is whether in light of the pandemic and the resulting significant increase in telehealth services, DOJ will begin to scrutinize telehealth providers for things like billing fraud or payment for services not provided, as opposed to the run-of-the-mill kickback schemes included in DOJ's health care fraud takedowns in recent years.

Clinical and Diagnostic Laboratory Enforcement

2021 saw two primary categories of AKS cases resolve in the clinical and diagnostic laboratory space: (1) referral schemes for testing conducted by the laboratories, and (2) commissions to independent sales contractors.

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[4] *See* https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes.

[5] *See* https://www.justice.gov/opa/pr/federal-law-enforcement-action-involving-fraudulent-genetic-testing-results-charges-against.

[6] *See* https://www.justice.gov/usao-sdga/pr/operation-rubber-stamp-major-health-care-fraud-investigation-results-significant-new.

[7] *See* https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-charges-involving-over-14-billion.

[8] *See* https://www.justice.gov/usao-wdmi/pr/2021_0824_Happy_Clickers.

Inducements for Testing Referrals

With respect to testing referral schemes, two laboratory executives entered into settlements related to traditional schemes to induce referrals to their labs.

- In March 2021, the owner of a diagnostic testing laboratory[9] paid $2 million to resolve allegations that he participated in kickback schemes that included providing urine drug testing equipment, volume based-commissions, and loans to induce the referral of quantitative urine drug tests to Physicians Choice Laboratory Services, LLC.
- In October 2021, a part owner and CEO of a diagnostic laboratory[10] paid $1.1 million to resolve allegations that the lab paid remuneration to providers in exchange for referrals.

Commission-Based Independent Sales Agents

In April 2021, the U.S. Court of Appeals for the Fourth Circuit affirmed a $114 million judgment against individual founders of a diagnostic laboratory and its marketing consultant[11] for making commission-based payments to independent sales contractors in violation of the AKS.[12]

The laboratory contracted with its consultant to market and sell its blood tests in return for a percentage of the revenue. At trial, the government argued that these volume-based commissions plainly violated the AKS because the commissions "constituted 'remuneration' intended to induce sales representatives to sell as many tests as possible" and that the defendants violated the AKS by knowingly entering into agreements to pay these independent contractors based on volume.

At trial, the defendants attempted to assert an advice of counsel defense, arguing that attorneys had drafted the contracts between the laboratory and its marketing consultant. But the defendants did not present sufficient evidence reflecting that they fully disclosed all relevant facts to counsel or sought a legal opinion on this issue during the relevant period of time. As a result, the court did not deliver an "advice-of-counsel" jury instruction, and the jury concluded that the defendants' improper payments to its marketing consultant amounted to a kickback in violation of the FCA, and assessed damages of $16 million.

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[9] *See* https://www.justice.gov/usao-wdnc/pr/owner-defunct-urine-drug-testing-laboratory-agrees-pay-over-2-million-resolve.

[10] *See* https://www.justice.gov/usao-wdwa/pr/doj-and-ceo-defunct-medical-testing-laboratory-settle-false-claims-act-and-anti.

[11] *See* https://www.justice.gov/opa/pr/united-states-obtains-114-million-judgment-against-three-individuals-paying-kickbacks.

[12] *See* https://www.ca4.uscourts.gov/opinions/181811.P.pdf.

On appeal, the defendants' principal argument was that the government failed to prove that they knowingly and willfully violated the AKS. However, the Fourth Circuit found "abundant evidence" to support the finding of knowledge and intent, including that lawyers for both companies had warned them that the arrangement presented AKS risk.

Despite OIG's longstanding position that the use of independent sales agents poses risk under the AKS because sales agents are "in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals," the defendants also argued that "commissions to salespeople can never constitute kickbacks under the [AKS]."

In rejecting that argument, the Fourth Circuit cited the AKS's statutory safe harbor for commissions paid to employee salespeople, and OIG's repeated refusal to extend that safe harbor to independent contractors.[13]

This case is instructive on a number of fronts.

First, it reminds us that DOJ will not hesitate to bring cases against health care companies that employ independent commission-based sales agents, and the importance of carefully structuring arrangements to comply with the AKS's safe harbors where applicable.

Second, the Fourth Circuit's analysis of the legal advice the companies received on this issue demonstrates the rigorous scrutiny that follows when companies seek to rely on an advice-of-counsel defense to negate intent.

Lastly, the jury award of $16 million and the court's subsequent $114 million judgment highlight the risks of treble damages and civil penalties required by the FCA.

Much like in the telehealth arena, the 2021 enforcement actions against laboratories focused on the same issues and theories we have seen in prior years. But given the meteoric rise of COVID-19 testing in 2021 and DOJ's continued focus on COVID-19 fraud, laboratory operators should be particularly mindful

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[13] As always, noncompliance with a safe harbor is not a per se kickback, but rather requires a facts-and-circumstances analysis. For arrangements with sales representatives that cannot be structured to comply with the personal services and management contracts safe harbor, OIG has identified several characteristics associated with increased potential for abuse, including: compensation based on a percentage of sales; direct billing of a federal health care program by the seller for the item sold; direct contact between the sales agent and physicians; direct contact between the sales agent and federal health care program beneficiaries; the use of sales agents who are HCPs or in a similar position to influence purchases; and marketing of items that are separately reimbursable by a federal health care program. Here, the jury clearly saw sufficient indicia of intent to induce referrals.

of compliance in all areas, as many predict that enforcement focus could shift to the medical necessity and appropriate billing and coding for COVID-19 testing.

M&A Referral Schemes

2021 saw a number of settlements involving allegations of improper inducements paid in connection with mergers or acquisitions.

- In June 2021, a health care company operating acute care hospitals and outpatient locations[14] paid $37.5 million to resolve allegations that it, and its affiliated entities, engaged in multiple AKS schemes in violation of the FCA. Among other things, the government alleged that the defendants' above-fair-market-value purchase price for a physician practice and surgery center was an improper inducement because it took into account the value of the physician seller's referrals to one of the company's hospitals.
- In September 2021, an international home health care provider[15] paid $17 million to resolve allegations that it purchased two home-health agencies in Arizona, which were owned by a company that operated retirement communities, in order to induce the seller to refer its retirement community residents to the buyer for their home healthcare needs.
- In November 2021, a hospital[16] agreed to pay $18.2 million to resolve allegations that it violated the AKS and the Stark Law by selling ownership shares to selected physicians to induce those physician-owners to refer patients to the hospital.

These settlements illustrate that even sophisticated transactions in the health care space pose AKS risk. Beyond the four corners of a transaction, DOJ is focused on whether the consideration exchanged involves the referral of federal health care business. When structuring a transaction for health care related assets or services, health care companies and providers should take deliberate steps to minimize risk.

First, any exchange of consideration should be documented in detail, and any referrals of federal health care business should be expressly excluded from the

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[14] *See* https://www.justice.gov/opa/pr/prime-healthcare-services-and-two-doctors-agree-pay-375-million-settle-allegations-kickbacks.

[15] *See* https://www.justice.gov/opa/pr/home-health-agency-operator-bayada-pay-17-million-resolve-false-claims-act-allegations-paying.

[16] *See* https://www.justice.gov/opa/pr/flower-mound-hospital-pay-182-million-settle-federal-and-state-false-claims-act-allegations.

exchange. Without a clear exclusion of referral business, subsequent referrals between the parties can become tainted under the AKS.

Second, because the AKS contains a number of safe harbors that may be relevant to a particular referral arrangement, contracting parties should consider structuring their agreement with the safe harbors in mind.

Physician Inducements *Meals, Travel, Entertainment, & Royalty Payments to Physicians*

Unsurprisingly, remuneration paid to physicians in the form of gifts, meals, entertainment, and consulting payments remains an AKS enforcement focus.

In January 2021, the U.S. District Court for the District of Minnesota denied a relator's motion for summary judgment in a case involving allegations that the defendant, a manufacturer of interocular lenses, provided kickbacks in the form of meals, travel, and entertainment to induce purchases of defendant's lenses.[17] The relator alleged that the defendant paid remuneration to physician customers in the form of, among other things, private flights to Napa Valley, New York City, hunting trips in South Dakota, skiing in Colorado, and the Super Bowl.

In considering the motion for summary judgment, the court concluded that while the relator had established defendants had paid remuneration to 12 doctors, that the claims were paid by the federal health care programs, and that the defendants were knowingly and willfully provided the remuneration, there was a dispute of material fact as to defendant's intent. In particular, the court found that while the relator cited evidence from which a factfinder could infer that "one purpose" of the remuneration was to induce referrals, a genuine dispute of material fact existed because the defendant had presented evidence that:

(1) It sought legal and ethical advice on complying with the AKS;

(2) On at least some occasions, the defendant charged physicians for the trips and entertainment and believed that the rates it charged were fair;

(3) Some physicians complained that the rates the defendant charged were too high;

(4) Defendant's founder, who hosted the events at issue, had years-long personal and social relationships with the physicians who attended; and

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[17] *See U.S., ex rel. Kipp Fesenmaier v. Cameron-Ehlen Group, Inc.*, No. 13-cv-3003 (WMW/DTS) (D. Minn. Jan. 12, 2021).

(5) Several of the physicians testified that they informally split costs for trips and events, or took turns paying, and believed the costs had been split evenly.

As a result, the court denied the relator's motion for summary judgment. 2021 settlements in this area also reflect a continued enforcement focus.

- In May 2021, a medical equipment manufacturer paid $2 million to resolve allegations that it violated the AKS by providing meals, alcoholic beverages, entertainment, and travel expenses to U.S.-based physicians who attended events in France in 2013.[18] This relatively small settlement, to resolve allegations focused on a single event, reflects that DOJ will continue to bring these cases regardless of the scale of the conduct.
- In November 2021, a pharmaceutical company paid $12.7 million to resolve allegations that its sales representatives, among other things, paid kickbacks to physicians in the form of deliveries of food and beverages, in addition to holiday gifts, to induce prescriptions of its narcotic overdose treatment.[19]
- In November 2021, a medical device manufacturer paid $16 million to resolve allegations that the company's royalty agreement with an orthopedic surgeon violated the AKS.[20] On its face, the royalty agreement was to compensate the orthopedic surgeon for his contributions to the development of two product lines for joint repair surgery. However, the government alleged that the facts and circumstances around the royalty agreement suggested that the agreement was truly intended to induce referrals, as evidenced by the fact that the company originally denied the orthopedic surgeon's request for royalties, but changed its position years later when the orthopedic surgeon threatened to realign his loyalty to a competitor. The agreement also provided for royalties for past and future sales of the products at a higher rate than was the company's typical practice.

These cases demonstrate that DOJ and relators continue to focus on remuneration paid to health care customers and prescribers in the form of

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[18] *See* https://www.justice.gov/usao-edpa/pr/french-medical-device-manufacturer-pay-2-million-resolve-alleged-kickbacks-physicians.

[19] *See* https://www.justice.gov/opa/pr/kal-o-inc-agrees-pay-127-million-resolve-allegations-false-claims-anti-overdose-drug.

[20] *See* https://www.justice.gov/opa/pr/medical-device-company-arthrex-pay-16-million-resolve-kickback-allegations.

meals, travel, entertainment, and consulting agreements—even in situations where the remuneration is discrete or of relatively low value.

But the District of Minnesota decision is an important reminder that the central issue in prosecuting or defending any AKS case is whether one purpose of the remuneration was to induce referrals, and a defendant or target may be able to present evidence to create a disputed issue of material fact as to their intent—including that the remuneration was provided for another purpose (here, purely a social one), or that defendant made a good faith effort to comply by sharing costs with customers.

Medical Director Payments to Physicians

2021 saw at least two cases in which individual physicians resolved allegations that they received medical director payments from health systems to induce referrals.

- In February 2021, a physician paid $215,228 to resolve allegations that he received over $15,000 per month in medical director payments from a hospital, but performed no services.[21] The relator and the government alleged that the compensation was paid in violation of the Stark Law and the AKS to induce the physician to refer patients to the hospital.
- Similarly, in October 2021, an internal and family medicine physician paid $640,000 to resolve allegations that for nearly a decade he received payments in excess of fair market value from a home health care company for his services as a medical director.[22] Specifically, the company paid the physician $2,000 per month—and eventually up to $8,000 per month—in medical director fees, which the government alleged was intended to induce referrals of home health patients to the company.

While neither of these cases is particularly significant in terms of the size of the settlement, they illustrate the risks associated with physician compensation arrangements under both the AKS and Stark Law. When entering into medical director agreements, health systems and individual physicians should endeavor where possible to draft agreements to conform with the personal services and management contracts safe harbor, and execute the agreements with careful and continued assessment of the services the medical director is to perform and the fair market value for those services.

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[21] *See* https://www.justice.gov/usao-cdca/pr/south-bay-doctor-settles-federal-lawsuit-alleging-he-accepted-illegal-kickbacks-patient.

[22] *See* https://www.justice.gov/usao-wdla/pr/physician-agrees-pay-640000-resolve-allegations-anti-kickback-violations.

Patient Inducements *Copay Waivers*

2021 saw the resolution of a number of civil FCA and AKS cases involving inducements to patients in the form of copay waivers—some of which resulted in significant settlement amounts.

- In January 2021, a Florida pain management provider paid $1.6 million to resolve allegations that from 2013 to 2018, it caused the submission of false claims by routinely waiving Medicare beneficiaries' copays for surgical facility fees without an individualized determination of financial hardship.[23]
- In July 2021, one of the largest Medicare mail-order diabetic testing suppliers in the country paid $160 million to resolve allegations that, from 2010 through 2016, it provided kickbacks to Medicare beneficiaries in the form of free or no-cost home blood glucose monitors, and routinely waived beneficiary copay obligations for meters and diabetic testing supplies.[24] The government alleged that the company advertised the meters as free to new customers, and would provide customers a "no cost guarantee" if Medicare denied payment, which apparently happened often, because beneficiaries were often not yet eligible for a new meter. The company also allegedly had a practice of systemically waiving small copays by failing to invoice beneficiaries. For more substantial copays, it also automatically waived unpaid amounts after sending three invoices and made no other collection efforts—such as letters or phone calls.
- In December 2021, a Michigan pharmacist paid $1 million to resolve allegations that, from 2017 to 2019, he caused the submission of false claims for an injectable naloxone product by, among other things, failing to collect or attempt to collect copays.[25] Specifically, the pharmacist allegedly waived copay obligations ranging from less than $10 to $3,000, and failed to take steps to confirm financial hardships.

The DOJ has repeatedly expressed its view that routine waiver of deductibles and copayments by charge-based providers, practitioners, or suppliers is

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[23] *See* https://www.justice.gov/usao-mdfl/pr/pain-clinic-pays-more-16-million-settle-false-claims-act-and-kickback-allegations.

[24] *See* https://www.justice.gov/opa/pr/mail-order-diabetic-testing-supplier-and-parent-company-agree-pay-160-million-resolve-alleged.

[25] *See* https://www.justice.gov/opa/pr/pharmacist-and-two-pharmacies-agree-pay-1-million-resolve-allegations-false-claims-anti.

unlawful because it results in: (1) false claims; (2) violations of the AKS; and (3) excessive utilization of items and services paid for by Medicare.[26]

All that said, providers are generally free to waive a copayment if they make an individual determination that the patient suffers financial hardship or if reasonable collection efforts fail.[27] This hardship exception, however, must not be used routinely; it should be used occasionally to address the special financial needs of a particular patient. Except in such special cases, a good-faith effort to collect deductibles and copayments must be made. Otherwise, claims submitted to Medicare may violate the statutes discussed above and other provisions of the law.[28]

To be considered a reasonable collection effort, the effort to collect Medicare coinsurance/deductible amounts must be similar to the effort made to collect comparable amounts from non-Medicare patients. It also must involve the issuance of a bill to the beneficiary or to the party responsible for the patient's personal financial obligations. In addition, it may include other actions, such as subsequent billings, collection letters and telephone calls or personal contacts which constitute a genuine, rather than token, collection effort.[29]

Generic Price Fixing

In October 2021, three generic pharmaceutical manufacturers[30] agreed to pay a total of $447 million to resolve allegations that the companies paid and received compensation prohibited by the AKS through an alleged conspiracy with competitors to fix prices and/or allocate markets for generic drugs. As part of the settlements, each company entered into a five-year CIA, all of which include price transparency provisions.

Although price fixing and improper market share allocation commonly implicate the antitrust laws,[31] DOJ's theory of liability appears to have

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[26] OIG, Special Fraud Alert, December 19, 1994, https://oig.hhs.gov/documents/special-fraud-alerts/876/121994.html.

[27] OIG, Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse, https://oig.hhs.gov/compliance/physician-education/.

[28] OIG, Special Fraud Alert, December 19, 1994, https://oig.hhs.gov/documents/special-fraud-alerts/876/121994.html.

[29] CMS Medicare Claims Processing Manual, Section 80.8.1, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c23.pdf.

[30] *See* https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability.

[31] The three pharmaceutical manufacturers all agreed to deferred prosecution agreements in companion criminal cases brought by DOJ's the Antitrust Division.

considered the anticompetitive arrangements between pharmaceutical manufacturers to constitute "remuneration." There is little precedent for such an application of the AKS, and its use in these civil FCA settlements likely reflects DOJ's interest in continuing to apply the FCA aggressively to recover significant additional damages on top of the hefty criminal antitrust penalties that were levied in these cases.

Speaker Programs: *Updated PhRMA Code*

On January 1, the updated PhRMA Code on Interactions with Health Care Professionals[32] went into effect. These revisions to the PhRMA Code relate primarily to company-sponsored speaker programs, and address many of the concerns raised by the Department of Health and Human Services Office of Inspector General ("OIG") in a Special Fraud Alert issued in fall 2020.

The PhRMA Code's ("Code") updated guidance on speaker programs reiterates the educational value of these programs, which the OIG called into question in its Special Fraud Alert. To that end, the Code emphasizes that the purpose of speaker programs "should be to present substantive educational information designed to help address a bona fide educational need among attendees." The revised Code also provides new guidance as to how speaker programs should be conducted to mitigate the risks that OIG identified in the Special Fraud Alert.

- The Code now includes the directive that companies should not pay for or provide alcohol in connection with speaker programs, in direct alignment with the OIG's view.
- The Code clarifies that companies should select modest venues conducive to informational communication, which explicitly excludes "[l]uxury resorts, high-end restaurants, and entertainment, sporting or other recreational venues or events." Unlike the Special Fraud Alert, the revised Code does not go so far as to advise that restaurants are categorically inappropriate venues for speaker programs and specifically reaffirms that a private room at a restaurant is a suitable forum for a speaker program. The Code also includes these parameters for company-sponsored speaker training programs and meetings with HCP consultants.
- The Code defines appropriate attendees as those individuals who have a "bona fide educational need to receive the information presented." Repeat attendance at a speaker program on the same or substantially the same topic is generally not appropriate, nor is attendance by

[32] *See* https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/PhRMA-Code---Final.pdf.

speakers as participants at programs after speaking on the same or substantially the same topic. Further, friends, significant others, family members, or other guests of a speaker or invited attendee are not appropriate attendees, unless they have the bona fide educational need to receive the information presented.

- Regarding companies' engagements with HCPs as speakers, the Code pulls language directly from the OIG alert that decisions to select and retain speakers should not be based on "past revenue that the speaker has generated or potential future revenue that the speaker could generate by prescribing or ordering a company's products." Relatedly, any compensation provided to a speaker should be reasonable and based on fair market value and should not account for "the volume or value of past business that may have been or potential future business that could be generated for the company" by that speaker. This latter directive also applies to companies' consultant arrangements with HCPs.

PhRMA also updated the Code's principles on "incidental meals" offered to HCPs for informal presentations made by company representatives in an office or hospital setting. The Code advises that these meals can only be provided "where there is a reasonable expectation, and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with the company representative"—in other words, company representatives cannot offer "grab-and-go" meals.

Equally noteworthy are the ways the revised PhRMA Code deviates from the OIG Special Fraud Alert. As noted above, PhRMA recognizes the educational import of speaker programs and encourages the continued, appropriate use of such programs—despite the OIG's strong suggestion that companies eliminate them altogether, considering the availability of similar educational information through means that do not involve remuneration to HCPs. Importantly, the revised Code does not adapt the OIG's novel concerns about the involvement of sales and marketing in speaker selection or a company's return on investment analysis as a basis for attendee selection. Though, as discussed above, the Code does align with the OIG's position that return on investment is not an appropriate consideration for speaker selection.

CONCLUSION

While the areas outlined above do not reflect any new or novel theories of AKS enforcement or any significant influx of AKS enforcement activity, AKS enforcement will clearly continue to be an enforcement priority in 2022.