II. FRAUD AND ABUSE

Healthcare Fraud and Abuse 2022 Update

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I. Introduction

This chapter reviews significant developments in healthcare fraud and abuse in 2022. We begin with a review of legislative and regulatory changes involving the federal Anti-Kickback Statute (AKS)[2] and physician self-referral law (Stark Law),[3] as well as key court decisions and settlements involving these laws. Although the year lacked the high-profile regulatory changes of recent years, it saw significant output from the U.S. Department of Health and Human Services Office of Inspector General (OIG), with the agency issuing more advisory opinions than in any year since 2010. We then turn to the federal government's primary tool for addressing healthcare fraud, the False Claims Act (FCA). Courts this year issued significant opinions analyzing allegations under the FCA, and parties entered into a number of noteworthy settlements to resolve FCA allegations. In February 2023, the Department of Justice (DOJ) announced that it recovered more than $2.2 billion in FCA settlements and judgments in fiscal year 2022, bringing its total recovery under the act to more than $72.5 billion since 1986.

II. Anti-Kickback Statute and Stark Law—New Statutory Exceptions for Physician Wellness Programs

On December 29, 2022, President Biden signed the Consolidated Appropriations Act, 2023 (the Act), providing

[2] 42 U.S.C. § 1320a-7b(b).

[3] 42 U.S.C. § 1395nn.

for nearly $1.7 trillion in funding across a wide range of domestic initiatives. Tucked into the Act are new exceptions to the AKS and Stark Law for physician wellness programs.[4] In addition, the Act directs OIG to conduct a review on whether to establish a safe harbor for evidence-based contingency management incentives.[5]

1. Statutory Exceptions

The new statutory exceptions are substantially similar, with only minor changes reflective of the differences in scope between the AKS and Stark Law. The exceptions protect remuneration in the form of a *bona fide* mental health or behavioral health improvement or maintenance program that meets the following conditions:

(1) The program must consist of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;
(2) The program must be made available to a physician (or, in the case of the AKS, another clinician) for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of the physician (or other clinician);
(3) The program must be set out in a written policy that is approved in advance of the operation of the program by the governing body of the entity providing the program that includes (a) a description of the content and duration of the program, (b) a description of the evidence-based support for the design of the program, (c) the estimated cost of the program, (d) the personnel conducting the program (and their qualifications), and (e) the method by which the entity will evaluate the use and success of the program;
(4) The program may be offered by only certain types of entities with a formal medical staff, including hospitals, ambulatory surgery centers, community health centers, rural emergency hospitals, skilled nursing facilities, and other entities specified by regulation;

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[4]Consolidated Appropriations Act, 2023, Pub. L. 117-328, § 4126 (Dec. 29, 2022).

[5]*Id.* at § 4127.

(5) The program must be offered to all physicians (and, in the case of the AKS, other clinicians) who practice in the entity's geographic service area, including all physicians who have clinical privileges at the entity;
(6) The program must be offered to all physicians (and, in the case of the AKS, other clinicians) on the same terms and conditions and without regard to the volume or value of referrals or other business generated by the individual for the entity (and, relatedly, neither the provision of the program, nor the value of the program, may be contingent on the number or value of referrals or other business generated by the individual for the entity);
(7) The program must be evidence-based and conducted by a qualified health professional; and
(8) The program must meet any other requirements imposed by regulation.

The exceptions enable hospitals and other healthcare organizations to provide comprehensive wellness programs for physicians and other clinicians in their communities by providing assurance that, if all of the elements are met, such programs will not constitute remuneration under the AKS or Stark Law.

2. Review of Evidence-Based Contingency Management Incentives

The Act also directs OIG to conduct a review on whether to establish a safe harbor for evidence-based contingency management incentives. The review is to be conducted not later than one year after the date of enactment (i.e., December 29, 2023). In addition, not later than two years after the date of enactment (i.e., December 29, 2024), OIG is to submit to Congress recommendations for improving access to evidence-based contingency management interventions while ensuring quality of care and fidelity to evidence-based practices, and including strong program integrity safeguards.

It is worth noting that OIG previously considered contingency management interventions in the Regulatory Sprint

rulemaking.[6] Although it declined to expand the patient engagement and support safe harbor to include cash and cash-equivalent payments offered as part of contingency management interventions, OIG noted that such payments are not necessarily unlawful. The agency further observed that in-kind remuneration and certain limited-use gift cards offered as part of contingency management interventions could receive protection under the patient engagement and support safe harbor. It remains to be seen whether the Act will cause the agency to revisit the conditions under which such interventions may receive safe harbor protection.

III. Stark Law—Regulatory Changes for Rural Emergency Hospitals

CMS made several changes to the regulations that implement the Stark Law—and declined to make certain other changes that it proposed—to avoid inhibiting the growth of rural emergency hospitals (REHs). The REH is a new Medicare provider type created by the Consolidated Appropriations Act, 2021 that aims to preserve access to outpatient hospital services in rural communities whose hospitals cannot sustain inpatient operations.[7] REHs must provide emergency department and observation care, may provide other outpatient services, and cannot provide inpatient services, except for certain skilled nursing facility services.

By their terms, many of the familiar Stark Law compensation arrangement exceptions—those for employment relationships, personal services arrangements, and fair market value compensation—are available to any type of entity, including an REH. Some exceptions, however, apply only to certain types of entities, such as hospitals, federally qualified health centers, and rural health clinics. CMS modified several of these exceptions—specifically, those for physician recruitment, obstetrical malpractice insurance subsidies, retention payments in underserved areas, and assistance to compensate a nonphysician practitioner—by adding REHs to the list

[6] *See generally* 85 Fed. Reg. 77684, 77791 (Dec. 2, 2020).

[7] Consolidated Appropriations Act, 2021, Pub. L. 116-260, § 125 (Dec. 27, 2020).

of entities which must be party to the compensation arrangement for the exceptions to be available.[8]

CMS also proposed, but did not finalize, a new exception for ownership or investment interests in REHs. In many respects, the proposed exception resembled the so-called "whole hospital" exception.[9] But, the proposed exception did *not* incorporate the limitations imposed on physician-owned hospitals by the Affordable Care Act (ACA),[10] because in the proposed rule CMS did not classify REHs as "hospitals" for purposes of the Stark Law. CMS ultimately did not finalize the proposed exception, citing concern that the proposed exception did not satisfy the statutory standard that authorizes CMS to create exceptions that it determines "do[] not pose a risk of program or patient abuse."[11] Although there is no REH-specific exception for ownership or investment interests, CMS did confirm that REHs can use the rural provider exception. The rural provider exception requires the DHS to be furnished in a rural area and that no less than 75 percent of the DHS be furnished to residents of a rural area.[12]

Notably, CMS did finalize its decision to not classify REHs as "hospitals" for purposes of the Stark Law. As a result, the ACA's limitations are inapplicable to REHs. Unlike other providers that are "hospitals" for purposes of the Stark Law, REHs are not subject to the ACA's caps on physician ownership or facility expansion. Providers that convert to an REH can, for the first time, syndicate and be owned in whole or part by physicians who make referrals to the REH. They can also increase capacity without regard to the constraints that

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[8] *See* 42 C.F.R. §§ 411.357(e) (physician recruitment), (r) (obstetrical malpractice insurance subsidies), (t) (retention payments in underserved areas), and (x) (assistance to compensate nonphysician practitioners). The exception for medical staff incidental benefits, § 411.357(m), is available to REHs under § 411.357(m)(8), which makes the exception available to facilities and clinics that have *bona fide* medical staffs.

[9] 42 C.F.R. § 411.356(c)(3).

[10] *See* 42 U.S.C. § 1395nn(i); 42 C.F.R. § 411.362.

[11] 42 U.S.C. § 1395nn(b)(4).

[12] 42 C.F.R. § 411.356(c)(1). For hospitals, the rural provider exception incorporates the limitations set forth at § 411.362 that were required by the ACA. These do not apply to REHs, however, because they are not classified as "hospitals" under the Stark law.

apply to other facilities that the Stark Law considers to be physician-owned hospitals.[13]

The nature of the rural provider exception, however, means the continuous applicability of the exception is not guaranteed. The provider's locale can be reclassified or its patient mix can change. The proposed exception would have created a pathway to ensure the continued availability of an exception. Since it was not finalized, physician-owned REHs relying on the rural provider exception will need to vigilantly monitor their patient mix (and, of course, the classification of their locale).

IV. Anti-Kickback Statute—OIG Special Fraud Alert on Telehealth Arrangements

In recent years, government agencies have devoted considerable resources toward alleged schemes involving companies and individuals that purport to provide telehealth services and exploit the increased adoption of telehealth. These efforts have resulted in numerous coordinated law enforcement actions, including DOJ's nationwide enforcement action in July 2022 through which it brought criminal charges against 36 defendants in 13 federal districts for more than $1.2 billion in alleged telemedicine, cardiovascular and cancer genetic testing, and durable medical equipment schemes.[14]

On the same day that DOJ announced its nationwide takedown, OIG issued a Special Fraud Alert concerning telehealth arrangements.[15] The Special Fraud Alert encourages practitioners to exercise caution when entering into

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[13]Although REHs are not hospitals for purposes of the Stark Law, they are hospitals for other Medicare purposes. This includes the physician-owned hospital enrollment rules that require disclosure of physician ownership similar to the ACA's requirements that are incorporated into the Stark Law's whole hospital and rural provider exceptions. *See* 42 C.F.R. §§ 489.20(u) (setting forth requirements on disclosure of physician ownership), 489.3 (defining "physician-owned hospital" for enrollment purposes).

[14]*See* Section IX.8 *infra* (further discussing this nationwide action and DOJ's press release on the same).

[15]OIG, Special Fraud Alert: OIG Alerts Practitioners to Exercise Caution When Entering into Arrangements with Purported Telemedicine Companies (July 20, 2022).

certain telehealth arrangements and identifies a handful of suspect characteristics that may suggest that an arrangement presents a heightened risk of fraud and abuse. The suspect characteristics largely concern limited practitioner-patient relationships (such that the practitioner lacks sufficient information to meaningfully assess the medical necessity of the items or services that the practitioner orders), how the patient comes to the practitioner (often through the telehealth company or a marketer paid by the telehealth company), how the telehealth company pays the practitioner (namely, payments based on the volume of items or services ordered or prescribed, or based on some proxy therefor, like the number of medical records the practitioner reviews), and the often limited scope of items or services furnished by the telehealth company (e.g., durable medical equipment, genetic testing, diabetic supplies, prescription creams).

OIG underscored that the Special Fraud Alert is not intended to discourage legitimate telehealth arrangements, including many of the arrangements that practitioners entered into to provide medically necessary care to their patients during the COVID-19 public health emergency. Nevertheless, the Special Fraud Alert, as well as the government's sustained focus on investigating telehealth and related arrangements, serve as important reminders for healthcare providers to carefully consider the risks telehealth arrangements may pose under the fraud and abuse laws, including the AKS and FCA.

In addition, government agencies have begun conducting significant oversight work assessing telehealth services, including the impact of the flexibilities implemented in response to the public health emergency. In September 2022, OIG issued a data brief analyzing program integrity risks associated with Medicare telehealth services during the first year of the pandemic.[16] And in November 2022, the Pandemic Response Accountability Committee released a report examining the emerging program integrity risks identified by six participating Offices of Inspectors General related to the expansion of telehealth across federal programs during

[16]OIG, Medicare Telehealth Services During the First Year of the Pandemic: Program Integrity Risks, OEI-02-20-00720 (Sept. 2, 2022), https://oig.hhs.gov/oei/reports/OEI-02-20-00720.pdf.

the pandemic.[17] Rapid changes in telehealth payment policies and a dramatic increase in the use of the telehealth all but ensure a continued emphasis on telehealth arrangements by government enforcement agencies.

V. OIG Advisory Opinions

OIG issued 22 advisory opinions in 2022, more than it has in any year since 2010. The opinions are limited in scope to the particular arrangements described therein and to the parties who request them, but they nevertheless provide insight into how OIG applies certain fraud and abuse enforcement authorities. The following highlights several of the year's noteworthy advisory opinions.

1. OIG Advisory Opinion 22-09

In April, OIG issued Advisory Opinion 22-09, declining to approve a laboratory company's proposal to pay hospitals a fair market value, per-patient encounter fee to collect, process, and handle specimens.[18] The requestor, a network of clinical labs, proposed to contract with hospitals to pay fees for hospital personnel to collect, process, and handle specimens. The lab company, in turn, would bill third-party payors, including federal healthcare programs, for the testing. The lab company proposed several important safeguards, including that the fees would be consistent with fair market value and the contracts would prohibit double billing (i.e., hospitals would not bill payors or patients for specimen collection).

OIG nevertheless declined to protect the arrangement for two key reasons. First, in OIG's view, lab services are particularly susceptible to the risk of steering under the AKS. Second, the "per-click" fee structure, even if consistent with fair market value, inherently reflects the volume or value of referrals or other business that the hospital sends to the labs. Together, these dynamics create risk that the fees would be intended to induce hospitals to steer business

[17]Pandemic Response Accountability Committee, Insights on Telehealth Use and Program Integrity Risks Across Selected Health Care Programs During the Pandemic (Nov. 30, 2022), https://www.pandemicoversight.gov/media/file/telehealthfinal508nov30pdf.

[18]OIG Advisory Opinion No. 22-09 (Apr. 28, 2022).

to the labs. Fair market value and the prohibition against double billing would not, in OIG's words, "overcome" the per-encounter incentive to inappropriately steer business to the requestor.

Advisory Opinion 22-09 marks yet another unfavorable advisory opinion for lab arrangements. But it arguably goes a step further. Earlier opinions and guidance, including a Special Fraud Alert on laboratory payments to referring physicians,[19] feature clear fraud and abuse risks that led to predictable outcomes: above fair market value payments, payments for services already paid for by a third party, and free services that relieve referral sources of expenses they would otherwise incur.

2. OIG Advisory Opinion 22-14

In June, OIG issued Advisory Opinion 22-14, approving in part, and denying in part, a request from an ophthalmology practice regarding four variations of its proposed continuing education (CE) programs designed for local optometrists.[20] The requestor, an ophthalmology practice with one ophthalmologist and three optometrists, specializes in cataract and refractive surgery and receives half of its surgical referrals from local optometrists, with 30 percent of those patients returning to the referring optometrist for post-operative care co-managed by the requestor's ophthalmologist. The practice proposed to offer two annual CE programs to local optometrists, designed to address new ophthalmic technology and pharmaceutical practice treatment protocols. The CE programs would be open to all local optometrists, regardless of historical or anticipated referral patterns, and would include modest food and non-alcoholic refreshments. The practice proposed various registration fee and payment structures for the CE programs. Under one proposal, the practice would charge attendees a fair market value registration fee; under another, the practice would not charge any fee and would cover the cost of the programs itself. Under the other proposals, the practice would solicit funding from pharmaceutical and device manufacturers and use the funding to subsidize all or some portion of the registration fee.

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[19]OIG Special Fraud Alert: Laboratory Payments to Referring Physicians (Jun. 25, 2014).

[20]OIG Advisory Op. No. 22-14 (Jun. 29, 2022).

OIG concluded that each of the proposed arrangements implicated the AKS because, under each, the requestor would give something of value (the CE programs) to potential referral sources. OIG first looked to its Special Fraud Alert for Speaker Programs[21] and determined that the proposed CE programs did not exhibit any suspect characteristics. OIG went on to approve the proposal to charge a fair market value fee for the CE but did not analyze the arrangement under the personal services safe harbor. However, OIG found that each of the other three proposals presented too high of a risk to approve because the free or subsidized CE could induce attendees to refer surgical patients to the requestor or to order the sponsoring companies' products.

This opinion is notable because it reinforces OIG's concerns with free CE programs, applies recent OIG guidance related to speaker programs funded by pharmaceutical and device manufacturers to programs organized by physicians, and potentially generates confusion regarding why the opportunity to pay a fair market value fee for CE may constitute an inducement.

3. OIG Advisory Opinion 22-19

In September, OIG issued Advisory Opinion No. 22-19, finding that a proposal by an entity funded entirely by manufacturers of oncology drugs to provide cost-sharing assistance to Medicare Part D beneficiaries for funding the manufacturers' own drugs, as well as certain other assistance, could violate the AKS.[22]

Under the proposed arrangement, participating manufacturers, through the requestor, would subsidize cost-sharing amounts for their own products, as well as provide assistance for health insurance premiums for eligible Part D beneficiaries. Part D beneficiaries would be eligible for cost-sharing assistance if they have a cancer diagnosis, have a household income between 150-300% of the federal poverty level, and have been prescribed a participating manufacturer's oncology drug that the beneficiary's Part D plan covers. The health insurance premium subsidies would be available to qualifying Part D beneficiaries regardless of whether they

[21] OIG Special Fraud Alert: Speaker Programs (Nov. 16, 2020).

[22] OIG Advisory Op. No. 22-19 (Oct. 5, 2022).

have been prescribed an oncology drug manufactured by a participating manufacturer. All manufacturers of branded or generic oncology drugs covered under Part D would be eligible to participate in the proposed arrangement and would reimburse the requestor for the amount of the cost-sharing subsidies attributable to their own products as well as their share of the premium subsidy amounts.

OIG acknowledged that facilitating access to medically necessary oncology drugs "is of paramount concern" but declined to approve the proposed arrangement, finding that the cost-sharing subsidies likely would influence beneficiaries' decisions regarding whether to purchase the participating manufacturers' drugs. Despite having acknowledged the possibility of a "coalition model" patient assistance program in its Special Advisory Bulletin on Patient Assistance Programs,[23] OIG noted that its enforcement experience has led it to conclude that allowing manufacturers to subsidize copayments for their own drugs may encourage manufacturers to increase the list prices of their drugs.

This unfavorable advisory opinion follows Pfizer's loss in the U.S. Court of Appeals for the Second Circuit, where Pfizer challenged OIG's issuance of an unfavorable advisory opinion involving Pfizer's direct co-payment assistance program,[24] and appears to foreclose another potential avenue for pharmaceutical manufacturers to provide cost-sharing assistance for their own drugs.

4. OIG Advisory Opinion 22-20

On December 14, OIG issued Advisory Opinion 22-20, approving an acute care hospital's arrangement under which its employed nurse practitioners perform certain services that the patients' attending physicians traditionally perform.[25]

The requestor, an acute care hospital, uses its employed nurse practitioners to perform various tasks for the patients of participating physicians who are inpatients or in observation status in two designated general care medical units.

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[23]OIG Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005).

[24]*See* Section VI.1 *infra* (discussing case).

[25]OIG Advisory Op. No. 22-20 (Dec. 19, 2022).

The participating physicians are predominantly primary care physicians, and the nurse practitioners perform a variety of tasks the physicians normally would perform in collaboration with the participating physicians. The treating physicians cannot bill for the nurse practitioners' services and remain ultimately responsible for their patients' care; however, the arrangement allows their patients to be treated and diagnosed more quickly. OIG considered this arrangement low risk because it is limited to non-surgical and non-specialty hospital units and incorporates several safeguards, including the fact that physicians may not bill for the work the nurse practitioners perform. OIG also determined that the arrangement may improve patient care through more timely evaluations.

This favorable opinion represents a departure from OIG's typical approach to arrangements involving remuneration from hospitals to referring physicians. However, the opinion addresses only the AKS and does not address the potential hurdles such arrangements may face under the Stark Law, thus limiting its potential relevance.

VI. Anti-Kickback Statute—Key Court Decisions

1. Intent

In July 2022, the Second Circuit affirmed a district court's order granting summary judgment to HHS as to Pfizer's request for a declaratory judgment that its copay assistance program did not violate the AKS.[26] The underlying litigation stems from Pfizer's attempt in June 2019 to obtain an OIG advisory opinion regarding its proposed direct co-payment assistance program for an expensive, rare disease drug. In late 2020, OIG issued an unfavorable advisory opinion, in which it concluded that the program would involve prohibited conduct under the AKS because the subsidy would induce Medicare beneficiaries to purchase the drug by removing the financial impediment of the cost-sharing obligation.[27] Shortly before OIG published the advisory opinion, Pfizer filed a lawsuit, challenging OIG's conclusions as contrary to law

[26]Pfizer, Inc v. U.S. Dep't of Health & Hum. Servs., 42 F.4th 67 (2d Cir. 2022).

[27]OIG Advisory Op. No. 20-05 (Sept. 18, 2020), at 26-27.

under the Administrative Procedure Act. In September 2021, the U.S. District Court for the Southern District of New York granted summary judgment in favor of the government.[28]

Before the Second Circuit, Pfizer argued that its proposed program must be administered with a "corrupt" intent in order to violate the AKS. As support, Pfizer cited to three phrases within the AKS that, in its view, suggested an element of "corrupt" intent—specifically, (1) "any remuneration . . . to induce"; (2) "including any kickback, bribe, or rebate"; and (3) "willfully."[29] As to the first phrase, Pfizer contended that it necessarily requires a *quid pro quo*, which are "designed to corrupt the recipient's behavior" and that the word "induce" implies corruption.[30] After examining the plain meaning of the phrases, the AKS's statutory construction, and certain case law, the Second Circuit found that none of those phrases indicate that the AKS requires a corrupt intent or limits the statute to corrupt payments.[31] The court declined to decide whether the AKS requires a *quid pro quo* because OIG had already determined in its advisory opinion that the proposed program would operate as a *quid pro quo* and, the court noted, it has "no doubt that at least some kind of *quid pro quo*, direct or indirect, exists here."[32] In October, Pfizer filed a certiorari petition with the Supreme Court. On January 9, 2023, the Court denied Pfizer's petition.[33]

The U.S. District Court for the Northern District of Georgia analyzed the AKS's intent element in the context of a criminal prosecution alleging hospitals and physicians entered into "sham" contracts to disguise kickbacks in exchange for patient referrals.[34] The court noted that because application of the one-purpose rule under the AKS is

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[28]Pfizer v. U.S. Dep't of Health and Hum. Servs., 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021).

[29]Pfizer, 42 F.4th at 74.

[30]*Id.* at 74-75.

[31]*Id.* at 74-77.

[32]*Id.* at 74.

[33]Pfizer, Inc. v. Dep't of Health and Human Servs., No. 22-339 (U.S.), Order Denying Petition (Jan. 9, 2023).

[34]United States v. Holland, Criminal Action No. 1:17-CR-0234-AT (N.D. Ga.), Dkt. No. 610 (Nov. 21, 2022 Order).

"unsettled and unclear," merely establishing that one purpose of the contracts was to induce referrals was insufficient to show the defendants acted willfully in violation of the AKS.[35] The court held instead that "the government must show that the individuals in question must have known they were breaking the law beyond knowing that one purpose of the deal was to induce referrals."[36] Without evidence the contracts were not performed, the payments exceeded FMV, or other "nefarious conduct," the court could not conclude that the defendants had reason to believe they were violating the law.[37]

2. Causation

The Affordable Care Act amended the AKS to provide that claims "resulting from" an AKS violation are "false or fraudulent" for FCA purposes.[38] For over a decade, courts have wrestled with the significance of the "resulting from" requirement and the degree of causation it warrants for an FCA violation premised on an illegal kickback.

In July, the Eighth Circuit added to the debate, splitting with the Third Circuit and holding that "resulting from" requires but-for causation between the AKS violation and the alleged false claim.[39] In the FCA case at hand, the relator alleged that the defendants—a neurosurgeon, his medical practice, his fiancée, and a medical device distributor owned by his fiancée—engaged in a prohibited kickback scheme whereby the neurosurgeon ordered spinal implants from his fiancée's device company generating substantial sales commissions and lucrative stock options from the device manufacturer. These financial gains allegedly led the neurosurgeon to order even more implants. The government intervened in the *qui tam* action, asserting that the defendants' claims for federal reimbursement were false because they were "tainted" by illegal kickbacks. The case proceeded

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[35] *Id.* at 19.

[36] *Id.* at 21.

[37] *Id.* at 38.

[38] 42 U.S.C. § 1320a-7b(g).

[39] U.S. ex rel. Cairns v. D.S. Med. LLC, 42 F.4th 828, 836 (8th Cir. 2022) (noting that the Third Circuit "came out differently" in U.S. ex rel. Greenfield v. Medco Health Solutions, Inc., 880 F.3d 89 (3d Cir. 2018)).

to a jury trial, in which the district court instructed the jury that the government could establish falsity if it proved that the claim for reimbursement merely "failed to disclose the [AKS] violation."[40] The jury subsequently returned a verdict in favor of the government on two of its three claims and awarded treble damages on statutory penalties totaling more than $5.49 million.[41]

The defendants appealed to the Eighth Circuit, arguing for the reversal of the jury verdict because the lower court failed provide a jury instruction on but-for causation. The Eighth Circuit ultimately agreed with defendants and reversed the district court's judgment. In so ruling, the Eighth Circuit evaluated the plain meaning of "resulting from" within the AKS, applying a prior U.S. Supreme Court decision that had interpreted the phrase to require but-for causality in the context of the Controlled Substances Act.[42] Rejecting the government's list of "alternative causal standards" and the Third Circuit's reliance on "legislative history and 'the drafters' intentions' to interpret" the AKS, the Eighth Circuit explained that the phrase "resulting from" is "unambiguously causal."[43] Therefore, the court held that proving falsity or fraud based on an AKS violation requires the government to show that "a defendant would not have included particular 'items or services' but for the illegal kickbacks."[44]

VII. Anti-Kickback Statute and Stark Law—Noteworthy Settlements

In February, a hospital agreed to pay $3.8 million to settle allegations related to the provision of back-up practice coverage services for an independent cardiologist at no charge.[45] According to the settlement agreement, the government as-

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[40]Cairns, 42 F.4th at 831.

[41]*Id.* at 831-832.

[42]*Id.* at 834-835 (discussing Burrage v. United States, 571 U.S. 204 (2014)).

[43]*Id.* at 836.

[44]*Id.*

[45]Press Release, U.S. Dept. of Justice, Catholic Medical Center Agrees to Pay $3.8 Million to Resolve Kickback-Related False Claims Act Allega-

serted that the hospital paid its own cardiologists to cover for, and to be available to provide medical services for, an independent cardiologist's patients while she was on vacation or otherwise unavailable. The hospital allegedly provided these practice call coverage services to the independent cardiologist at no charge in order to induce the cardiologist to refer patients to the hospital in violation of the AKS.

In June, a large health system agreed to pay $4.375 million and enter into a five-year Corporate Integrity Agreement to resolve allegations that certain of its financial relationships with physicians violated the FCA based on violations of the AKS and Stark Law.[46] The government alleged that one of the health system's hospitals entered into an agreement with a urology practice under which the practice would run a prostate cancer center of excellence at the hospital. The health system admitted, however, that the prostate cancer center ceased to exist shortly after the arrangement began and that the urology practice did not provide the services specified in the agreement but it was nevertheless paid by the hospital for several years. The government further alleged that the hospital entered into a similar arrangement with another physician practice to provide medical director services for its prostate cancer program, but that the physician practice never provided the agreed-upon services. In addition, in the course of the government's investigation, the health system disclosed facts concerning (i) another medical director arrangement for which it could not confirm that the physician provided the agreed-upon services and (ii) the hospital's failure to charge the proper rent in certain leases with physicians, resulting in below-fair market value rent rates.

In July, a hospital agreed to pay $1.5 million to resolve allegations that it entered into compensation arrangements with certain of its employed physicians that exceeded fair market value or took into account the volume or value of the

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tions (Feb. 9, 2022), https://www.justice.gov/usao-nh/pr/catholic-medical-center-agrees-pay-38-million-resolve-kickback-related-false-claims-act.

[46]Press Release, U.S. Dept. of Justice, Steward Health Care System Agrees to Pay $4.7 Million to Resolve Allegations of False Claims Act Violations (June 10, 2022), https://www.justice.gov/usao-ma/pr/steward-health-care-system-agrees-pay-47-million-resolve-allegations-false-claims-act.

physicians' referrals to the hospital, in violation of the Stark Law.[47] In announcing the settlement, the government noted that the settlement resulted from a voluntary disclosure made by the hospital in May 2019, and that the settlement amount was based on the hospital's financial condition. Notably, this settlement came on the heels of a $50 million settlement that a nearby hospital entered into in 2020 that involved similar allegations and, according to public reporting, the same management firm involved in the earlier settlement.[48]

In August, an optical lens manufacturer agreed to pay $16.4 million and entered into a five-year Corporate Integrity Agreement to resolve allegations that the company improperly paid remuneration to optometrists and ophthalmologists to induce them to purchase the company's products.[49] The remuneration, which allegedly included among other things matching contributions to retirement savings plans, free practice management consulting services, subsidized loans, and software rebates, was paid through a range of marketing and similar incentive programs.

In October, a home health company and two of its former corporate officers agreed to pay $22.9 million to resolve allegations that the company paid physicians to induce referrals of home health patients under the guise of medical

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[47]Press Release, U.S. Dept. of Justice, West Virginia Hospital to Pay $1.5 Million to Settle Allegations Concerning Impermissible Financial Relationships with Referring Physicians (July 7, 2022), https://www.justice.gov/opa/pr/west-virginia-hospital-pay-15-million-settle-allegations-concerning-impermissible-financial.

[48]Press Release, U.S. Dept. of Justice, West Virginia Hospital Agrees to Pay $50 Million to Settle Allegations Concerning Improper Compensation to Referring Physicians (Sept. 9, 2020), https://www.justice.gov/opa/pr/west-virginia-hospital-agrees-pay-50-million-settle-allegations-concerning-improper. *See also* WTOV9, WMC to Pay Settlement for Impermissible Financial Relationships with Referring Physicians, https://wtov9.com/news/local/weirton-medical-center-agrees-to-pay-settlement ("Weirton Medical Center's prior management firm was also the prior management firm for Wheeling Hospital.")

[49]Press Release, U.S. Dept. of Justice, Essilor Agrees to Pay $16.4 Million to Resolve False Claims Act Liability for Paying Kickbacks (Aug. 23, 2022), https://www.justice.gov/usao-edpa/pr/essilor-agrees-pay-164-million-resolve-false-claims-act-liability-paying-kickbacks.

directorships.[50] Contemporaneous with the settlement, the company entered into a five-year Corporate Integrity Agreement. The former corporate officers also agreed to be excluded from federal healthcare programs for five years. In addition, on the same date, the defendants agreed to pay $7.175 million to settle a separate FCA suit concerning allegations that the company submitted claims for therapy services without regard to medical necessity and overbilled therapy services by upcoding patients' diagnoses.

In November, an electronic health record (EHR) technology vendor agreed to pay $45 million to resolve allegations that it violated the FCA and AKS through three marketing programs.[51] The government alleged that the EHR company (1) solicited and received kickbacks from a lab company in exchange for recommending and arranging for its users to utilize the lab company's pathology services; (2) conspired with the lab company to improperly donate its EHR to healthcare providers in an effort to increase referrals to the lab company and simultaneously add customers to the EHR company's user base; and (3) paid kickbacks to its current healthcare provider customers and to other influential sources in the healthcare industry to recommend its EHR and refer potential customers. On the basis of this alleged conduct, the government contended that the EHR company improperly generated sales for itself and for the lab company, while causing healthcare providers to submit false claims for reimbursement to the federal government for pathology services, and for incentive payments from the government for the adoption and meaningful use of EHR technology.

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[50]Press Release, U.S. Dept. of Justice, Oklahoma City Home Health Company and Two Former Corporate Officers Agree to Pay $22.9 Million to Settle Federal False Claims Act and Kickback Allegations Arising from Improper Payments to Referring Physicians (Oct. 18, 2022), https://www.justice.gov/usao-wdok/pr/oklahoma-city-home-health-company-and-two-former-corporate-officers-agree-pay-229.

[51]Press Release, U.S. Dept. of Justice, Modernizing Medicine Agrees to Pay $45 Million to Resolve Allegations of Accepting and Paying Illegal Kickbacks and Causing False Claims (Nov. 1, 2022), https://www.justice.gov/opa/pr/modernizing-medicine-agrees-pay-45-million-resolve-allegations-accepting-and-paying-illegal.

VIII. Eliminating Kickbacks in Recovery Act—Key Court Decisions

The Eliminating Kickbacks in Recovery Act (EKRA) was enacted in 2018 as part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (the SUPPORT Act). EKRA is a criminal statute that broadly prohibits kickbacks in connection with clinical treatment facilities, laboratories, and recovery homes. Unlike other federal fraud and abuse laws, it generally applies to all payers, not just federal healthcare programs. Although the statute contemplates that DOJ and HHS may promulgate regulations to clarify the statutory exceptions, no such regulations have been issued.

To date, there have been very few cases interpreting EKRA. There have, however, been two federal district court cases that offer conflicting approaches as to how the law should be interpreted. In October 2021, the U.S. District Court for the District of Hawaii held that an employee's commission-based compensation from a lab company did not violate EKRA.[52] The arrangement at issue was an employment agreement under which the individual would be paid a base salary and a bonus that was based on the percentage of monthly net profits generated by the individual's client accounts and those that he managed. After EKRA was enacted, the lab company terminated the bonus arrangement and entered into negotiations to revise the arrangement. When negotiations fizzled, the lab company terminated the individual. That individual then filed a lawsuit, asserting various civil claims, including breach of contract, the viability of which turned on whether the compensation structure violated EKRA. The district court determined that the exception to EKRA for payments to employees did not apply, but it found in favor of the employee because it held that the arrangement did not violate EKRA. The court focused on whether the employee was paid remuneration to induce the referral of individuals to the lab. Because the employee was paid based on the client accounts of physicians

[52]S&G Labs Hawaii v. Graves, 2021 WL 4847430 (D. Haw. Oct. 18, 2021).

and the like, not individuals, the court held EKRA was not violated.[53]

In May 2022, the U.S. District Court for the Northern District of California reached the opposite result—expressly rejecting the reasoning of the 2021 opinion—in a criminal healthcare fraud case involving charges of conspiracy to violate EKRA.[54] The court found, in denying the defendant's motion to dismiss the indictment, that EKRA applies even where compensation was paid for referrals obtained through marketing to physicians and related organizations, not just marketing to individuals.[55] In September, a jury convicted the defendant on all charges.[56]

IX. False Claims Act Developments

1. DOJ Dismissal Authority

In June, the Supreme Court granted a certiorari petition in an FCA case, *U.S. ex rel. Polansky v. Executive Health Resources, Inc.,* for the first time in more than three years to address questions surrounding the DOJ's authority to control *qui tam* lawsuits after initially declining to intervene in an action.[57] The FCA enables DOJ to control *qui tam* lawsuits brought by relators on behalf of the United States through exercise of its intervention and dismissal authority. If the government initially declines to intervene in a *qui tam* lawsuit, the statute provides that it may intervene at a later time upon a showing of "good cause."[58] Under Section 3730(c)(2)(A) of the statute, the government may dismiss *qui tam* lawsuits even where a relator is pursuing the underly-

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[53]*Id.* at *9-12.

[54]USA v. Schena, 2022 WL 1720083 (N.D. Cal. May 28, 2022).

[55]*Id.* at *4-5.

[56]Press Release, U.S. Dept. of Justice, Medical Technology Company President Convicted in $77 Million COVID-19 and Allergy Testing Scheme (Sept. 2, 2022), https://www.justice.gov/opa/pr/medical-technology-company-president-convicted-77-million-covid-19-and-allergy-testing-scheme.

[57]U.S. ex rel. Polansky v. Executive Health Resources, Inc., No. 21-1052 (U.S.); *see also* Polansky, 17 F.4th 376 (3d Cir. 2021).

[58]31 U.S.C. § 3730(c)(3).

ing FCA claims and opposes dismissal.[59] In the *Polansky* case, the Supreme Court will evaluate a longstanding circuit split concerning the appropriate standard to apply when deciding whether to grant a motion to dismiss by the government pursuant to 31 U.S.C. § 3730(c)(2)(A). In doing so, the Court will evaluate whether the government can move to dismiss if it previously declined to intervene and, if so, whether it has to move to intervene and show "good cause" before it can move to dismiss. The Court heard oral argument in December, and the Court issued its opinion in June 2023.[60]

2. Pleading Submission of Claims and Fraudulent Scheme

Courts this year continued to reach varying conclusions in determining whether an FCA complaint sufficiently pleads fraud with particularity under Federal Rule of Civil Procedure 9(b). As in years past, this variation was seen most notably when courts weighed how much detail allegations must contain in tying a scheme to actual claims submitted to federal healthcare programs.

In late 2021, the Supreme Court received three certiorari petitions requesting that the Court address the long-simmering divide within lower courts as to whether a relator must identify an actual false claim in a *qui tam* complaint to satisfy Rule 9(b), or instead can allege sufficient indicia of reliability to support a strong inference that false claims for payment were submitted.[61] Although the Court continually has declined to take up this issue, this year speculation arose that this time might be different after the Court asked for the Solicitor General to provide the United States' position on two of those petitions. As it did in 2010 and 2014, though, the Solicitor General recommended that the Court decline to address this question because, it argued, no real circuit split exists and any divide in the lower courts' approaches derives

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[59] 31 U.S.C. § 3730(c)(2)(A).

[60] U.S. ex rel. Polansky v. Executive Health Resources, Inc., 143 S. Ct. 1720 (2023).

[61] Johnson v. Bethany Hospice and Palliative Care, LLC, No. 21-462 (U.S.); U.S. ex rel. Owsley v. Fazzi Associates, Inc., No. 21-936 (U.S.); Molina Healthcare of Illinois Inc. v. Prose, No. 21-1145 (U.S.).

from the "fact-intensive" nature of the pleading standard.[62] In October, the Supreme Court summarily denied all three petitions, and thus the status quo within the lower courts remains.

In March, the U.S. District Court for the District of Maryland dismissed a relator's FCA claims predicated on a kickback scheme in which defendants allegedly marketed physicians on a website to perform surgeries to implant a gastric banding device only if the physicians performed a minimum number of procedures with the device.[63] The district court outlined how, within the Fourth Circuit, there are "two ways to adequately plead" the presentment of a false claim under Rule 9(b): a relator can allege either (1) details of a specific false claim or (2) "a pattern of conduct that would *necessarily* have led to submission of false claims."[64] The district court ruled that the relator's allegations failed under either avenue. The district court first rejected the relator's argument that "tables purport[ing] to show Medicare claims data for procedures performed by several doctors" constituted the identification of false claims. The court noted that the table omitted important information, such as the dates when procedures were performed and when claims were submitted, and explained that the relator's complaint "provides nothing more than [his] say-so to support his conclusion that the listed claims" submitted using billing code 43770 corresponded to the specific type of surgeries at issue.[65] As to why the relator's complaint failed under the alternative route for pleading presentment, the district court highlighted that the relator was asking the court "to blindly accept his conclusory assertions that because several surgeons submitted reimbursement requests at unspecified times, for surgeries that took place at unspecified times, using a Medicare code that is not specific" to the surgeries at issue, "that false claims were necessarily

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[62]Johnson v. Bethany Hospice and Palliative Care, LLC, No. 21-462 (U.S.), Amicus Curiae Brief for United States (May 24, 2022), at 10, 15-16, 18.

[63]U.S. ex rel. Fitzer v. Allergan, Inc., 2022 WL 846211 (D. Md. Mar. 22, 2022).

[64]*Id.* at *6.

[65]*Id.* at *6.

submitted for reimbursement."[66] Such unsupported inferences, the district court concluded, fail to satisfy Rule 9(b)'s standard for pleading FCA claims predicated on AKS violations.

In August, the Seventh Circuit affirmed dismissal of *qui tam* allegations against a hospital and a debt collection agency under Rule 9(b) but reversed dismissal as to allegations against a second debt collection agency.[67] The alleged scheme at issue involved a debt collection agency causing its clients to submit false cost reports when seeking reimbursement from CMS for bad debts without first performing "reasonable collection efforts." The district court dismissed the FCA claims against all three defendants because the relators failed to provide "specific representative examples" of any bad debts that were included on a cost report without reasonable collections efforts having been undertaken. In affirming dismissal as to the hospital and one agency, the Seventh Circuit reasoned that the relators did not plead enough details about the agency's "day-to-day" activities or the hospital's failure to make independent collection efforts.[68] Even though the relators alleged that the agency billed the hospital for nine employees when only two were actually doing the work, the Seventh Circuit noted that the complaint lacked details about "the number of individual debts" referred to the agency or "how long it would take an average employee to complete reasonable collection efforts" under the regulation at issue.[69]

By comparison, the Seventh Circuit reversed the dismissal of the allegations against the second debt collection agency because the relator alleged the mechanics as to how specific representative examples were improperly declared as bed debt and included on a cost report—specifically, the relators alleged three examples where the agency improperly declared debts as Medicare bad debts prior to the expiration of the required 120-day period for reasonable collection efforts, and alleged that those debts were written off inap-

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[66] *Id.* at *8.

[67] U.S. ex rel. Sibley v. University of Chicago Medical Center, 44 F.4th 646 (7th Cir. 2022).

[68] *Id.* at 658.

[69] *Id.* at 660.

propriately as bad debt by another hospital that then sought reimbursement for them from the federal government.[70]

Also in August, the Ninth Circuit held that a relator need not identify specific payment invoices to satisfy Rule 9(b) when his complaint included specific allegations of a fraudulent scheme to submit false claims along with "reliable indicia" that lead to a strong inference that claims were actually submitted.[71] The relator alleged a "rent-a-vet" scheme through which a service-disabled veteran-owned small business (SDVOSB) and a non-SDVOSB company misled the government into awarding the SDVOSB a contract to provide radiopharmaceutical products to VA hospitals, when the non-SDVOSB company conducted most of the work and retained the majority of the revenue. The Ninth Circuit reversed the district court's dismissal of the complaint, finding the relator met Rule 9(b)'s requirements by alleging "[t]he *who* (defendants), *what* (th[e] eight contracts), *where* (in the locations identified in the contracts), *when* (at the time the contracts were bid on, negotiated, and executed), and *how* (by falsely promising that the SDVOSBs would perform the contract)."[72] Even though the relator failed to plead allegations about the specific invoices for reimbursement that the SDVOSB submitted for work actually performed by the non-SDVOSB, the Ninth Circuit concluded it was sufficient that the relator detailed the contracts at issue, set forth the specifics of the scheme, and alleged that fraudulent invoices were submitted by the defendants and paid by the government.[73]

In July, the U.S. District Court for the Western District of Kentucky adhered to the Sixth Circuit's more stringent Rule 9(b) pleading standard and granted an ambulance company's motion to dismiss FCA claims relating to medically unnecessary transports.[74] In rejecting the relator's argument that some alleged documentation constituted representative false

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[70]*Id.* at 660.

[71]UPPI LLC v. Cardinal Health, Inc., 2022 WL 3594081, at *3 (9th Cir. Aug. 23, 2022).

[72]*Id.* at *2 (emphasis added).

[73]*Id.* at *3.

[74]U.S. ex rel. Dunn v. Procarent, Inc., 2022 WL 2834685 (W.D. Ky. July 20, 2022).

claims, the district court emphasized that nothing on the face of the documents indicated whether the billing concerned government healthcare programs or private insurance.[75] The district court further held that relators did not qualify for a relaxed pleading standard because, even though they alleged to have worked in the ambulance company's "billing department" or been "involved in billing," they did not "provide any detail about their specific job duties" or their "personal involvement in [the company's] billing process."[76]

The limits of the Sixth Circuit's pleading standard were tested earlier in the year, when the U.S. District Court for the Middle District of Tennessee denied a defendant's motion to dismiss under Rule 9(b) where the defendant sought to narrow the government's FCA claims to the time period and locations corresponding to the specific representative examples of the alleged scheme identified in the government's complaint.[77] The district court declined the defendant's request to limit the government's allegations in that manner, explaining that Rule 9(b) did not require the plaintiff to allege examples for each of the defendant's various locations or examples covering the full timeframe of the conduct at issue.[78] Alleging exemplary claims with particularity—as the district court determined the government had done—was sufficient under Rule 9(b).

The underlying purpose behind Rule 9(b)'s heightened pleading requirement is to deter frivolous lawsuits, prevent fishing expeditions, and guard defendants' reputations—all of which the Fourth Circuit underscored in a July opinion affirming dismissal of an FCA complaint predicated on AKS violations.[79] The relator alleged that a skin graft manufacturer violated the AKS by making commission payments to independent contractors based on their sales to VA hospitals. The complaint lacked any factual details concerning how the commissions were paid, who made the payments, or who

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[75]*Id.* at *11.

[76]*Id.* at *12.

[77]U.S. ex rel. Anderson v. Curo Health Servs. Holdings, Inc., 2022 WL 842937 (M.D. Tenn. Mar. 21, 2022).

[78]*Id.* at *11-12.

[79]U.S. ex rel. Nicholson v. MedCom Carolinas, Inc., 42 F.4th 185 (4th Cir. 2022).

received them—leading the Fourth Circuit to observe that the relator's allegation "sounds like a neighbor's conversation only half overheard through the walls."[80] Before affirming dismissal of the *qui tam* complaint with prejudice, the court cautioned "future relators" that "it may be wise to err on the side of saying too much to avoid a kick from Rule 12(b)(6)."[81]

3. Pleading and Proving Falsity

Prior decisions in both appellate and district courts have produced a split among federal courts as to whether a disagreement of medical opinion can establish that a physician's clinical judgment about patient care and any related certifications were "false" under the FCA. In 2021, the Supreme Court declined an opportunity to provide clarity on this issue, thus leaving lower courts to continue grappling with the issue of objective falsity.

In March, the U.S. District Court for the Middle District of Tennessee addressed a defendant's motion seeking dismissal of the government's FCA allegations that claims for hospice services were false because the patients were not terminally ill.[82] The defendant contended that the government's theory of falsity failed because it rested on disagreements with the certifying physician's clinical judgments, citing the Eleventh Circuit's opinion in *United States v. AseraCare* as support.[83] The district court was unpersuaded and denied the defendant's motion to dismiss, underscoring that the government did not allege a mere clinical disagreement, but rather "fraud, in the simplest and most straightforward sense."[84] In denying the defendant's motion to dismiss, the district court cited to the Sixth Circuit's opinion in *United States v. Paulus* and concluded that "it is well settled that opinions are not,

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[80] *Id.* at 196.

[81] *Id.* at 196.

[82] U.S. ex rel. Anderson v. Curo Health Servs. Holdings, Inc., 2022 WL 842937 (M.D. Tenn. Mar. 21, 2022).

[83] *Id*. at *12 (citing United States v. AseraCare, 938 F.3d 1278, 1297 (11th Cir. 2019)).

[84] *Id.* at *12.

and have never been, completely insulated from scrutiny for fraud."[85]

In September, the U.S. District Court for the Northern District of Alabama denied the defendant's motion for summary judgment on allegations that the reimbursement the defendant sought for nuclear stress tests violated Medicare regulations and the FCA.[86] Relying on *AseraCare*, the defendant argued that the relator failed to present evidence identifying an objective falsehood because the claims for nuclear stress testing were dependent on "whether the billing physicians reasonably believed that they were qualified to and had supervised the procedures that they billed for."[87] The district court explained that unlike *AseraCare*, which involved "a question of debatable clinical judgment," a jury question on falsity can exist where the regulation at issue is "subject to multiple interpretations" but "ultimately only one of the two possible interpretations could be deemed correct." Such was the case here, the district court reasoned, given that "either the billing physicians exercised general supervision over the nuclear stress tests" and adhered to the regulation, "or they didn't."[88] Because the relator had offered sufficient evidence to allow a reasonable jury to find that the billing physicians were not as involved in the nuclear stress tests as necessary to bill for the procedures, the district court denied the defendant's motion for summary judgment on the issue of falsity.

Appellate and trial courts this year continued to address other issues related to establishing falsity in FCA litigation. In March, the Ninth Circuit affirmed the district court's dismissal of a *qui tam* lawsuit alleging that the defendant failed to implement adequate security protocols for its supply chain of controlled substances, which caused it to falsely certify that it was in compliance with "all applicable" laws and

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[85]*Id*. at *12 (citing United States v. Paulus, 894 F.3d 267 (6th Cir. 2018)).

[86]Livingston v. Digirad Corp., 2022 WL 4110897, at *10 (N.D. Ala. Sept. 8, 2022).

[87]*Id.* at *10 (citing United States v. AseraCare, 938 F.3d 1278, 1297 (11th Cir. 2019)).

[88]*Id.* at *10.

regulations, including various supply chain requirements.[89] The Ninth Circuit held that the defendant's "failure to disclose that the supplies were delivered through a noncompliant supply chain did not render misleading the representation that the supplies were delivered."[90] The court noted that the defendant's claims for payment lacked any "specific representations" about its medical supplies that became misleading half-truths by failing to disclose the alleged supply chain issues.[91]

The Ninth Circuit addressed an implied certification theory of falsity again in August in evaluating a *qui tam* lawsuit in which the relator alleged that the defendants misled the government into awarding contracts to SDVOSBs for distribution of products to VA hospitals where a non-SDVOSB company did most of the work and retained the majority of the revenue.[92] The district court initially dismissed the relator's FCA action, holding that it failed to plead falsity under either a fraud-in-the-inducement or implied certification theory. The Ninth Circuit then reversed the dismissal on both counts. As to the relator's implied certification theory, even though the VA had knowledge that the non-SDVOSB company "would somehow be *involved*," the Ninth Circuit found the relator's pleading sufficient because it alleged that the defendants "failed to disclose the *extent* of [the non-SDVOSB company's] involvement and the extremely limited role the SDVOSBs intended to play.[93]

In January, in a case before the U.S. District Court for the District of Utah, a vascular surgeon relator alleged that anesthesiologist and hospital defendants submitted false claims because anesthesiologists were distracted by use of their personal electronic devices (PEDs) during surgeries.[94] The relator contended that use of a PED during surgery

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[89]McElligott v. McKesson Corp., 2022 WL 728903 (9th Cir. Mar. 10, 2022).

[90]*Id.* at *1.

[91]*Id.*

[92]UPPI LLC v. Cardinal Health, Inc., 2022 WL 3594081 (9th Cir. Aug. 23, 2022).

[93]*Id.* at *3.

[94]U.S. ex rel. Khoury v. Intermountain Healthcare, Inc., 2022 WL 271760 (D. Utah Jan. 28, 2022).

caused the defendants to falsely certify that they had provided "reasonable and necessary" services. After highlighting that the Tenth Circuit had endorsed a "broad" definition of falsity under the reasonable and necessary standard, the district court held that the relator had adequately alleged false certification claims against the anesthesiologist defendants for certifying that their services were reasonable and necessary.[95] But, the court dismissed claims against the hospital defendant, ruling that the conduct alleged by the relators failed to state a claim for violation of any conditions of participation applicable to the hospital.[96]

In March, the U.S. District Court for the Northern District of Mississippi granted summary judgment in favor of the defendants on the issue of falsity, where the relator alleged that the defendants falsely certified compliance with licensure laws in claims for payments because they employed a director of nursing who did not have a valid state license to practice in Mississippi.[97] The relator argued that a license is rendered invalid as soon as conduct inconsistent with the license occurs—even if the state governing board has not yet determined if the conduct violates its rules. The defendants contended that the license would become invalid only following a determination from the state governing board that it was invalid in a final adverse action without further appeal.[98] The district court determined that "CMS unequivocally took" the defendants' interpretation and "that fact resolves this case" because it was undisputed that no final adverse action was taken against the nurse's license.[99]

4. Pleading and Proving Materiality

The Supreme Court's seminal 2016 decision in *Universal Health Services v. U.S. ex rel. Escobar* underscored the "rigorous" and "demanding" nature of the FCA's materiality element and outlined several non-exclusive factors that continue to guide lower courts in assessing whether the

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[95] *Id.* at *8-9.

[96] *Id.* at *9-10.

[97] U.S. ex rel. Jehl v. GGNSC Southaven, LLC, 2022 WL 983644 (N.D. Miss. Mar. 30, 2022).

[98] *Id.* at *3-4.

[99] *Id.* at *5.

materiality element is satisfied in any given case.[100] These factors include: (1) whether compliance with a particular statute, regulation, or other requirement is an express condition of payment; (2) whether the violation of the relevant requirement goes to the essence of the bargain or instead is only "minor" or "insubstantial;" and (3) whether the government consistently pays, or refuses to pay, claims in the "mine run of cases" where it has knowledge of noncompliance.

In June, the Fourth Circuit affirmed the dismissal of a *qui tam* complaint alleging that two physicians, five medical companies, and an accounting firm violated the FCA by billing Medicare even though they knew that the medical license of one of the companies had been administratively revoked for failure to pay an annual registration fee.[101] The Fourth Circuit held that the medical license revocation was not material to payment given that the relator could not cite any instances where Medicare had denied claims in a similar context. As to the examples that the relator had provided, the court noted that all but one of those involved an individual physician's license, and that one example involved a physician convicted for a felony, not revocation based on a failure to pay a minor registration fee.[102]

In August, the Ninth Circuit reversed a district court order granting summary judgment where a relator alleged that a medical device manufacturer falsely certified that it adhered to certain Medicare payment criteria by using a billing modifier that triggered automatic payment, instead of submitting claims without the modifier, which would have led to a multi-level administrative review process.[103] Unlike the district court, the Ninth Circuit ruled that the allegedly false use of the modifier was material to payment. The court weighed extensive evidence of the government's history of reviewing claims submitted without the modifier and concluded that the government often denied such claims.[104] Because the government had denied a significant portion of

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[100]579 U.S. 176, 181, 194 (2016).

[101]U.S. ex rel. Taylor v. Boyko, 39 F.4th 177 (4th Cir. 2022).

[102]*Id.* at 191-192.

[103]U.S. ex rel. Hartpence v. Kinetic Concepts, Inc., 44 F.4th 838 (9th Cir. 2022).

[104]*Id.* at 847-850.

unmodified claims in the "mine run of cases," the Ninth Circuit held that there was a genuine issue of material fact as to whether the manufacturer's use of the modifier to sidestep the administrative review process constituted a material misrepresentation.[105]

In October, the Second Circuit affirmed the dismissal of a *qui tam* complaint for failure to state a viable FCA claim because none of the alleged misrepresentations and regulatory violations were material to payment. The relator alleged that a pharmaceutical manufacturer made false representations to the FDA to obtain approval for its drugs and to construct a new manufacturing facility.[106] Finding that the relator failed to plead materiality adequately, the Second Circuit first noted that the complaint did not allege that any of the manufacturer's contracts conditioned payment on compliance with specific Current Good Manufacturing Practices (cGMPs) that the relator alleged were violated.[107] While the relator alleged that the contracts incorporated by reference all cGMPs by requiring that drugs not be considered adulterated, the court found this insufficient to establish materiality, as even the relator acknowledged that "not every violation of a cGMP would be material for purposes of a FCA claim."[108] The Second Circuit also determined that the misrepresentations and regulatory violations did not go to the essence of the bargain because the relator "allege[d] only that the various violations 'may' or 'could' cause negative consequences" and had not detailed any specific adverse impacts.[109]

In November, the U.S. District Court for the Northern District of California evaluated the FCA's materiality requirement in a government-intervened *qui tam* action involving the Medicare Advantage program.[110] The government alleged that the defendants violated the FCA by failing

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[105]*Id.* at 851.

[106]U.S. ex rel. Yu v. Grifols USA, LLC, 2022 WL 7785044 (2d Cir. Oct. 14, 2022).

[107]*Id.* at *3.

[108]*Id.* at *3.

[109]*Id.* at *4.

[110]U.S. ex rel. Osinek v. Permanente Med. Group, Inc., __ F.Supp.3d __, 2022 WL 16925963 (N.D. Cal. Nov. 14, 2022).

to comply with International Classification of Diseases (ICD) Guidelines after adding diagnosis codes unrelated to the patient visit. The defendants moved to dismiss the government's complaint, arguing that compliance with ICD guidelines was not material to payment. The district court disagreed and found materiality sufficiently pled. The court highlighted that CMS determines its payments based on the diagnosis codes the MA providers submit and that the defendants' internal documents emphasized the necessity of compliance with ICD Guidelines.[111]

Earlier in the year, the U.S. District Court for the Middle District of Louisiana found that a relator adequately pled materiality even while failing to allege instances where the government had denied claims for violations similar to those alleged in the *qui tam* complaint.[112] The relator alleged that the defendant hospitals violated the FCA by submitting claims for services performed by an advanced practice registered nurse who worked without a valid practice agreement or supervision. In denying the defendants' motion to dismiss, the court noted that the relator alleged that the defendants previously entered into a settlement agreement related to the same allegations with the State of Louisiana and that this "one instance of a Government enforcement action" constituted "strong support for the conclusion" that the practice agreement requirement was material.[113]

By contrast, in August, the U.S. District Court for the Western District of Missouri dismissed a *qui tam* complaint for failure to plead materiality where the relator alleged that the defendant committed various violations of Medicare marketing regulations.[114] In concluding that violation of these regulations was immaterial to CMS's payment decisions, the district court reasoned that CMS often imposed a range of intermediate sanctions for these regulatory violations, which did not involve payment recoupment or denial, and that the complaint failed to identify any instance in which CMS

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[111] *Id.* at *14-15.

[112] U.S. ex rel. Byrd v. Acadia Healthcare Co., 2022 WL 879492 (M.D. La. Mar. 23, 2022).

[113] *Id.* at *15.

[114] U.S. ex rel. Holt v. Medicare Medicaid Advisors, Inc., 2022 WL 3587358 (W.D. Mo. Aug. 22, 2022).

recouped payment based on the regulatory violations at issue.[115]

5. Knowledge/Scienter

Following its decision last year in *U.S. ex rel. Schutte v. SuperValu, Inc.*, this year in April the Seventh Circuit again affirmed a district court's grant of summary judgment in favor of a defendant in *U.S. ex rel. Proctor v. Safeway, Inc.*, applying the objective scienter standard from the Supreme Court's 2007 decision in *Safeco Insurance Co. v. Burr*.[116] Under *Safeco*'s standard, defendants do not act "knowingly" under the FCA if their interpretation of the relevant statute or regulation was objectively reasonable, even if mistaken, and "authoritative guidance" did not warn them away from their interpretation.[117] As the Seventh Circuit reiterated in its *Safeway* decision this year, when the objective scienter standard applies, "a defendant's subjective intent is irrelevant."[118]

The relator alleged that a defendant pharmacy chain falsely reported their "usual and customary" (U&C) prices to government healthcare programs by listing their retail cash prices as their U&C price, rather than lower prices provided to customers requesting a match of a competitor's price or who joined a membership discount club. The Seventh Circuit held that the relator could not establish scienter because it was objectively reasonable for the pharmacy chain to report its retail price as its U&C price and no authoritative guidance had warned it away from that interpretation.[119] In reaching the latter finding, the Seventh Circuit reasoned that a footnote in the CMS Manual was not authoritative guidance "[i]n light of the totality of the circumstances" surrounding that footnote—specifically, that it (1) was not binding on CMS, (2) could be revised at any time, (3) was not in a section of the manual directed at the disputed pharmacy

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[115] *Id.* at *7.

[116] U.S. ex rel. Proctor v. Safeway, Inc., 30 F.4th 649, 652-653 (7th Cir. 2022) (discussing U.S. ex rel. Schutte v. SuperValu, Inc., 9 F.4th 455 (7th Cir. 2021) and Safeco Ins. Co. v. Burr, 551 U.S. 47 (2007)).

[117] Proctor, 30 F.4th at 652-653.

[118] *Id.* at 658.

[119] *Id.* at 659-662.

programs, and (4) was removed from the manual by CMS during the relevant time without explanation.[120]

On January 13, 2023, the Supreme Court granted certiorari petitions filed by the relators in *SuperValu* and *Safeway*, indicating its intent to address the FCA's scienter requirement and the *Safeco*'s standard relation to it. The Supreme Court issued its opinion in both casesin June 2023.[121]

In April 2022, the Eleventh Circuit applied *Safeco*'s scienter standard at the pleading stage in dismissing FCA allegations.[122] There, the relator alleged that a seller of mail-order diabetic testing supplies violated Medicare rules requiring the seller to obtain signatures from patients on assignment of benefit forms before billing the government. Relying on *Safeco*, the Eleventh Circuit held that the relator failed to plead scienter because the defendant's interpretation of the Medicare rules was "objectively reasonable."[123]

The Fourth Circuit also evaluated *Safeco*'s standard at the pleading stage of an FCA case this year. In January, a divided panel of the Fourth Circuit held that the objective scienter standard from *Safeco* applied to the FCA's scienter element and affirmed a district court's order granting dismissal of the relator's complaint.[124] But, the Fourth Circuit later agreed to rehear the case en banc and vacated the panel's earlier opinion. In September, following its rehearing en banc, the Fourth Circuit issued a per curiam order, noting that the full appellate court was "equally divided" on the outcome and thus affirming the lower court's dismissal of the complaint, without any substantive opinion.[125]

In May, before the initial opinion in *Sheldon* was vacated, a divided panel on the Fourth Circuit relied on that precedent in affirming a district court's order granting summary

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[120]*Id.* at 662.

[121]U.S. ex rel. Schutte v. SuperValu, Inc., 143 S. Ct. 1391 (2023).

[122]Olhausen v. Arriva Medical, LLC., 2022 WL 1203023 (11th Cir. Apr. 22, 2022).

[123]*Id.* at *2.

[124]U.S. ex rel. Sheldon v. Allergan Sales, LLC, 24 F.4th 340 (4th Cir. 2022).

[125]U.S. ex rel. Sheldon v. Allergan Sales, LLC, 49 F.4th 873 (4th Cir. 2022).

judgment on scienter grounds in favor of the defendants.[126] The relator alleged that an operator of adult care homes and its facilities violated the FCA by submitting claims to Medicaid for personal care services that did not comply with a state clinical coverage policy. The Fourth Circuit held that the relator could not show scienter when the billing requirement was "ambiguous" and the defendant's "interpretation of the policy and agency guidance is reasonable."[127] The Fourth Circuit also observed that the relator failed to show any evidence that the defendant subjectively knew or even suspected that its interpretation of the billing requirement was incorrect.[128]

In June, the Fourth Circuit affirmed the dismissal of *qui tam* allegations for failure to plausibly plead scienter under Rule 8.[129] Recognizing that allegations of scienter need not satisfy the heightened pleading standard of Rule 9(b), the Fourth Circuit explained that allegations still must satisfy Rule 8's plausibility standard and that conclusory assertions are insufficient. The relator alleged that the defendant hospital billed the government for physician-level services provided by mid-level practitioners but "offer[ed] only bald and vague allegations" that the defendants knowingly made false records for the relator's medical care "through their shared ownership and control" and "direct or indirect contractual arrangements with" each other.[130] In dismissing the complaint, the Fourth Circuit underscored that it can disregard such conclusory assertions and that the relator's otherwise threadbare allegations fell short of meeting Rule 8(a)'s requirement.[131]

6. Public Disclosure Bar

Under the FCA's public disclosure bar, courts should dismiss *qui tam* claims that are "substantially the same" as

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[126]U.S. ex rel. Gugenheim v. Meridian Senior Living, LLC, 36 F.4th 173 (4th Cir. 2022).

[127]*Id*. at 181.

[128]*Id.*

[129]U.S. ex rel. Taylor v. Boyko, 39 F.4th 177 (4th Cir. 2022).

[130]*Id.* at 199.

[131]*Id.* at 199-200.

allegations that were previously disclosed to the public, unless the relator is an original source of the FCA allegations.[132] To constitute a "public disclosure," the FCA requires the information to be disclosed: "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party; (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or (iii) from the news media."[133] Courts this year continued to analyze each of those elements in applying the public disclosure bar in *qui tam* actions.

In June, the Fourth Circuit affirmed a district court's order ruling that the FCA's public disclosure bar did not foreclose a relator's *qui tam* action.[134] The defendants there argued that a 2013 investigation by the West Virginia Department of Health and Human Services at CMS's request publicly disclosed the basis of the relator's FCA claims. Agreeing with the lower court that the public disclosure did not apply, the Fourth Circuit held that nothing in the state investigation or the resulting report involved "substantially the same allegations or transactions" as the relator's present FCA allegations. The court explained that the investigation and report "focused entirely on asserted deficiencies in medical care" and that "[n]othing in the report or investigation touched on billing or alleged fraud."

In August, the Ninth Circuit ruled, as a matter of first impression, that a patent prosecution constitutes an "other Federal. . .hearing" under the public disclosure bar.[135] There, the relator alleged that the defendant pharmaceutical company "fraudulently obtained patents on two drugs to combat Alzheimer's disease and, by virtue of these fraudulent patents, prevented generic drug competitors from entering the market."[136] The defendant procured the patents through its participation in the *ex parte* administrative proceeding referred to as a patent prosecution. Although the government was not a "party" to the patent prosecutions, the Ninth Circuit found that immaterial, explaining that the

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[132]31 U.S.C. § 3730(e)(4)(A).

[133]*Id.*

[134]U.S. ex rel. Taylor v. Boyko, 39 F.4th 177 (4th Cir. 2022).

[135]U.S. ex rel. Silbersher v. Allergan, 46 F.4th 991 (9th Cir. 2022).

[136]*Id.* at 993.

government need not be a party to the "Federal report, hearing, audit, or investigation," which are focused more on collecting information and data, unlike an adversarial proceeding.[137] Because the relator's *qui tam* allegations were based on information disclosed in the patent prosecution process, the Ninth Circuit determined that his FCA claims were barred.[138]

In December, the Second Circuit evaluated whether a relator qualified as an "original source" under either the pre-ACA or post-ACA version of the FCA's public disclosure bar, as the relator alleged claims pre- and post-dating the ACA's enactment.[139] The relator alleged that the defendants engaged in a kickback scheme by acquiring controlling interests in dialysis clinics and paying the physician-owners of the clinics well-above fair market value to induce them to refer patients back to the clinics. One of the defendants previously disclosed information regarding several aspects of the transactions at issue.[140] In addressing the pre-ACA original source elements, the Second Circuit held that the relator did not have "direct and independent knowledge of the information on which the allegations are based" because the relator was an entity created solely for that litigation and obtained the information forming the basis of its complaint from a third party.[141] As to the post-ACA "original source" requirements under the FCA, the relator argued that it qualified as an original source because it acquired some additional information regarding one of the transactions "from an insider to [that] transaction."[142] The Second Circuit determined that this alleged "additional information" only provided "detail or color to previously disclosed elements of an alleged scheme," and thus the relator did not "materially

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[137]*Id.* at 998.

[138]*Id.*

[139]U.S. ex rel. CKD Project, LLC v. Fresenius Med. Holdings, Inc., 2022 WL 17818587 (2d Cir. Dec. 20, 2022).

[140]*Id.* at 1, 4.

[141]*Id.* at 3.

[142]*Id.* at 4.

add" to the publicly disclosed information to qualify as an original source.[143]

7. Relators—Retaliation

In August, the Seventh Circuit addressed what facts plaintiff-employees must allege, at the pleading stage, to show that they had an objectively reasonable belief that fraud on the government was occurring, and thus engaged in protected activity under the FCA's anti-retaliation provision, and whether that differs based on their position at the defendant-employer.[144] Three plaintiff-employees asserted FCA retaliation claims, alleging they were terminated after complaining that their employer violated Medicare debt collection regulations. The Seventh Circuit held that two of the plaintiffs sufficiently pled that they engaged in protected activity due to their managerial roles at their employer—specifically, a director supervising 12 employees and a manager in the legal and bad debt collections departments—and because they alleged how their employer violated the Medicare regulations and their direct, personal knowledge of the same.[145] The third plaintiff, however, failed to plead an objectively reasonable belief that her employer was causing the submission of false claims, according to the Seventh Circuit, as she was a lower-level, customer service representative who raised billing issues but did not allege how the practice was illegal or how any of her complaints involved claims submitted to the government.[146] As a result, the Seventh Circuit affirmed dismissal of the plaintiff's retaliation claim for failure to plead protected activity.

Also in August, the Eleventh Circuit affirmed summary judgment for a defendant-employer where the plaintiff, a physiatrist, was terminated after she complained that her employer was pushing physiatrists to bill for a diagnosis

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[143]*Id.*

[144]U.S. ex rel. Sibley v. Univ. of Chicago Med. Ctr., 44 F.4th 646 (7th Cir. 2022).

[145]*Id.* at 662-664.

[146]*Id.* at 664-665.

(disuse myopathy) that she viewed as illegitimate.[147] In finding that the plaintiff did not demonstrate she had an objectively reasonable belief that her employer was submitting false claims to the government, the Eleventh Circuit reasoned that she did not "establish[] that disuse myopathy is not a valid condition such that it is a false claim to submit billing based on it for government reimbursement."[148] The court also emphasized that the plaintiff herself had diagnosed patients with disuse myopathy and that she provided no evidence as to whether other doctors rendered such diagnoses for patients so that they could fraudulently receive government funds.[149] At bottom, the plaintiff offered nothing beyond her own medical opinion, which the Eleventh Circuit concluded was not enough to survive summary judgment.[150]

In November, in reversing a district court's order of dismissal, the Third Circuit addressed what a compliance officer plaintiff must plead to satisfy the notice element of an FCA retaliation claim.[151] The Third Circuit recognized that many courts require compliance officers (and employees with similar responsibilities) to act outside their job duties in order to provide an employer with sufficient notice of protected activity.[152] The plaintiff-compliance officer at issue alleged that he made several complaints about his employer falsely certifying compliance with safety standards to secure federal funds by emailing management and then alerting the company that hired his employer. The Third Circuit held that by alleging he went outside his normal chain of command and typical job responsibilities to inform management that his employer was in receipt of fraudulent government funds, the plaintiff had sufficiently pled that his employer was on notice of his protected activity.[153] The Third Circuit also referenced, as additional support, the compliance of-

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[147]Simon ex rel. Fla. Rehab. Assocs., PLLC v. Healthsouth of Sarasota Ltd. P'ship, 2022 WL 3910607 (11th Cir. Aug. 31, 2022).

[148]*Id.* at *7.

[149]*Id.*

[150]*Id.* at *7-8.

[151]U.S. ex rel. Ascolese v. Shoemaker Constr. Co., 55 F.4th 188 (3d Cir. 2022).

[152]*Id.* at 195.

[153]*Id.* at 196-197.

ficer's allegations that he made several external reports about his concerns and continued to do so, even after management expressly told him to "keep his concerns to himself and not relay them [externally]."[154]

In August, the Third Circuit analyzed how a plaintiff asserting an FCA retaliation claim must establish a causal connection between an adverse employment action and the protected activity.[155] If a plaintiff establishes a prima facie FCA retaliation claim—*i.e.*, the plaintiff engaged in protected activity and the employer knew of it and took adverse action as a result—the burden shifts to the employer to provide a legitimate, non-retaliatory reason for the adverse action. The plaintiff then can rebut that reason by demonstrating that it was pretext for retaliatory action.[156] In upholding the district court's grant of summary judgment, the Third Circuit ruled that the plaintiff had not established that the employer's rationale for his termination was pretextual, where the former employee claimed he was fired for reporting fraud a year earlier, and the defendants contended that they had fired him after an internal investigation confirmed he had mistreated a colleague.[157] In response to the relator's argument that the investigation's sloppiness demonstrated pretext, the Third Circuit explained that was not enough; the question was whether the investigation was a "sham" or a "façade" for pretext.[158] Regardless, the Third Circuit noted that "an investigation's quality or timing can support an inference of pretext only if those running the investigation know of the protected activity," which was not the case here.[159]

8. Healthcare Fraud—Criminal Enforcement

As it did the year prior, DOJ announced a COVID-19 Health Care Fraud Takedown in April 2022, in which it brought criminal charges against 21 defendants in nine

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[154] *Id.* at 196-197.

[155] Crosbie v. Highmark Inc., 47 F.4th 140 (3d Cir. 2022).

[156] *Id.* at 144.

[157] *Id.* at 145-146.

[158] *Id.* at 145.

[159] *Id.*

federal districts regarding $149 million in COVID-19 related false billing. The alleged schemes at issue included offering COVID-19 testing to induce patients to provide their personal identifying information and a saliva or blood sample for use in submitting false claims for unrelated, medically unnecessary, far more expensive tests or services.[160] In September 2022, the government obtained a conviction in a healthcare fraud criminal trial against a medical technology president who orchestrated a marketing scheme that made false claims about what Dr. Anthony Fauci and other government officials had mandated regarding COVID testing, and about the accuracy of his company's COVID-19 test.[161]

In May 2022, DOJ announced the results of its 2022 Opioid Enforcement Action directed by its Appalachian Regional Prescription Opioid (ARPO) Strike Force.[162] DOJ brought criminal charges in eight federal districts against 14 individuals, including 12 medical professionals, accused of the unlawful distribution of over 5.1 million opioid pills. Beyond the criminal charges, CMS's Center for Program Integrity took administrative actions against six providers for their role in these opioid allegations.

In July 2022, DOJ announced that it brought criminal charges against 38 defendants in 13 federal districts for more than $1.2 billion in alleged healthcare fraud, in what DOJ described as a "Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Du-

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[160]Press Release, U.S. Dept. of Justice, Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat Health Care-Related COVID-19 Fraud (Apr. 20, 2022), https://www.justice.gov/opa/pr/justice-department-announces-nationwide-coordinated-law-enforcement-action-combat-health-care.

[161]Press Release, U.S. Dept. of Justice, Medical Technology Company President Convicted in $77 Million COVID-19 and Allergy Testing Scheme, https://www.justice.gov/opa/pr/medical-technology-company-president-convicted-77-million-covid-19-and-allergy-testing-scheme.

[162]Press Release, U.S. Dept. of Justice, Justice Department Announces Enforcement Action Charging 12 Medical Professionals with Opioid Distribution Offenses (May 4, 2022), https://www.justice.gov/opa/pr/justice-department-announces-enforcement-action-charging-12-medical-professionals-opioid.

rable Medical Equipment Fraud."[163] The defendants included a telemedicine company executive, owners and executives of clinical laboratories, durable medical equipment companies, marketing organizations, and medical professionals. By far the largest portion of the fraud losses charged in connection with this coordinated action originated from telemedicine schemes, which accounted for more than $1 billion. DOJ also noted that the charges included "some of the first prosecutions in the nation" related to provider referrals for medically unnecessary cardiovascular genetic testing, which DOJ described as a "burgeoning" fraud scheme. Telemedicine companies allegedly arranged for medical professionals to order these expensive tests and DME regardless of patient need and without patient interaction. The government contended that many times the DME and test results were not given to the patients and were of no use to the patients' primary care doctors. The 2022 coordinated telemedicine enforcement action follows four prior similar nationwide actions targeting telemedicine schemes since 2019 and involving over $8 billion in fraud, according to the DOJ.

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[163]Press Release, U.S. Dept. of Justice, Justice Department Charges Dozens for $1.2 Billion in Health Care Fraud, https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud.