Healthcare Fraud and Abuse 2020 Update

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2021 Health Law Handbook

Pre-Publication Draft

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I. Introduction

Amidst the first significant public health emergency in the United States in our lifetimes, healthcare regulatory rules seemingly changed overnight and continuously evolved throughout the year. At the same time, after a few months of figuring out how to function in the new world order, regulatory agencies implemented significant changes to existing fraud and abuse laws as part of the administration's regulatory sprint to coordinated care and effort to realign pharmaceutical discounts to promote transparency. Despite the upheaval caused by the pandemic and circumstances unlike any other year in memory, it was essentially business as usual for government enforcement agencies in 2020. As in years past, this year brought a number of noteworthy False Claims Act (FCA) cases and settlements. In January 2021, the Department of Justice announced that it recovered $2.2 billion in FCA settlements and judgments, bringing its total recovery under the act to $64 billion since 1986.[2]

II. COVID-19 Public Health Emergency

In March 2020, as the number of confirmed cases of the novel coronavirus disease (COVID-19) grew in the United States, administrative agencies took steps on a national scale to ensure that adequate healthcare items and services were available to individuals. Emergency declarations made by U.S. Department of Health and Human Services (HHS) Secretary Alex Azar on January 31, 2020, and President Donald Trump on March 13, 2020 (and throughout the year), triggered an expansion of authority under which HHS became permitted to waive or modify certain requirements applicable to healthcare items and services furnished under the Medicare and Medicaid programs and the Children's Health Insurance Program (CHIP) pursuant to Section 1135 of the Social Security Act (1135 Waivers). Intended to temporarily ease regulatory constraints and reimbursement-related issues that might otherwise preclude or delay healthcare providers, practitioners and suppliers from effectively combating COVID-19 and caring for affected individuals, 1135 Waivers were used widely throughout 2020 despite many never having heard of them before providing flexibility on topics ranging from EMTALA to the federal physician self-referral law.[3] In addition, in March and April 2020, the HHS Office of Inspector General (OIG) issued two policy statements: (1) addressing the ability of physicians and other practitioners to reduce or waive patient cost-sharing amounts for telehealth services during the COVID-19 outbreak and (2) exercising enforcement discretion with respect to issues covered by blanket 1135 waivers.[4]

To quickly increase cash flowing to Medicare providers and suppliers impacted by COVID-19, CMS temporarily expanded its Accelerated and Advance Payment (AAP) Program. Funded by the Medicare trust funds, the accelerated and advance payments were loans that providers must pay back. In accordance with the Continuing Appropriations Act, 2021 and Other Extensions Act enacted on October 1, 2020, the timelines for repaying these funds were extended substantially. Many of these loans remain outstanding with repayment obligations beginning

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2 Press Release, U.S. Dept. of Justice, Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (January 14, 2021), https://www.justice.gov/opa/pr/justice-department-recovers-over-22-billion-false-claims-act-cases-fiscal-year-2020.

3 Bass Berry & Sims PLC, 1135 Waivers: HHS Authority to Alleviate Healthcare Regulatory Requirements During the COVID-19 National Emergency (Mar. 2020), https://www.bassberry.com/news/1135-waivers-hhs-alleviate-regulatory-requirements-covid-19/; Bass Berry & Sims PLC, CMS Rapidly Approves Section 1135 Waivers in Response to the COVID-19 Pandemic (Apr. 2020), https://www.bassberry.com/news/cms-section-1135-waivers-covid-19/.

4 OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID-19) Outbreak (Mar. 17, 2020), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf; OIG Policy Statement Regarding Application of Certain Administrative Enforcement Authorities Due to Declaration of Coronavirus Disease 2019 (COVID-19) Outbreak in the United States as a National Emergency (April 3, 2020), available at https://oig.hhs.gov/coronavirus/OIG-Policy-Statement-4.3.20.pdf.

one year after the payment was received. If not repaid, these loans could present program integrity risk and related sanctions.

As the weeks of the COVID-19 public health emergency turned into months, CMS issued a variety of interim final rules that added substantial flexibility to its regulations during the course of the public health emergency.[5] Among a host of other things, flexibilities included substantially expanding the ability and coverage for telemedicine and other telehealth services, adding coverage and reimbursement for COVID-19 testing, and allowing hospital care to be provided in new settings (*i.e.*, hospitals without walls).

Perhaps most notable from a potential fraud and abuse perspective, however, was the injection of billions of dollars in stimulus funding. Pursuant to the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), Paycheck Protection Program and Health Care Enhancement Act ("Enhancement Act"), and Consolidated Appropriations Act, 2021 ("2021 Appropriations Act"), Congress appropriated $178 billion to the U.S. Department of Health and Human Services' ("HHS") Public Health and Social Services Emergency Fund ("Provider Relief Fund") to reimburse eligible healthcare providers for lost revenues and increased expenses due to COVID-19 and to operate a reimbursement program to cover COVID-19-related testing and treatment for the uninsured.[6] Throughout 2020, and into 2021, HHS distributed these funds through a series of general distributions and targeted distributions. The targeted distributions generally focused on a particular subset of the industry, such as rural providers and skilled nursing facilities that were particularly impacted by the public health emergency.

Despite initially being touted as "no strings attached" funding, there are a number of terms and conditions that apply to the receipt and use of distributions from the Provider Relief Fund. While the precise terms and conditions of accepting Provider Relief Funds varied somewhat depending on the type of distribution, most generally include, among other things, that the recipient treated patients after January 31, 2020, that the funds will be used only to support COVID-19 attributable expenses and cover COVID-19 attributable losses, and will not be used to pay any individual at a rate above $197,300. In addition, the recipient agreed to comply with documentation and reporting requirements; agreed not to balance bill any out-of-network patient for COVID-19-related treatment; and certified that all information it provides is true, accurate and complete. Perhaps most notable for fraud and abuse purposes, however, is that the recipient was also required to acknowledge that any deliberate omission, misrepresentation or falsification of any information provided to HHS in relation to the HHS Provider Relief Fund may be punishable by criminal, civil or administrative penalties, including but not limited to revocation of Medicare billing privileges, exclusion from federal healthcare programs and/or the imposition of fines, civil damages, and/or imprisonment, as well as subject the recipient to potential False Claims Act liability, which can result in statutory penalties and tremble damages.

Curiously, just a couple of weeks after HHS distributed the first Provider Relief Funds, on April 24, 2020, the OIG published a proposed rule to update its enforcement authorities with respect to HHS grants, contracts and information blocking. While this proposed rule was not initiated by the public health emergency necessarily, it certainly seems broadly drafted to capture the misuse of Provider Relief Funds. The proposal, if finalized, will authorize the OIG to impose civil monetary penalties ("CMPs"), assessments, and exclusions upon individuals who commit fraud or other misconduct in connection with "a broad array of situations in which HHS provides funding, directly or indirectly, in whole or in part, pursuant to a grant, contract, or other agreement." [7] The proposed rule also expands the definition of obligation and adds new prohibitions that, if finalized, would arguably capture the failure to repay any Provider Relief Funds that should be returned to HHS. Commentators to the proposed rule raised concerns regarding the impact and timing of the proposed rule in light of the COVID-19

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5 *See e.g.*, CMS-9912 Interim Final Rule (Oct. 28, 2020), available at https://www.cms.gov/files/document/covid-vax-ifc-4.pdf; CMS-3401 Interim Final Rule (Aug. 25, 2020), available at https://www.cms.gov/files/document/covid-ifc-3-8-25-20.pdf; CMS-5531 Interim Final Rule (Apr. 30, 2020), available at https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf.

6 Coronavirus Aid, Relief, and Economic Security Act of 2020, Pub. L. No. 116-136, Division B; Paycheck Protection Program and Health Care Enhancement Act of 2020, Pub. L. No. 116-139, Division B; Consolidated Appropriations Act, 2021 and Other Extensions Act, H.R. 133, 116th Cong. (2020) (enacted).

7 85 Fed. Reg. 22979 (April 24, 2020), https://www.federalregister.gov/documents/2020/04/24/2020-08451/grants-contracts-and-other-agreements-fraud-and-abuse-information-blocking-office-of-inspector.

pandemic, noting that the potential for such sanctions is "especially daunting…where grant funding and related requirements" have been extremely complex and issued on a "very rapid and fluid basis."[8] Commentators are thus requesting that the OIG exercise its discretion to focus on parties who demonstrate a "true showing of bad intent" rather than applicants and recipients who make a good faith effort to comply with applicable guidance and/or terms or conditions. It is yet unknown whether the OIG will take the commentator's concerns into consideration in a final rule.

The commenters are right; the guidance related to the Provider Relief Funds evolved almost weekly since the first Provider Relief Funds were released, sometimes being directly inconsistent or completely reversing direction. HHS has stated informally that their initial goal was to distribute funds quickly to assist ailing businesses and support the healthcare infrastructure as they responded to COVID-19. However, it expected reviews and audits later would reconcile payments and uses of the funding. As a result, the Provider Relief Funds continue to retain a halo of uncertainty as the industry braces to handle 2021 reporting and auditing related to the funds.

Although fraud enforcement efforts related to COVID-19 relief funding remained in the early stages as the calendar flipped to 2021, the government has made clear its commitment to dedicate significant resources to such efforts in the coming months and years. The government has created two directives specifically to investigate potential pandemic-related fraud: the Pandemic Response Accountability Committee (PRAC) and the Special Inspector General for Pandemic Recovery (SIGPR). PRAC is an independent oversight committee within the Council of the Inspectors General on Integrity and Efficiency that is authorized to conduct its own investigations and audits, issue subpoenas for documents and testimony, and hold public hearings. The SIGPR is an Inspector General position created to oversee the spending of government funds in response to the COVID-19 pandemic. The SIGPR has subpoena power and has been instructed to conduct investigations and audits related to the CARES Act.

In addition to those specific directives, more traditional government enforcement bodies such as the Department of Justice (DOJ), Federal Bureau of Investigation (FBI), and the OIG each have indicated that pursuing fraud enforcement actions related to COVID-19 funding will be a priority moving forward. In March 2020, the then-Deputy Attorney General directed all U.S. Attorney Offices to designate a Coronavirus Coordinator who would serve as the legal counsel for the federal district on matters related to the coronavirus; prosecute or assist in prosecuting coronavirus-related cases; and conduct public outreach and awareness activities related to the coronavirus.[9]

When the government's COVID-19 funding enforcement efforts ramp up, they likely will find a very fertile enforcement environment in the healthcare industry. An unprecedented amount of funding was distributed in an extremely short period of time. Government guidance related to the funding has been consistently evolving and at times unclear, but retrospective scrutiny by the government is virtually certain. Healthcare providers and players in an already highly-regulated industry should expect intensified enforcement efforts on the horizon.

8 *See e.g.*, Comment of the Federation of American Hospitals (June 23, 2020).

9 Memorandum from the Deputy Attorney General, Mar. 19, 2020, available at https://www.justice.gov/file/1268521/download.

III. Regulatory Sprint: CMS and OIG Issue Final Rules

In a coordinated effort, on November 20, 2020, the CMS and the OIG published final rules to modernize regulations implementing the federal physician-self-referral law, commonly referred to as the "Stark Law" (Stark), the federal Anti-Kickback Statute (AKS), and the beneficiary inducement provisions of the Civil Monetary Penalties Law (CMP Law).[10] Part of HHS' regulatory sprint to coordinated care initiative, the final rules include new value-based care exceptions and safe harbors, changes to enable improvements in technology infrastructure, including a new cybersecurity safe harbor and exception, and a host of new rules, definition and clarifications aimed at modernizing the federal

With one exception, these final rules became effective **January 19, 2021**. The changes to the Stark group practice regulations at 42 CFR § 411.352(i) related to the distributions of profits will be effective **January 1, 2022**.

IV. AKS: Pharmaceutical Discounts and Pharmacy Benefit Manager Service Fees[11]

With the stated goal of furthering transparency in drug pricing and lowering drug prices, the OIG released a final rule in November 2020, to amend the AKS regulations related to pharmaceutical discounts, rebates and pharmacy benefit manager (PBM) fees.[12] Specifically, the final rule amended the discount safe harbor at 42 CFR § 1001.952(h) to exclude from the safe harbor rebates from drug manufacturers to Medicare Part D (Part D) plan sponsors, including those offered through PBMs, and to add two new safe harbors related to drug reimbursement:

1. A safe harbor to protect point-of-sale reductions from a drug manufacturer to a Part D or Medicaid Managed Care Organization (Medicaid MCO); and
2. A safe harbor to protect drug manufacturer payments to PBMs for PBM services.

The OIG stated that such changes will increase transparency by allowing patients to choose drugs that minimize their out-of-pocket costs, providing Part D plans with more insight into PBM negotiations and increasing program integrity. The effective date of the new safe harbors was **January 29, 2021**. In recognition of the necessary changes to current industry practices to implement the new rules, the effective date of the exclusion to the discount safe harbor is **January 1, 2022**.

DISCOUNTS SAFE HARBOR (42 CFR § 1001.952(H))

Generally, the AKS discount safe harbor at 42 CFR § 1001.952(h) protects discounts and rebates provided on items or services payable by federal healthcare programs if certain reporting requirements are met. The new changes categorically exclude rebates from drug manufacturers to Part D plan sponsors from allowable "discounts" under the safe harbor, except for such rebates required by law.

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10 85 Fed. Reg. 77492 (Dec. 2, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf (Stark); 85 Fed. Reg. 77684 (Dec. 2, 2020), https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf (AKS and CMP Law).

11 With permission, the material in this section is substantially based on information published by Bass Berry & Sims PLC in December 2020. The authors wish to thank Shannon Wiley and Maleaka Guice to the contributions to this summary.

12 85 Fed. Reg. 76666 (Nov. 30, 2020).

This new exclusion applies only to Part D plans and the PBMs administering such plans. The proposed rule contemplated excluding rebates to Medicaid MCOs. As finalized, however, rebates between drug manufacturers and Medicaid MCOs may continue to utilize the discount safe harbor, including discounts and rebates to Medicaid MCOs that are contingent on formulary placement. Additionally, rebates for drugs payable under Medicare Part B may still be protected under the discount safe harbor, if all safe harbor criteria are met.

In issuing the final rule, the OIG provided some insight into how other discount and rebate relationships between PBMs and drug manufacturers should be viewed under the AKS. The OIG explained that a manufacturer "rebate" to a PBM that is retained by the PBM and not passed to the health plan is not, and has never been, covered by the discount safe harbor. The OIG also warned that "swapping arrangements" – giving a discount on commercially insured products to incentivize referrals of federal healthcare program covered items and services – could violate the AKS, as well as discounts given to a pharmacy owned by a Part D plan sponsor or PBM to induce referrals for federal healthcare program business from that sponsor or PBM.

POINT-OF-SALE REDUCTIONS IN PRICE FOR PRESCRIPTION PHARMACEUTICAL PRODUCTS (42 CFR § 1001.952(CC))

The OIG implemented a new safe harbor protecting certain reductions in the price of pharmaceuticals offered by drug manufacturers and provided to Part D plan sponsors or Medicaid MCOs that are reflected at the point-of-sale. As such, rather than through rebates, drug manufacturers may issue price reductions through point-of-sale chargebacks to pharmacies or other mechanisms that allow the patient to receive a reduction in drug price at the time of dispensing. To utilize this safe harbor, the drug manufacturer and Part D plan sponsor, Medicaid MCO or PBM must meet three requirements and ensure the following conditions are met: (i) The reduction in price must be in writing and set out in advance of the first purchase that will reflect the reduced price; (ii) The full value of the reduction in price must be provided by the manufacturer to the dispensing pharmacy through point-of-sale chargebacks, unless provided as a rebate where required by law; and (iii) The reduction in price must be completely reflected in the price of the drug at dispensing.

In the final rule, point-of-sale chargebacks are defined as an amount "equal to the reduction in price agreed upon in writing between the plan sponsor under Part D, the Medicaid MCO, or a PBM acting under contract with either, and the manufacturer of the prescription pharmaceutical product." This definition is intended to protect pharmacies from dispensing drugs at a loss due to gaming of the system by entities that fail to pass through reductions.

As required under the new safe harbor, reductions in price must be reflected in full at the point-of-sale or, if earlier, at the pharmacy when patient cost-sharing amounts are determined. Any portion of the price reduction that is retained by the health plan sponsor or PBM will not be protected by the new safe harbor. Where a beneficiary is responsible for the entire amount under a deductible plan cost-sharing obligation, the beneficiary will pay the full discounted price of the drug, (*i.e.*, the drug's list price less the negotiated reduction in price). Accordingly, bundled arrangements where contingencies hinder application of the reduction at the point-of-sale will likely not qualify for safe harbor protection.

The OIG declined to define how this new point-of-sale chargeback system should be administered in order to allow the industry flexibility on structuring how the chargebacks will be implemented.

PBM SERVICE FEES (42 CFR § 1001.952(DD))

The OIG issued a new safe harbor for PBM service fees which protects fees paid by a drug manufacturer to a PBM for prescription benefit management services provided to the drug manufacturer related to the services the PBM provides to health plans. This safe harbor must meet five requirements, including for example, a signed written agreement that covers all of the services the PBM provides to the manufacturer.

The OIG declined to include a definition of "prescription benefit management services." Rather, in its commentary, the OIG provided a non-exhaustive list of services that may be considered prescription benefit management services, including contracting with a network of pharmacies; negotiating rebates and discount arrangements; developing and managing formularies, preferred drug lists and prior authorization programs; and controlling the costs of covered prescription drugs, among others. It is important to note that only services provided to drug manufacturers may be covered under the new PBM safe harbor and not services to the health plan. The services must be legitimate and cannot be duplicative of services the PBM provides to health plans for compensation.

As stated in the safe harbor, the PBM's compensation must be a fixed, flat fee, not based on a percentage of sales; and, it cannot be tied to volume or value of referrals. However, the OIG explained that per-unit-of-work fees may be allowed if they are fixed in advance, not based on the volume or value of federal healthcare business, and the unit-based compensation does not vary by volume during the course of the arrangement. For example, a payment of $x per unit of work could be protected by the safe harbor, but a payment of $x for the first 100 units of work and $x+1 for additional units would not be protected by the safe harbor.

Under the new safe harbor, PBMs must annually disclose to each health plan what services the PBM renders to manufacturers, and upon request, the PBM must disclose such services and the associated payment arrangement to the Secretary. The OIG acknowledged that when PBMs provide services to manufacturers for a fee, it can create tension between the PBM's obligations to the drug manufacturer and obligations to health plans. The OIG believes disclosure to health plans will increase transparency and help alleviate this tension.

V. OIG Advisory Opinions & Special Fraud Alerts

As if there were not enough going on in 2020 with the public health emergency, the regulatory sprint, and other new rules, the OIG Industry Guidance branch also released a special fraud alert and nine new advisory opinions in late 2019 and 2020.

SPECIAL FRAUD ALERT: SPEAKER PROGRAMS

On November 16, 2020, the OIG published a Special Fraud Alert highlighting the fraud and abuse risks inherent to speaker programs held and organized by pharmaceutical and medical device companies and signaling such programs (and speakers) may be subject to increased scrutiny.[13] The alert indicates that, in the last three years alone, Open Payments data shows physicians and other healthcare professionals (collectively, HCP) were paid nearly $2 billion for speaker-related services by drug and device companies. In the alert, the OIG points to numerous recent investigations involving allegations that drug and device companies organize and pay for speaker programs with the intent to induce HCPs to prescribe or order the companies' products. The OIG states that it has become skeptical about the educational value and intent of speaker programs, particularly those that include generous compensation to speak at programs that are not conducive to learning (*e.g.*, sports venues) or to speak to audience members who have no legitimate reason to attend. The OIG recognizes that there are many other ways for HCPs to obtain information about products and diseases that do not involve remuneration, such as online resources, package inserts, third-party educational conferences, and journals. The OIG provides an illustrative list of eight suspect characteristics, which together or separately, potentially indicate a problematic arrangement. For example, little or no substantive information is actually presented; the company sponsors a

13 OIG Special Fraud Alert: Speaker Programs (November 16, 2020), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf.

large number of programs on substantially the same product or topic, especially when there has been no substantive change in relevant information; HCPs attend programs on the same topics more than once; and, sales and marketing teams influence the selection of speakers.

OIG ADVISORY OPINION 19-06

On December 12, 2019, the OIG issued a positive advisory opinion regarding a supermarket's proposal to expand its current loyalty program to allow customers to earn rewards points on out-of-pocket costs paid in connection with purchases in its in-store pharmacies. As part of its loyalty program, the supermarket's customers are awarded one point for every $1 spent on purchases in the supermarket. The requestor proposed to allow customers to earn points for out-of-pocket expenditures made at the pharmacy (capped annually at the equivalent of $75 off purchases in the supermarket); points earned would not be redeemable at the pharmacy. Despite implicating both the Beneficiary Inducement provisions of the CMP and the AKS, the OIG concluded that the proposed expansion of the customer loyalty program would satisfy the CMP exception to the Beneficiary Inducements prohibition related to retailer rewards and posed a low risk of fraud and abuse under the AKS. In its analysis, the OIG focused on the following: the loyalty program being offered on equal terms to all customers regardless of their health insurance status; there was no tie to federally reimbursable items on the "redeeming" side of the transaction; the program was unlikely to steer beneficiaries to the requestor's supermarkets to purchase federally reimbursable items or services; and, it would be unlikely to increase costs to federal healthcare programs.

OIG ADVISORY OPINION 20-01

On January 13, 2020, the OIG issued a positive advisory opinion regarding a non-profit hospital's provision of discounted training to a fire department's personnel. As part of the hospital's community benefits program, the hospital offers a discount for training sessions that are in furtherance of its charitable mission. The Fire Department operates an emergency medical services (EMS) system, including an ambulance fleet. Although within the purview of the AKS, the OIG concluded that the arrangement presents a low risk of fraud and abuse. It explained that, first, the arrangement poses little risk of overutilization or increased costs to any Federal healthcare program, since neither the number of beneficiaries who receive EMS services nor the treatment they receive at a hospital is related to the existence of the arrangement. Second, several factors, in combination, sufficiently mitigate the risk that the Fire Department will steer patients to the hospital as a result of the arrangement (*e.g.*, objective protocols governing hospital-destination decisions; written agreement disclaims any referral requirements; discount not tied to volume or value or referrals). Third, the arrangement may benefit the community by improving the quality of EMS services. Finally, the remuneration (*i.e.*, the training facility discount) ultimately benefits the public, since the discount reduces the funds the city must allocate for clinical training of the fire department's personnel.

OIG ADVISORY OPINIONS 20-02

On January 15, 2020 the OIG issued a positive advisory opinion regarding financial assistance for travel, lodging, and other expenses provided by a pharmaceutical manufacturer to financially needy patients prescribed the manufacturer's drug. The drug is a personalized medicine made from the patient's own cells and is a one-time, potentially curative drug. Because of certain life-threatening risks, only physicians who agree to implement necessary safety protocols (that have been vetted by the FDA) may prescribe and administer the drug. Significantly, patients must remain within close proximity of the administering facility for at least four weeks after infusion for monitoring. The requesting manufacturer operates a program that assists eligible patients and caregivers with travel, lodging (if patient is not eligible to receive lodging from the treatment center), and certain out-of-pocket expenses (*e.g.*, meals, parking) during and after infusion. To be eligible for assistance, patients must: be prescribed the drug; have a household income not exceeding 600% of the Federal Poverty Level; live either two hours driving distance or 100 miles from the nearest infusion center; and lack insurance for non-emergency medical travel. The assistance is not advertised, and is offered to eligible patients regardless of their provider or insurance status. Patients must agree not to request reimbursement from federal healthcare programs for

costs covered under the arrangement, and the requesting manufacturer certified that it does not bill or shift the costs of the arrangement to federal healthcare programs.

Despite implicating the AKS and the Beneficiary Inducement provisions of the CMP, the OIG concluded that it presented low risk under the AKS and would qualify for the "promotes access to care" exception to the CMP law. It reasoned, among other things, that the FDA requires certain safety measures, including that patients remain in close proximity for monitoring, and that without the financial arrangement patients might not have access to this care. Although concerned about manufacturers limiting drug distribution networks, here the OIG recognized that the limited network is a function of meeting patient safety and FDA standards - the network is open to anyone willing to meet those standards. The OIG also pointed to the fact that the drug is a one-time, potentially curative treatment; the arrangement is unadvertised; and, patients must live a significant distance from the infusion center to be eligible for assistance.

OIG ADVISORY OPINION 20-03

On June 26, 2020, the OIG issued a positive advisory opinion regarding an arrangement under which a discount medical plan organization ("DMPO") pays chiropractors and chiropractic clinics a $5 fee for each new DMPO member referred by the chiropractor or chiropractic clinic. The requestor, a DMPO, contracts with any willing licensed chiropractors and chiropractic clinics who agree to reduce their fees for the DMPO's members. Participating chiropractors and chiropractic clinics do not pay a fee to participate but agree to discount their fee schedule rates by 10% to 50%. DMPO members pay an annual membership fee for access to the discounted rates. Medicare beneficiaries are permitted to use the DMPO only for non-covered services. Chiropractors may explain the DMPO's services and facilitate enrollment, but referring chiropractors are not required to take any action to facilitate enrollment. The fee is only paid for new initial memberships.

The OIG analyzed two streams of remuneration: the DMPO's $5 payments to chiropractors and the discounted rates offered by participating chiropractors through the DMPO, which allow the DMPO to earn membership fees. The OIG concluded that the $5 payments did not implicate the AKS because the payments reward referrals to the DMPO, and the DMPO does not furnish or arrange for the furnishing of federally reimbursable items or services. With regard to the discounted rates and membership fees, the OIG explains that the arrangement presented a low risk of fraud and abuse under the AKS for the following reasons: (1) the discounted rates apply only to services not covered by Medicare for Medicare patients (*i.e.*, channeling referrals of federal healthcare business is not a concern) and members are not required to use a particular chiropractor; (2) the DMPO markets its service to chiropractors and, because the DMPO contracts with any willing chiropractor, the membership may expand rather than limit a patient's access to chiropractors; and, (3) the DMPO serves essentially as an intermediary – it does not provide or bill for healthcare items or services.

OIG ADVISORY OPINION 20-04.

On July 21, 2020, the OIG issued a positive advisory opinion regarding a charitable organization's proposal to purchase or receive donations of unpaid medical debt owed by qualifying patients from certain types of healthcare providers and then forgive that debt. The requestor is a 501(c)(3) charitable organization that locates, buys, and forgives individual patients' medical debt using an objective, anonymous process based on financial need. The requestor's donors may make certain broad requests for debt forgiveness (*e.g.* medical debt in connection with patients who are veterans or children) but may not otherwise direct the debt forgiveness or its terms. The requestor has historically purchased debt through arms-length transactions with debt purchasing companies, and now proposes to purchase or receive donations of inpatient and outpatient debt directly from hospitals and certain other providers that such provider has already attempted and failed to collect. As a condition of participation, neither the provider nor the charitable organization would publicize the arrangement. In addition, if the provider is a hospital, the requestor would require the hospital to agree to offset the proceeds of any sale of Medicare bad debt against the hospital's reimbursable Medicare bad debt expenses.

The OIG concluded that it would not impose sanctions under the CMP and that the proposal was sufficiently low risk under the AKS. The OIG reasoned, among other things, that neither the debt forgiveness nor the cost sharing waiver, if any, would be routine – conducted only after attempting to collect and an individualized determination of financial need. In addition, the arrangement would not be publicized, limiting providers' ability to use the program as a tool to generate future business and, because providers would attempt to collect first, the arrangement should not lead to increased costs to Federal healthcare programs. The OIG also noted that donors would have only limited control over how their donations are used to forgive medical debt.

OIG ADVISORY OPINION 20-05

On September 18, 2020, the OIG issued a negative advisory opinion regarding a pharmaceutical manufacturer's proposal to provide cost-sharing assistance directly to Medicare beneficiaries who are prescribed either of two formulations of its drug used to treat a progressive, rare disease. The drug, list price of $225,000 a year, is the only FDA-approved treatment for the disease and alternatives are limited. The manufacturer proposed to offer a subsidy program for Part D enrolled Medicare beneficiaries who meet financial criteria pursuant to which the eligible beneficiaries would pay a small monthly copayment each time they filled a prescription for the drug and the manufacturer would pay all of the beneficiary's remaining cost-sharing obligations for its drugs.

The OIG was seemingly swayed by publicly available information, including a 2020 study indicating that the manufacturer's drugs were the most expensive cardiovascular drugs ever launched in the United States and a commentary co-authored by an investigator in the drugs' phase 3 clinical trial criticizing the drugs' pricing, and recent enforcement history involving pharmaceutical manufacturers and foundations that operate assistance programs. The OIG concluded that the subsidy program posed more than a minimal risk under the AKS reasoning, among other things, that the subsidy program could improperly increase costs to the Medicare program by virtually eliminating the beneficiary cost-sharing requirement. The OIG also observed a risk of patient steering by potentially inappropriately diverting many beneficiaries from any other treatment option – available now or in the future; and, a risk that the subsidy program could potentially affect clinical decision-making because some, if not most, physicians would consider a patient's out-of-pocket costs for a drug when deciding on a treatment option.

OIG ADVISORY OPINION 20-06

On December 23, 2020, the OIG issued a positive advisory opinion regarding a management company's provision of Medicaid enrollment application assistance services to incoming patients of skilled nursing facilities (SNF) and a home health agency (HHA), with which the management company is affiliated, for a fee below fair market value. The affiliated SNFs and HHA would refer individuals that have selected the SNF but not yet began receiving services to the management company for enrollment assistance services; and in return, the individuals or the SNF on the individual's behalf, would pay the management company the below fair market value fee.

The OIG concluded that the services would satisfy the CMP exception to the Beneficiary Inducements prohibition related to remuneration that promotes access to care and would pose a low risk of fraud and abuse under the AKS. In its CMP analysis, the OIG recognized that the Medicaid enrollment assistance would provide individuals who might struggle with the Medicaid application with an opportunity to obtain coverage and services through Medicaid. Further, the OIG considered factors indicating that the arrangement posed a low risk of harm to patients, such as the unlikeliness that the services would skew clinical decision-making, increase costs to Federal healthcare programs or beneficiaries, or raise patient safety or quality-of-care concerns. Also, while the SNFs received some Federal reimbursement as a result of listing the services in their annual cost reports, OIG accepted that the amount received per patient was de minimis. The OIG pointed to some of these same facts in its AKS analysis and also emphasized that, under the arrangement, services were offered only to individuals who had already selected a SNF or HHA for healthcare services, and advertising would be limited.

OIG ADVISORY OPINION 20-07

On December 28, 2020, the OIG issued a positive advisory opinion regarding a web-based platform where healthcare facilities and clinicians would remit to patients and the patients' payors a portion of the claims for certain services for which payment may be made by the Medicare program as a secondary payor. The requestor operates a platform from which providers may offer remittances (effectively rebates) to patients and their third-party payors upon the claims meeting certain hassle-free processing and prompt payment requirements. The requestor proposed establishing a platform pathway exclusively for patients who have Medicare as a secondary payor through which: (i) providers could offer remittances to such patients and their third-party payors for care that is potentially payable by the Medicare program as a secondary payor; and (ii) patients could enter into agreements with providers, where the patients and their third-party payors could receive a portion of the remittances from providers. After analyzing each remuneration stream, the OIG concluded the arrangement would present minimal risk of fraud and abuse under the AKS and it would not impose sanctions under the CMP Law. In coming to those conclusions, the OIG focused on five factors. First, it determined that the risk of increased federal costs from overutilization was low because of various safeguards including written disclosure of the remittances to payors. Second, the requestor would only be compensated with a percentage of the remittances given to patients, thereby reducing the potential for overutilization because the provider could, without feeling pressure, change its mind about the appropriate service for the patient. Third, the remittance methodologies minimized the incentive for providers to increase prices because it was either based on the payor contracted amount or a flat fee. Fourth, the risk of anti-competitive effects was minimized by the accessibility of the platform for providers without charge and the transparency the platform offered patients. Finally, the requestor certified that it would not steer patients to certain providers through such mechanisms as prioritizing patient search results on the platform.

OIG ADVISORY OPINION 20-08

On December 30, 2020, the OIG issued a positive advisory opinion regarding a federally qualified health center's (FQHC) proposal to offer gift cards to incentivize certain pediatric patients to attend rescheduled preventive and early intervention care appointments. The FQHC proposed to contact patients under the age of 19 who had missed two or more previously scheduled preventive and early intervention care appointments, notify the patients of an opportunity to receive a $20 gift card upon rescheduling and attending their appointment, and furnish the gift card at checkout after eligible patients attend their rescheduled appointment. More than 96% of the FQHC's patients report incomes below 200% of the federal poverty level, but the gift cards would be issued irrespective of insurance status or ability to pay.

The OIG concluded that it would exercise its discretion to not impose sanctions under either the AKS or the CMP Law. Notably, the arrangement did not qualify for either the "promotes access to care" exception or the "preventative care" exception to the beneficiary inducement prohibition. Nonetheless, the OIG specified four reasons for its positive conclusion. First, the OIG believed that the risk of patient steering was low because only patients with a preexisting relationship with the requestor would qualify for the gift cards. Second, the OIG concluded that any increase in federal costs resulting from the proposed program would be appropriate utilization. Third, the OIG estimated that the proposed program would be unlikely to harm competition because of the modest value of the gift cards, the limited outreach to a defined category of existing patients, and the lack of any advertisement of the proposed program. Fourth, the OIG believed that the proposed program was reasonably tailored to accomplish the goal of improving appointment attendance rates because of policies proposed by the requestor, such as an eligibility verification process.

OIG ADVISORY OPINION 20-09

Similar to OIG Advisory Opinion 20-02, on December 28, 2020, the OIG analyzed an arrangement in which a requester assisted eligible patients and one caregiver with travel, hotel lodging, and certain out-of-pocket expenses that are incurred during leukapheresis, chemotherapy, infusion and monitoring. Although the

arrangement could potentially generate prohibited remuneration under the AKS, the OIG concluded it would not impose administrative sanctions based on the following factors (among others): (i) the remuneration is intended to assist indigent and rural patients stay in proximity to a center for drug treatment; (ii) the modest lodging provided by the requestor enables physicians to meet the FDA requirements in the drug's prescribing information and mitigate patient harm from potentially lethal drug side effects.; (iii) the drug's safety risks, and the requestor's assurance that any facility that meets all REMS requirements and the requestor's uniform criteria may participate in the arrangement, limit the likelihood that the requestor uses the arrangement to reward a limited number of prescribers who prescribe and administer its drug; (iv) the drug is a treatment of last resort and is a one-time, potentially curative treatment, so the arrangement does not pose a risk of inducing patients to continue purchasing the drug when it would be payable by a Federal health program. In addition, the arrangement is not advertised, reducing the likelihood that the arrangement serves as a marketing tool to drive patients to the requestor's drug; and the assistance does not duplicate other charitable assistance, as patients cannot receive lodging under the arrangement if they are eligible for other free lodging from a center.

VI. Federal Healthcare Program Anti-Kickback Statute—Key Court Decisions

In April, the Seventh Circuit reversed the trial court's entry of judgment in favor of defendant home healthcare companies facing AKS violations, finding that the court had applied too narrow an understanding of the term "refer" when analyzing a management services agreement the companies had entered with a third party non-profit providing in-home assessments of low-income seniors.[14] The evidence at trial showed that the defendants made monthly payments to the non-profit, which gave them access to client records containing information the defendants then used to solicit the clients.[15] Following a bench trial, the district court entered judgment for the defendant, finding that no AKS violations had been proven.[16] In reversing, the Seventh Circuit explained that a referral under the AKS broadly captures both direct and indirect means of connecting a patient with a provider and "goes beyond explicit recommendations to include more subtle arrangements."[17] The Seventh Circuit remanded the case to the district court to apply that broad understanding of the term "refer" to the management services agreement.[18]

In August, the Northern District of California denied a laboratory company's motion to dismiss FCA claims predicated on two allegedly illegal kickback schemes: (1) a "processing fee scheme" where the defendant entered into phlebotomy contracts with physicians' families and staff members that included processing, handling, and collection fees well above FMV for laboratory tests that were often not medically reasonable or necessary and performed by non-phlebotomists; and (2) a "waiver scheme" under which the defendant agreed to cap private pay patients' cost-sharing amounts at $25 and not to send any patients to collections.[19] Regarding the "processing fee scheme," the district court rejected the defendant's argument that its fees covered a "panoply" of services other than the blood draw and collection, reasoning it was inappropriate on a motion to dismiss to consider evidence to contradict the relators' allegations. The district court highlighted factors that raised the risk of the arrangements, including that payments were made on a per-specimen basis (even where multiple specimens

14 U.S. ex rel. Stop Ill. Health Care Fraud, LLC v. Sayeed, 957 F.3d 743 (7th Cir. 2020).

15 957 F.3d at 746.

16 957 F.3d at 747-748.

17 957 F.3d at 747-750.

18 957 F.3d at 751.

19 U.S. ex rel. STF, LLC v. Vibrant America, LLC, 2020 WL 4818706 (N.D. Ca. Aug. 19, 2020).

were collected during a single patient encounter) and that the defendant made payments directly to the contracting family and staff members, rather than their practice, leaving the practices to bear the costs of the services while the family and staff reaped the benefits of the arrangement.[20] For the "waiver scheme," the district court dismissed the argument that the cost-sharing waivers did not violate the AKS because they were given to private, rather than federal healthcare program, beneficiaries. The district court reasoned that because "physicians typically wish to minimize the number of laboratories to which they refer for reasons of convenience and administrative efficiency," the waivers could have been intended to influence physician referrals of federal healthcare program business.[21] The district court also declined to require the relator to establish the waivers were not based on financial hardship, emphasizing the relevant inquiry is whether *one purpose* of the remuneration was to induce or reward federal healthcare program referrals.[22]

In October, the First Circuit upheld the criminal conviction of a physician accused of receiving kickbacks from a pharmaceutical company in exchange for prescribing the company's synthetic opioid Subsys.[23] The court sustained the conviction on appeal, finding that the government met its burden to prove that the physician's conduct fell outside the AKS's personal services safe harbor provision.[24] The physician was among the top five prescribers of Subsys nationwide, and received nearly $50,000 in speaking fees over the course of a year for participating in a purported educational program by the pharmaceutical company.[25] Evidence showed, however, that the speaking events were often sham meetings with no attendees, and that the physician forged names on sign-in sheets to make the events appear legitimate.[26]

In November, the Eleventh Circuit upheld the criminal conviction of a podiatrist accused of writing prescriptions to expensive compound drugs in exchange for monthly $5,000 payments, which were disguised as sham medical director and speaker fees.[27] The appeals court found the district court erred by instructing the jury it had to find that *one* reason the podiatrist accepted the payments was in return for writing prescriptions.[28] That is because the AKS requires no proof of the defendant's motivation for accepting the payment; liability attaches so long as the defendant knowingly and willfully accepted the kickback.[29] Despite the erroneous instruction, the court upheld the conviction, reasoning that the error was harmless because the government proved more than required under the statute.[30]

In November, the Northern District of Illinois denied motions for summary judgment by the relator and the defendant in a case involving allegations that a revenue cycle management (RCM) services vendor caused hospitals to submit false claims by recommending the hospitals "upgrade" certain admissions from outpatient or observation to inpatient to collect higher Medicare reimbursement.[31] The relator alleged that the fee paid to the defendant RCM vendor was a kickback under the AKS, as the defendant was paid to refer or recommend patients to be classified as inpatients where not medically supported. The district court denied the defendant's motion for summary judgment, finding there was sufficient evidence to support the relator's claim that the defendant's determinations of inpatient status were motivated by a desire to increase Medicare reimbursement for its hospital clients.[32] For instance, defendant's marketing materials emphasized the return on investment hospital clients could make for using its services. The court also denied the relator's motion for partial summary

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20 2020 WL 4818706 at *11-14.
21 2020 WL 4818706 at *14-15.
22 2020 WL 4818706 at *16.
23 United States v. Clough, 978 F.3d 810 (1st Cir. 2020).
24 978 F.3d at 822.
25 978 F.3d at 812, 815.
26 978 F.3d at 815.
27 United States v. Shah, 981 F.3d 920 (11th Cir. 2020).
28 981 F.3d at 922.
29 981 F.3d at 925-926.
30 981 F.3d at 926.
31 U.S. ex rel. Graziosi v. R1 RCM Inc., 2020 WL 7025082 (N.D. Ill. Nov. 30, 2020).
32 2020 WL 7025082 at *14.

judgment that defendant's contracts with hospitals and hospital systems violated the AKS as a matter of law, finding material factual disputes and inferences as to relator's claims.[33]

VII. Federal Healthcare Program Anti-Kickback Statute and Stark Law—Key Settlements

In January, an electronic health records vendor agreed to pay a $145 million settlement, resolving criminal and civil AKS investigations regarding the company's software.[34] The government alleged that in exchange for "sponsorship" payments from opioid manufacturers, the EHR vendor programmed its software to provide clinical decision support alerts to healthcare providers. These alerts, the government alleged, were designed with input from pharmaceutical manufacturers, did not always reflect accepted medical standards, and caused doctors to prescribe more of the manufacturers' opioids.

In February, a regional medical center agreed to pay $4.1 million to settle allegations that it provided excessive compensation, bonuses, perks, and other benefits to its employed physicians in exchange for their referrals.[35] The relator, a former executive at the medical center, claimed the center knowingly tolerated large losses in physician practices due to the excessive incomes paid to the physicians, which could only be justified by the downstream revenue generated by the physicians' referrals.

In April, a Virginia hospital system and a physician practice group agreed to pay $9.3 million to settle claims that they had entered into improper financial arrangements.[36] The underlying *qui tam* case was filed by a doctor formerly with the group, who claimed that the hospital system and the group were working together to improperly classify expenses, so that the hospital could channel money to the group through a lucrative recruiting agreement which guaranteed the relator's salary and his associated practice expenses. The case settled after a nearly three-year investigation.

In July, an Oklahoma specialty hospital agreed to pay $72.3 million to resolve allegations that between 2006 and 2018, the hospital and its part-owner and management company provided improper remuneration to certain physicians in exchange for patient referrals in the form of: (1) free or below-fair market value office space, employees and supplies; (2) compensation in excess of fair market value for their services; (3) equity buyback provisions and payments for certain physicians that exceeded fair market value; and (4) preferential investment opportunities in connection with the provision of anesthesia services at the hospital.[37]

In July, a pharmaceutical company agreed to pay over $642 million to resolve allegations that it violated the FCA by paying kickbacks to Medicare patients and doctors.[38] The government alleged that the drug company

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33 2020 WL 7025082 at *8-9.

34 Press Release, U.S. Dept. of Justice, Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations (January 27, 2020), https://www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0.

35 Press Release, U.S. Dept. of Justice, Cookeville Hospital Settles False Claims Act Allegations (February 14, 2020), https://www.justice.gov/usao-mdtn/pr/cookeville-hospital-settles-false-claims-act-allegations.

36 Press Release, U.S. Dept. of Justice, Centra Health Inc. and Blue Ridge Ear, Nose, Throat, and Plastic Surgery, Inc. Agree to Pay Nearly $10 Million to Settle False Claims Act Allegations (April 22, 2020), https://www.justice.gov/usao-wdva/pr/centra-health-inc-and-blue-ridge-ear-nose-throat-and-plastic-surgery-inc-agree-pay.

37 Press Release, U.S. Dept. of Justice, Oklahoma City Hospital, Management Company, And Physician Group To Pay $72.3 Million To Settle Federal and State False Claims Act Allegations Arising From Improper Payments To Referring Physicians (July 8, 2020), https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal.

38 Press Release, U.S. Dept. of Justice, Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians (July 1, 2020), https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians.

made payments to foundations providing copay assistance to Medicare patients in ways that ensured the copay assistance disproportionally assisted patients taking the company's drugs. The government also alleged that the drug company paid sham honoraria to physicians speaking at the company's educational events. In reality, the government alleged, the events were simply social gatherings, and some did not even take place. According to the government, these payments were bribes to induce the physicians to prescribe the company's drugs.

Likewise, in September, a pharmaceutical company agreed to pay $97 million to resolve allegations that it used a foundation to pay copays for Medicare patients taking the pulmonary arterial hypertension drug Letairis.[39] The government alleged that pharmaceutical company used data from the foundation it should not have and set up a fund to cover co-pays of just its own drug. The government also alleged that the company referred Medicare patients to the foundation to induce purchases of Letairis.

In August, a specialty pharmacy agreed to pay $3.5 million to settle allegations that the pharmacy facilitated kickback payments from a pharmaceutical manufacturer to Medicare patients taking Copaxone, a multiple sclerosis drug.[40] The patients received funding to cover their Medicare co-payments from two foundations. The specialty pharmacy is a contracted vendor for the drug manufacturer of Copaxone and allegedly provided the manufacturer with data regarding the foundations' payments to Copaxone patients, so the manufacturer could make corresponding payments to the foundations. When the foundations lacked funding, the specialty pharmacy notified the drug manufacturer of the number of Copaxone patients awaiting assistance, which the drug manufacturer used to determine its next payment to the foundations. The government accused ACS of knowingly enabling Teva to disguise kickbacks as charitable contributions.

In September, DOJ announced a $50 million settlement with West Virginia acute care hospital Wheeling Hospital Inc., to resolve claims that Wheeling violated the FCA, AKS, and Stark law. The government alleged that from 2007 to 2020, Wheeling, through its prior management company, paid compensation to referring physicians based on the volume or value of the physicians' referrals or that was above fair market value.[41]

In October, DOJ announced that a medical device maker agreed to pay $18 million to resolve allegations that it violated the FCA by paying illegal kickbacks to physicians.[42] The government alleged that the device maker engaged in a multi-year kickback scheme to provide free advertising and practice development services and unrestricted "educational" grants to physicians, medical practices, and hospitals to induce the use of its products. The government alleged that the company ignored numerous warnings against its conduct, including from the company's chief compliance officer.

In December, a partially physician-owned hospital agreed to pay $48 million to resolve allegations that it violated the Stark Law and AKS by requiring physician owners to meet a patient-contact requirement to maintain their ownership stakes. According to the government, the patient-contact requirement was in fact intended to induce referrals and generate business for the hospital.[43]

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39 Press Release, U.S. Dept. of Justice, Gilead Agrees To Pay $97 Million To Resolve Alleged False Claims Act Liability For Paying Kickbacks (September 23, 2020), https://www.justice.gov/opa/pr/gilead-agrees-pay-97-million-resolve-alleged-false-claims-act-liability-paying-kickbacks.

40 Press Release, U.S. Dept. of Justice, Specialty Pharmacy Advanced Care Scripts Agrees to Pay $3.5 Million to Resolve Allegations that it Served as a Kickback Conduit (August 13, 2020), https://www.justice.gov/usao-ma/pr/specialty-pharmacy-advanced-care-scripts-agrees-pay-35-million-resolve-allegations-it.

41 Press Release, U.S. Dept. of Justice, West Virginia Hospital Agrees To Pay $50 Million To Settle Allegations Concerning Improper Compensation To Referring Physicians (September 9, 2020), https://www.justice.gov/opa/pr/west-virginia-hospital-agrees-pay-50-million-settle-allegations-concerning-improper.

42 Press Release, U.S. Dept. of Justice, Medical Device Maker Merit Medical To Pay $18 Million To Settle Allegations Of Improper Payments To Physicians (October 14, 2020), https://www.justice.gov/opa/pr/medical-device-maker-merit-medical-pay-18-million-settle-allegations-improper-payments.

43 Press Release, U.S. Dept. of Justice, Texas Heart Hospital and Wholly-Owned Subsidiary THHBP Management Company LLC to Pay $48 Million to Settle False Claims Act Allegations Related to Alleged Kickbacks (December 18, 2020), https://www.justice.gov/opa/pr/texas-heart-hospital-and-wholly-owned-subsidiary-thhbp-management-company-llc-pay-48-million.

VIII. False Claims Act Developments

1. DOJ DISMISSAL OF CASES

Following issuance of the Granston Memo in January 2018, the increasing frequency of the government's requests to dismiss *qui tam* actions pursuant to its authority under § 3730(c)(2)(A)[44] has brought renewed attention to a long-existing circuit split concerning the appropriate standard by which to judge such a request. This split centers on whether the government's dismissal authority under the FCA is "unfettered" and thus not subject to judicial review, or instead is contingent upon the government demonstrating that its dismissal request bears a "rational relationship" to a valid government interest.

In April, the U.S. Supreme Court denied certiorari in a case seeking to resolve the split.[45] The D.C. Circuit had affirmed dismissal of the case under the "unfettered right" standard, and the petitioner filed for certiorari asking the Court to adopt the stricter "rational relationship" test, but the Court's cert denial left both the D.C. Circuit's ruling and the circuit split in place. Later, in August, the Seventh Circuit added a third standard, tracking the statutory language and holding that the government may dismiss a *qui tam* lawsuit without the relator's consent if the relator is given notice and an opportunity to be heard.[46]

2. PLEADING SUBMISSION OF CLAIMS

In 2020, courts continued to wrestle with the requirements for sufficiently pleading the submission of false claims and under what circumstances a relator might not need to identify a representative false claim to satisfy Rule 9(b). Some jurisdictions continued to contemplate a more relaxed standard that would allow relators to satisfy their pleading obligations by providing indicia of reliability leading to a strong inference that false claims were submitted to the government. However, even in these jurisdictions, courts applied this standard stringently, often requiring relators to allege details of a scheme to submit false claims and details regarding defendants' billing practices in order to satisfy the somewhat relaxed standard.

In a significant ruling in June, the Eighth Circuit affirmed dismissal with prejudice of a *qui tam* action that alleged FCA violations predicated on compensation arrangements between a health system and some of its physicians violating the AKS and Stark Law.[47] The relator, a former surgeon at one of the system's hospitals, argued on appeal that because approximately 29% of the defendant's revenue came from Medicare reimbursements, and any claims submitted by particular surgeons were tainted by AKS and Stark violations, it was more likely than not that the defendant submitted tainted claims for payment to the government. Although Eighth Circuit precedent permits a relator to satisfy the presentment element by pleading details of a scheme paired with "reliable indicia that lead to a strong inference that claims were actually submitted," the court held that the relator's "general inference" was not sufficient without pleading firsthand knowledge and details of the defendant's billing practices. The court rejected the relator's argument that under this rule only billing department or financial services employees could ever serve as relators, reasoning that although an insider may have an easier time obtaining information about billing practices and satisfying this pleading requirement, nothing "precluded others with reliable allegations from serving as relators."

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44 This statute allows the government to dismiss a relator's *qui tam* complaint over the relator's objection if the relator is provided notice and an opportunity for a hearing.

45 U.S. ex rel. Schneider v. JPMorgan Chase NA, No. 19-678 (U.S.).

46 U.S. ex rel. Cimznhca, LLC v. UCB, Inc., 970 F.3d 835, 850 (7th Cir. 2020).

47 U.S. ex rel. Benaissa v. Trinity Health, 963 F.3d 733 (8th Cir. 2020).

In March, the District Court for the District of South Carolina dismissed with prejudice a *qui tam* action alleging a wholesale pharmacy filled prescriptions with less-expensive generic medications while billing for more-expensive alternative medications.[48] In the Fourth Circuit, a relator can sufficiently plead submission of false claims either by pleading the details of specific claims presented or by alleging a scheme that necessarily led to the submission of false claims. The district court held that the complaint did neither because the relator did not "connect the dots" between the pharmacy's alleged conduct and any payment by the government.[49] The relator failed to plead details about the claims submission process, and the pharmacy's use of intermediary entities to submit claims left open the possibility that false claims were never submitted at all.[50]

In April, the District Court for the Eastern District of California applied Ninth Circuit precedent to dismiss a relator's claims that a defendant pharmaceutical company paid physicians kickbacks disguised as meals, speaker fees, and travel expenses in exchange for prescribing the defendant's medication, holding the relator's allegations did not satisfy Rule 9(b).[51] The relator failed to identify any claims that were submitted pursuant to the defendant's alleged scheme, but argued that a sales spreadsheet tracking Medicare and Medicaid patients for the purpose of evaluating the defendant's success at getting the drug on hospital formularies set forth reliable indicia to support an inference that claims for the drug were actually submitted to the government for payment.[52] The court rejected this argument, commenting that inclusion on a hospital's formulary does not speak at all to whether claims for payment were submitted.[53]

In May, the Fifth Circuit rejected a relator's attempt to rely on a statistical likelihood that a defendant submitted false claims for payment.[54] The court affirmed dismissal of allegations that the defendant health system pressured physicians to inflate patients' DRG codes in order to increase reimbursements. The relator, a data analytics company, based its allegations, in part, on an analysis of the defendant's inpatient claims data, arguing that the data indicated the defendant was documenting complications and comorbidities at higher rates than the national average.[55] The Fifth Circuit held that these statistics-based allegations did not plead the submission of false claims with sufficient particularity under Rule 9(b)—while the statistical allegations could be consistent with a fraudulent upcoding scheme, the trends could also indicate the health system was just better at implementing CMS's new guidelines for complete documentation than its peers.[56] Likewise, allegations that the defendant pressured physicians to upcode DRGs could also be considered "entirely consistent" with or "encouraged" by the new rules.[57] Additional allegations that a former coder was pressured to "code unethically" were not enough to save the claims, with the Fifth Circuit finding these allegations too vague to satisfy Rule 9(b).[58]

The Eleventh Circuit also requires "indicia of reliability" to support allegations that actual claims were submitted for payment in order to avoid dismissal. In August, the District Court for the Southern District of Florida held that the relator failed to plead with particularity his claims that a medical supply company sent patients supplies without properly signed forms and did not disclose locations that required independent accreditation and supplier numbers when it applied for and executed Medicare contracts.[59] Despite the relator touting his status as a

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48 U.S. ex rel. McClain v. Nutritional Support Servs., L.P., 2020 WL 2464655 (D.S.C. Mar. 16, 2020).

49 2020 WL 2464655, at *5.

50 2020 WL 2464655, at *5.

51 U.S. ex rel. Solis v. Millennium Pharm., Inc., 445 F. Supp. 3d 786 (E.D. Cal. 2020), appeal filed sub nom. Solis v. Millennium Pharm., Inc., 20-15863 (9th Cir. May 6, 2020).

52 445 F. Supp. 3d at 801.

53 445 F. Supp. 3d at 801.

54 U.S. ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health, 816 F. App'x 892 (5th Cir. 2020), cert. denied sub nom., 2020 WL 7132371 (U.S. Dec. 7, 2020).

55 816 F. App'x at 895.

56 816 F. App'x at 897.

57 816 F. App'x at 898-899.

58 816 F. App'x at 899-900. See also U.S. ex rel. Johnson v. Bethany Hospice & Palliative Care, LLC, 2020 WL 1542339 (S.D. Ga. Mar. 31, 2020) appeal filed sub nom. Estate of Debby Helmly v. Bethany Hospice & Palliative, 20-11624 (11th Cir. Apr. 28, 2020) (dismissing claim under Rule 9(b) because the court "cannot rely on mathematical probability to conclude that" a defendant hospice company must have submitted false claims based on the number of Medicare referrals it received from certain physicians).

59 U.S. ex rel. Olhausen v. Arriva Medical, LLC, 2020 WL 5077170 (S.D. Fla. Aug. 27, 2020).

corporate insider, the district court noted that allegations about attending weekly meetings and interacting with other employees did not amount to sufficient first-hand knowledge of billing processes that are required to show reliable indicia that claims were actually submitted as required to satisfy Rule 9(b).[60]

The Sixth Circuit has acknowledged that in some circumstances, a relator can satisfy Rule 9(b) by alleging first-hand knowledge of a defendant's billing practices instead of a representative false claim, but district courts have reached different outcomes under this analysis. One district court held that a procedure case log with patient details, invoice information, and insurance information provided "strong support" that claims were actually submitted to the government.[61] In light of additional allegations about emails discussing record notes needed for billing and a contract indicating the entity responsible for billing, the court held that the relator provided sufficient allegations to show that the defendant "in all likelihood" submitted false claims.[62] In contrast, another district court declined to apply the Sixth Circuit's relaxed standard and dismissed claims where the relator alleged a scheme to bill for services provided by unlicensed pathologists.[63] The district court explained that although the relator had alleged that "Defendants made false or fraudulent statements as part of their allegedly fraudulent scheme," there were "no allegations connecting these statements to any claim that was actually made to the Government."[64]

3. MEDICAL NECESSITY

Courts and litigants continued to wrangle this year with the appropriate standard for establishing falsity in FCA cases based on allegations that services provided were not medically necessary. Following more than ten years of litigation and a landmark decision by the Eleventh Circuit in 2019, hospice provider *AseraCare* reached a settlement with DOJ to resolve FCA allegations that it provided services that were not medically necessary. In April 2016, the district court vacated the jury's verdict against *AseraCare* following the first phase of a bifurcated trial and granted summary judgment to the defendant, holding that the government failed to establish the falsity of the claims at issue because it offered nothing more than a competing expert's testimony to prove the falsity of the claims. In September 2019, the Eleventh Circuit affirmed the district court's decision, ruling that a clinical judgment of terminal illness warranting hospice benefits cannot be deemed false for purposes of FCA liability where the only evidence to prove falsity is a reasonable disagreement between medical experts as to the accuracy of the clinical determination.[65] On remand, the district court denied the government's motion to reopen discovery in December 2019. In February 2020, the parties settled the long-running case for $1 million. Not only did the settlement resolve allegations that the government previously estimated to have caused more than $200 million in damages, but it also leaves in place the Eleventh Circuit's decision.

Other courts last year adopted a different approach than *AseraCare*. As discussed in more detail below, in March 2020 both the Third Circuit and Ninth Circuit rejected the "objective falsity" standard that the Eleventh Circuit adopted in *AseraCare*, instead holding that a physician's clinical judgment is subject to scrutiny and need not be objectively false in order to establish falsity based on medically unnecessary services.[66] Although some practitioners believe that these decisions create a circuit split regarding the issue of objective falsity, both the Third Circuit and Ninth Circuit attempted to draw distinctions from the ruling in *AseraCare*. The Third Circuit explained that under a theory of legal falsity, a medical opinion that differs from the certifying physician's opinion is relevant evidence of whether the certification was proper and can create an issue of fact for the jury. The Ninth Circuit noted that the court in *AseraCare* did not address whether a medical opinion could ever be false,

60 2020 WL 5077170, at *8-9.

61 U.S. ex rel. Lynch v. University of Cincinnati Medical Center, LLC, 2020 WL 1322790 (S.D. Ohio Mar. 20, 2020).

62 2020 WL 1322790, at *28-29.

63 U.S. ex rel. Sharma v. Miraca Life Sciences, Inc., 472 F. Supp. 3d 429 (N.D. Ohio 2020).

64 472 F. Supp. 3d at 447.

65 United States v. AseraCare, Inc., 938 F.3d 1278 (11th Cir. 2019).

66 *See* United States ex rel. Druding v. Care Alternatives, 952 F.3d 89 (3d Cir. 2020); Winter ex rel. United States v. Gardens Reg'l Hosp. and Med. Ctr., Inc., 953 F.3d 1108 (9th Cir. 2020).

but rather whether a reasonable disagreement between physicians "without more" was sufficient to establish falsity based on medical necessity. This issue may continue to garner attention in the upcoming year as the defendant in *Druding* filed a petition for a writ of certiorari with the Supreme Court pointing out the differing approaches to whether a subjective judgment of medical necessity can be false under the FCA and asking the Court to provide clarification on the issue.

In April, DOJ reached a settlement with a laboratory based on allegations that it performed tests that were not medically necessary.[67] The relator, the laboratory's former Chief Medical Officer, alleged in his *qui tam* complaint that clinical support for the medical necessity of certain tests was "weak to non-existent," and he was fired after raising concerns with the laboratory about billing the government for such tests. Under the settlement, the laboratory agreed to pay up to approximately $43 million—$17 million by surrendering claim funds held in suspension by the government and up to an additional $26 million if certain financial contingencies occur within the next five years.

4. PLEADING AND PROVING FALSITY

As referenced above, in March, the Third Circuit reversed the district court's grant of summary judgment in favor of a hospice provider alleged to have fraudulently billed Medicare and Medicaid by routinely admitting and recertifying patients who were allegedly inappropriate for hospice care.[68] Relators' expert examined the medical records of nearly fifty patients and concluded the documentation did not support a hospice-eligible certification for approximately thirty-five percent of those patients. The provider produced its own expert who testified a physician could have reasonably concluded and certified that the patients were terminally ill and thus needed hospice care.[69] The district court granted summary judgment, adopting an "objective falsity" test for the falsity element of an FCA claim and concluding that a difference of expert opinions was insufficient for relators to survive summary judgment.[70] The Third Circuit reversed, declining to adopt the district court's objective falsity standard. Instead, the court concluded a hospice provider's claim for reimbursement can be considered false under the FCA on the basis of expert opinion that the required physician certification did not support a terminal illness prognosis.[71] In other words, relators' expert proof created a triable issue of fact regarding falsity.[72]

Also in March, the Ninth Circuit revived an FCA suit alleging that a hospital, its management company, which also operated a nursing home, and various physicians orchestrated medically unnecessary inpatient admissions of Medicare beneficiaries.[73] Relator alleged that nursing home patients were admitted at the hospital operated by the management company at an unusually high rate as a result of false certifications of medical necessity. In rejecting defendants' argument that the FCA requires the plaintiff to plead an "objective falsehood," the Ninth Circuit explained that a physician's certification that admission is medically necessary may be false for the same reason any opinion may be false—including "if an opinion is not honestly held, or if it implies the existence of facts—namely, that inpatient hospitalization is needed to diagnose or treat a medical condition, in accordance with accepted standards of medical practice—that do not exist."[74] Relator pleaded detailed information regarding sixty-five patients the hospital admitted without medical necessity. Relator also alleged that defendants had a motive to certify falsely--to increase Medicare reimbursements, which constituted a "significant portion" of its revenue—and identified occupancy and admission rates, showing that hospitalizations increased sharply after

67 Press Release, U.S. Dept. of Justice, Testing Laboratory Agrees to Pay Up to $43 Million to Resolve Allegations of Medically Unnecessary Tests (April 27, 2020), https://www.justice.gov/opa/pr/testing-laboratory-agrees-pay-43-million-resolve-allegations-medically-unnecessary-tests.

68 United States ex rel. Druding v. Care Alternatives, 952 F.3d 89 (3d Cir. 2020).

69 952 F.3d at 91.

70 952 F.3d at 94.

71 952 F.3d at 95-101.

72 952 F.3d at 101.

73 Winter ex rel. United States v. Gardens Reg'l Hosp. and Med. Ctr., Inc., 953 F.3d 1108 (9th Cir. 2020).

74 953 F.3d at 1119.

the nursing home's management company gained control over the hospital.[75] These allegations, the Ninth Circuit concluded, were sufficient to survive a motion to dismiss.[76]

In May, the Fifth Circuit affirmed the district court's dismissal of an FCA suit where, based on statistical data, relator alleged that defendant hospital defrauded Medicare by using artificially inflated secondary diagnosis codes.[77] Relator alleged that the hospital pushed its physicians and coders to "upcode" complications and comorbidities, and provided medically unnecessary post-op ventilator care, all in an effort to maximize reimbursement.[78] The Fifth Circuit concluded that relator did not sufficiently plead the falsity element of an FCA claim under Rule 9(b). In particular, the court reasoned that statistical data did not satisfy the Rule 9(b) pleading requirement because the data was "also consistent with a legal and obvious alternative explanation."[79] The court noted that Baylor was ahead of its peers in using the codes in question and that other hospitals eventually followed suit.[80] And, the fact that Baylor placed post-op patients on ventilators more frequently than its peers did not in and of itself constitute a fraudulent scheme to provide unnecessary services.[81] Finally, though relator alleged coders were directed to code falsely, relator did not include the specific content of the directives, so as to substantiate the allegations.[82]

In July, the Ninth Circuit affirmed a grant of summary judgment in favor of a medical records review contractor on the grounds that the relator failed to establish any false statement or course of conduct as required for liability under the FCA.[83] The plaintiff argued that the contractor falsely certified that its "entire claims folder" was reviewed when its analysts answered "yes" to that question on a checklist that was submitted with its requests for payment to the government. The Ninth Circuit confirmed that nothing in the record indicated that analysts were, in fact, required to review "every page of every document in order to truthfully certify 'yes' on this question."[84] The court similarly rejected plaintiff's "worthless service" claim based on record evidence that the Department of Veterans' Affairs was pleased with its contractor's work and had "no complaints whatsoever."[85]

In February, the District Court for the Eastern District of Pennsylvania denied a long term care pharmacy's motion to dismiss a lawsuit filed by a former sales and marketing executive and others alleging that in order to increase its rebates and reimbursements, the company had fraudulently dispensed different medications than those prescribed by patients' physicians without consulting the physicians.[86] The motion to dismiss argued the relators had failed to identify *by name* those who "concocted" the alleged scheme or "oversaw its implementation," the pharmacists who altered the prescriptions, or the nursing home employees who signed for and administered the altered prescriptions.[87] The district court disagreed, noting that a careful review of the complaint revealed that relators "describe the alleged scheme in adequate detail, explaining the mechanism of the alleged fraud and the generic identities of those involved (*i.e.*, data clerks, pharmacists, etc.)."[88] The court also explained that there was "no authority for the proposition that Relators must identify *by name* the particular PharMerica employees who designed the [software] or those who allegedly altered prescriptions."[89] When paired with other

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75 953 F.3d at 1119-1120.

76 953 F.3d at 1121.

77 U.S. ex rel. Integra Med Analytics, L.L.C. v. Baylor Scott & White Health, 816 F. App'x 892 (5th Cir. 2020).

78 816 F. App'x at 895-896.

79 816 F. App'x at 898.

80 816 F. App'x at 897-898.

81 816 F. App'x at 900.

82 816 F. App'x at 899-900.

83 Vatan v. QTC Med. Servs., Inc., 812 F. App'x 485 (9th Cir. 2020).

84 812 F. App'x at 486. See also U.S. ex rel. O'Laughlin v. Radiation Therapy Servs., P.S.C., 2020 WL 6152977 (E.D. Ky. Oct. 20, 2020) (dismissing counts alleging defendants falsely certified that "incident-to" radiation oncology services were supervised by a radiation oncologist because relator did not identify a regulation or statute that required a radiation oncologist, as opposed to another type of physician, to supervise the services).

85 812 F. App'x at 487.

86 U.S. ex rel. Sturgeon v. Pharmerica Corp., 438 F. Supp. 3d 246 (E.D. Penn. 2020).

87 438 F. Supp. 3d at 271-272.

88 438 F. Supp. 3d at 272.

89 438 F. Supp. 3d at 272.

details, like the specific time frame of the scheme, the number and type of prescription alterations revealed by an audit, and specific examples identified by RX number, these allegations were enough to satisfy Rule 9(b).[90]

5. PLEADING AND PROVING MATERIALITY

Three years ago, in Ruckh v. Salus Rehabilitation, LLC, the U.S. District Court for the Middle District of Florida overturned a $348 million judgment entered following a jury verdict against defendants, finding trial proof lacking as to materiality, scienter, and causation.[91] On appeal this year, the Eleventh Circuit reversed the district court's ruling as to the FCA claims involving Medicare and reinstated most of the jury verdict. [92] The Eleventh Circuit determined that the evidence at trial permitted the jury to find that the defendants committed Medicare fraud by engaging in upcoding (billing for more and higher levels of therapy than actually provided) and ramping (artificially timing services to coincide with Medicare's regularly scheduled assessment periods to maximize reimbursement).[93] Reasoning that Medicare skilled nursing facility (SNF) reimbursement is based on both the level and amount of services provided, the court held the ramping and upcoding violations were material, as they "went to the heart of the SNFs' ability to obtain reimbursement from Medicare" and the "essence of the parties' economic relationship."[94]

By contrast, the Eleventh Circuit affirmed the district court's conclusion that the relator failed to prove the materiality of the purported Medicaid fraud.[95] Relator alleged defendants routinely submitted claims for Medicaid reimbursement without preparing and maintaining comprehensive care plans, as required by law. In finding that there was insufficient evidence to establish the materiality of this alleged noncompliance, the court noted the absence of any evidence that the state ever declined payment for violations of this kind or took enforcement actions in response to such violations. The court also pointed to the lack of evidence that the state ever refused reimbursement or sought recoupment after defendants self-reported this issue.[96]

In February, the Tenth Circuit affirmed a grant of summary judgment on materiality grounds in *U.S. ex rel. Janssen v. Lawrence Memorial Hospital*.[97] The relator alleged that the defendant hospital falsified records relating to patient arrival times and features of its compliance program. After acknowledging that, under *Escobar*, the materiality analysis is "holistic" and no factor is dispositive,[98] the court emphasized that: (1) the government continued to pay the defendant's claims, even after learning of the allegations[99]; (2) the defendant's alleged misconduct was relatively minor in the scheme of the regulations at issue, which involved "administrative procedures designed to address" the alleged noncompliance at issue[100]; and (3) the alleged reporting errors were not "sufficiently widespread…that they would likely affect the Government's payment decision" and thus there was no indication of a cover-up.[101]

In March, the Ninth Circuit overturned a district court's finding that the failure to meet Interqual criteria in the context of hospital admissions was not material for purposes of pleading an FCA claim. [102] The Ninth Circuit determined that the district court "misread" relator's complaint as to the underlying theory of falsity. The Ninth Circuit reasoned that relator was not alleging that "failure to satisfy Interqual criteria made Defendants' Medicare

90 438 F. Supp. 3d at 273.
91 304 F. Supp. 3d 1258 (M.D. Fla. 2018).
92 963 F.3d 1089 (11th Cir. 2020).
93 963 F.3d at 1104.
94 963 F.3d at 1105.
95 963 F.3d at 1108.
96 963 F.3d at 1109.
97 949 F.3d 533 (10th Cir. 2020).
98 949 F.3d at 541.
99 949 F.3d at 541-42.
100 963 F.3d at 543.
101 963 F.3d at 543-44.
102 Winter ex rel. United States v. Gardens Reg'l Hosp. and Med. Ctr., Inc., 953 F.3d 1108, 1121-1122 (9th Cir. 2020).

claims per se false," but rather was alleging that defendants' claims "were false in that the services claims (for inpatient hospital admissions) were not medically necessary and economical" and that defendants submitted false certifications of medical necessity.[103] The court held that such certifications could indeed be material and relator had sufficiently pled materiality at the motion to dismiss stage of the case with allegations focused on the centrality of medical necessity requirements to the Medicare program.[104]

In April, the Fifth Circuit affirmed dismissal on materiality grounds allegations that a coordinated care organization ("CCO") committed Medicaid fraud by staffing care manager and case manager positions by licensed practical nurses and not registered nurses.[105] The court noted the relator had not identified a specific provision in any contract between the hospital and Mississippi Medicaid's Coordinated Access Network requiring that these positions be staffed by a registered nurse, had not identified any specific federal or state statute or regulation mandating that a registered nurse provide those services, and had not otherwise established that the staffing of the case manager or care manager positions was a material term of the contracts.[106] Further, Mississippi Medicaid took no action after relator informed the agency that the CCO was staffing the positions with licensed practical nurses and instead renewed its contract with the CCO four times, including after the FCA case was unsealed.[107]

In December, the District Court for the Western District of Texas denied summary judgment to a defendant, explaining that the government's continued payment of claims after the filing of relators' *qui tam* action was probative but not dispositive of materiality.[108] The district court reasoned that "[t]here are simply too many possible explanations for an agency's action or inaction to impute a decision on the merits of an allegation of fraud unless it is clear that the agency has actual knowledge" of fraud, and courts cannot "speculate about what information the Government actually knows," particularly in lawsuits where "the Government has declined to intervene."[109] Although the government had declined intervention in this case, it filed a statement of interest citing a Medicare Manual that listed billing for services not provided as an example of Medicare fraud. The district court noted this evidence contradicted the inferences of immateriality from the government's continued payment of defendants' claims after it was on notice of relator's allegations, which centered on billing for ultrasound services using a global CPT code before the professional component of the service was completed.[110]

6. PROVING CAUSATION

For analyzing "cause to be presented" claims in FCA cases, the Eleventh Circuit in Ruckh adopted the proximate cause test, which looks to whether "the conduct was a substantial factor in inducing providers to submit claims for reimbursement" and whether "the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct."[111] In finding the trial evidence sufficient to establish causation, the court cited testimonial evidence that the defendant SNF management company (1) routinely pressured staff to elevate RUG scores irrespective of the services provided, (2) praised or reprimanded staff for meeting or falling short against RUG budgets, (3) made a presentation to staff that included the goal of "RUG enhancement" and "maximizing therapy minutes," and (4) potentially had a policy of prohibiting the submission of claims at the lowest RUG code without management approval.[112]

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103 953 F.3d at 1122.

104 953 F.3d at 1122.

105 U.S. ex rel. Porter v. Magnolia Health Plan Inc., 810 F. App'x 237 (5th Cir. 2020).

106 810 F. App'x at 241-42.

107 810 F. App'x at 242.

108 U.S. ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A., 2020 WL 7342662 (W.D. Tex. Dec. 14, 2020).

109 2020 WL 7342662, at *23-24.

110 2020 WL 7342662, at *17, 24.

111 Ruckh v. Salus Rehab., LLC, 963 F.3d 1089, 1107 (11th Cir. 2020).

112 963 F.3d at 1106-08.

7. KNOWLEDGE/SCIENTER

In February, the Fifth Circuit affirmed a district court's grant of summary judgment to the United States despite the defendants' argument that they lacked any intent to submit claims in violation of certain rules that govern the billing of travel costs for clinical testing services.[113] The court determined that the relevant statute "clearly forbids" the defendants' billing practices, and it described the defendants' argument that they did not fully understand the statute's requirements as "border[ing] on the absurd."[114] The court also rejected the defendants' argument that non-binding sub-regulatory guidance created ambiguity in the meaning of the relevant statute.[115]

In March, the Ninth Circuit affirmed a trial court's grant of summary judgment on FCA claims in favor of defendants by holding that the relator had not introduced sufficient evidence of scienter.[116] Although the relator had sought to demonstrate that the defendants had been deliberately ignorant, the Ninth Circuit agreed with the district court that the relator's evidence of "inexperienced coders, glitchy billing software, imperfect training practices, and even post-transition billing and coding errors" did not demonstrate that the defendants "sought to avoid learning about coding issues."[117] The Ninth Circuit concluded that, at most, the relator had demonstrated negligence, which could not support FCA liability.[118]

In May, the Ninth Circuit affirmed a district court's ruling that a relator failed to plausibly allege the scienter element of his FCA claim where he offered only conclusory allegations that the defendant hospital knowingly failed to satisfy certain regulatory requirements of the Critical Access Hospital program.[119] The court explained that while Federal Rule of Civil Procedure 9(b) allows plaintiffs to allege scienter generally, it must still be pleaded with the plausibility required by Rule 8(a).[120] The relator had alleged that the hospital's senior officials must have known that the hospital did not meet the "mountainous terrain" requirement for the program based on their own travel to and from the hospital.[121] The court held that this allegation amounted to "mere speculation," which was "too vague and conclusory to make plausible" the relator's conclusion that the hospital acted with the requisite scienter.[122]

In June, the Fourth Circuit affirmed the dismissal of FCA claims based on the alleged submission of false cost reports by two hospitals because the relator failed to adequately allege that the hospitals knew the cost reports were false.[123] The court explained that the relator asked the court "to infer scienter from [an] alleged regulatory violation itself," which is not sufficient in the FCA context.[124] The court also opined that "ambiguity" in the relevant regulation made it especially inappropriate to infer scienter.[125]

In June, the Central District of Illinois granted summary judgment in favor of a pharmacy defendant on the ground that the pharmacy chain's interpretation of its obligation to report its "usual and customary" prices—in relation to its practice of matching competitor's prices—was not objectively unreasonable.[126] Applying the Supreme Court's 2007 decision in *Safeco Insurance Co. v. Burr*, the court held that the pharmacy's subjective intent when reporting its usual and customary prices was legally "irrelevant" because the law was unclear and its interpretation

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113 U.S. ex rel. Drummond v. BestCare Lab. Servs. LLC, 950 F.3d 277 (5th Cir. 2020).
114 950 F.3d at 281-82.
115 950 F.3d at 281.
116 Vassallo v. Rural/Metro Operating Co. LLC, 798 F. App'x 1000 (9th Cir. 2020).
117 798 F. App'x at 1001.
118 798 F. App'x at 1001.
119 U.S. ex rel. Adomitis v. San Benardino Mountains Comm'ty Hosp. Dist., 816 F. App'x 64 (9th Cir. 2020).
120 816 F. App'x at 66.
121 816 F. App'x at 67.
122 816 F. App'x at 67.
123 U.S. ex rel. Complin v. N.C. Baptist Hosp., 818 F. App'x 179 (4th Cir. 2020).
124 818 F. App'x at 184.
125 818 F. App'x at 184.
126 United States v. Safeway, Inc., No. 11-cv-3406, 2020 WL 3132397 (C.D. Ill. Jun. 12, 2020).

of the law was reasonable.[127] In such circumstances, the court explained, a defendant cannot be said to have knowingly or recklessly violated the FCA.[128]

In August, the D.C. Circuit largely affirmed a district court's grant of summary judgment to the United States on claims that the defendant submitted false claims to the District of Columbia Medicaid program for home health services.[129] As to the scienter element, the D.C. Circuit held that the defendant had at least acted with reckless disregard of the requirement that home health services be supported by a valid Plan of Care (POC). The court pointed to an audit that had "revealed material deficiencies with regard to the POC for virtually every patient file" included in the audit, and then explained that "when even the shoddiest recordkeeping would have revealed that false submissions were being made, it is reckless for a provider to request reimbursement."[130] Rejecting the defendant's argument that it is not permissible to find scienter by aggregating the knowledge of individual employees, the court emphasized that "any single person who looked at the patient files should have known that the company sought reimbursements unsupported by adequate POCs."[131]

In November, the District of Maryland granted a pharmaceutical manufacturer's motion to dismiss FCA claims partly because the relator had not plausibly alleged that the defendant acted with the requisite scienter when submitting allegedly false "best price" reports to the government.[132] Finding that the statute defining "best price" was ambiguous—and that the defendant's interpretation of the term was objectively reasonable—the court held that the relator could not establish the requisite scienter as a matter of law unless there was evidence that the defendant "had been warned about its interpretation."[133] Because there was no judicial authority on point and relevant regulatory guidance was itself ambiguous, the court determined there was no such evidence.[134]

In December, the Western District of Texas granted a relator's motion for summary judgment on FCA claims alleging that a physician practice knowingly billed for services it did not perform.[135] Although the defendant had argued that its allegedly mistaken interpretation of a relevant regulatory requirement was objectively reasonable, the court concluded that there was "no indication that [the defendant] actually held the belief that its interpretation was legal and correct."[136] Furthermore, the court cited evidence that the defendant had at one point changed its practices to bring them into compliance with the regulation, only to later abandon that change when it realized its revenue would be negatively affected. In the court's view, this evidence showed that the defendant had acted at least with "deliberate ignorance" or "reckless disregard of the truth or falsity of the information" it provided to Medicare.[137]

8. PUBLIC DISCLOSURE BAR

Under the FCA, when the government declines to intervene in a *qui tam* action, the court must dismiss that action if "substantially the same" allegations alleged by the relator were publicly disclosed, unless dismissal is opposed by the government or the relator is an "original source." *See* 31 U.S.C. § 3730(e)(4).

Litigation surrounding the public disclosure bar often focuses on whether a relator's allegations are "substantially the same" as publicly disclosed information. For example, the Sixth Circuit dismissed a *qui tam* action under

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127 2020 WL 3132397, at *17.

128 2020 WL 3132397, at *25. The same court reached a similar conclusion this year in United States v. SuperValu, Inc., No. 11-3290, 2020 WL 3577996 (C.D. Ill. Jul. 1, 2020).

129 United States v. Dynamic Visions, Inc., 971 F.3d 330 (D.C. Cir. 2020).

130 971 F.3d at 337.

131 971 F.3d at 338.

132 U.S. ex rel. Sheldon v. Forest Labs., LLC, No. ELH-14-2535, 2020 WL 6545854 (D. Md. Nov. 6, 2020).

133 2020 WL 6545854, at *22.

134 2020 WL 6545854, at *22.

135 U.S. ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A., ---F.Supp.3d---, 2020 WL 7342662 (W.D. Tex. Dec. 14, 2020).

136 2020 WL 7342662, at *26.

137 2020 WL 7342662, at *26-27.

the public disclosure bar because the relator raised substantially the same allegations as those in several earlier *qui tam* complaints.[138] Although those earlier complaints were voluntarily dismissed in 2008 and focused on just one of defendants' facilities, the Sixth Circuit ruled that the relator's allegations of corporate-wide misconduct from 2004 to 2018 were nonetheless substantially the same as those in the earlier complaints.[139] In another case, the Sixth Circuit applied the public disclosure bar, even though the relator's *qui tam* action alleged a fraud scheme involving defendants and patient examples that differed from those in a previous *qui tam* action.[140] Despite those differences, the court reasoned that the relator alleged the "exact scheme" disclosed in that previous action and, in fact, "copie[d] much of the [prior] complaint verbatim."[141] By contrast, the Ninth Circuit held that the public disclosure bar did not apply where the relator "made allegations about a new fraud."[142] The court determined that the relator alleged a "new fraud" because his allegations focused on a product made by defendant that was different from the product previously disclosed in an earlier *qui tam* action.[143]

Even if a relator's allegations are "substantially the same" as a prior public disclosure, the public disclosure bar will not apply when the relator qualifies as an "original source." For instance, the First Circuit concluded that the relator satisfied the original source exception, applying the pre-2010 definition of "original source."[144] More specifically, the First Circuit held that the relator's allegations were based on "direct" and "independent" knowledge of the fraud, despite the relator not personally observing the fraud and learning of the fraud "after the fact."[145] However, the Second Circuit ruled that a relator was not an original source under the post-2010 definition of the exception, determining that the relator's allegations neither "materially add[ed]" to nor were "independent" of prior publicly disclosed allegations.[146] The relator's allegations did not materially add to the publicly disclosed allegations because the relator merely alleged more locations of the purported fraud scheme and were not independent because they were taken from prior public filings.[147]

9. THIRD-PARTY LITIGATION FUNDING

Continuing a growing trend from recent years, *qui tam* relators last year enlisted financial assistance from third parties to secure funding to enable them to pursue FCA lawsuits. Under these arrangements, the relator typically enters an agreement with the third party to receive funds in exchange for a percentage of the relator's recovery in the case.

In Ruckh v. Salus Rehab., LLC, the relator entered into a litigation funding agreement with ARUS, a third-party company that described itself as a "privately owned limited liability company focused on litigation funding."[148] To receive the necessary funds, the relator agreed to give ARUS "less than 4% of her share of the judgment originally entered by the district court, if the jury verdict were upheld on appeal, assuming a 30% share to the relator."[149] The defendants argued that by entering into the litigation funding agreement, the relator had partially reassigned her interest in the FCA action, violated the intent of both the Constitution and the FCA, and therefore forfeited her standing to bring a *qui tam* action on behalf of the United States. Specifically, the defendants argued that the relator was "no longer the assignee of the United States."[150]

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138 U.S. ex rel. Holloway v. Heartland Hospice, 960 F.3d 836 (6th Cir. 2020).
139 960 F.3d at 846-51.
140 U.S. ex rel. Maur v. Hage-Korban, 981 F.3d 516, 525-526 (6th Cir. 2020).
141 981 F.3d at 523, 526.
142 U.S. ex rel. Shahinian v. Kimberly-Clark Corp., 807 F. App'x 710, 711 (9th Cir. 2020).
143 807 F. App'x at 711.
144 U.S. ex rel. Banigan v. PharMerica, Inc., 950 F.3d 134 (1st Cir. 2020).
145 950 F.3d at 144-47.
146 Vierczhalek v. MedImmune Inc., 803 F. App'x 522 (2d Cir. 2020).
147 803 F. App'x at 525-26.
148 963 F.3d 1089 (11th Cir. 2020).
149 963 F.3d at 1100.
150 963 F.3d at 1101.

The Eleventh Circuit disagreed with the defendants and focused on two specific aspects of the litigation funding agreement. First, the relator assigned "less than 4%" of her recovery, which constituted "only a small interest." Second, the agreement clearly stated that the relator retained all decision making ability in the litigation, and thus ARUS had no power or influence over it. The Eleventh Circuit concluded that the relator retained "sufficient interest to meet the irreducible constitutional minimum of standing under Article III."[151]

The Eleventh Circuit also held that the FCA does not expressly prohibit relators from pursuing litigation funding agreements. The court noted that the FCA allows "a person" to bring suit under the FCA, and there are only three excluded types of persons set forth in the statute.[152] The court was "reluctant to imply additional exceptions in the absence of clear legislative intent to the contrary."

In a June 2020 speech, the then-Principal Deputy Assistant Attorney General for the U.S. Department of Justice (Ethan Davis) addressed the issue of litigation funding agreements in *qui tam* actions.[153] General Davis noted that often even the government attorneys involved with a *qui tam* action are unaware of whether relators are utilizing third-party funders, sharing information with such third parties, or allowing those third parties to exercise control over the litigation. Davis also mentioned that concerns have been raised that such agreements can affect conflicts of interest, fairness in litigation, and accountability.

To obtain more information about these litigation funding issues, General Davis stated that the DOJ has instructed its attorneys, when meeting with relators, to begin asking: (1) whether the relator or his or her counsel have an agreement with a third-party funder; (2) who any third-party funder is; (3) whether the relator has shared any information relating to the *qui tam* allegations with that funder; (4) whether a written litigation funding agreement exists; and (5) whether the agreement entitles the funder to exercise direct or indirect control over the relator's litigation or settlement decisions. DOJ attorneys will also ask to be updated on the answers to these questions throughout the course of the litigation. General Davis explained that, at least for now, the information gathered from these questions is solely for informational purposes so that the DOJ can examine the use of such agreements.

10. RELATORS—RETALIATION

In January, the Eleventh Circuit addressed the issue of causation under the FCA's retaliation provision and held that a plaintiff must show "but-for" causation between his engagement in protected conduct and retaliation against him, not simply that the protected conduct was a "motivating factor" for the retaliation.[154] The court recognized that other circuits (Sixth, Seventh, and D.C.) have concluded the "motivating factor" standard is the proper standard for assessing FCA retaliation claims, but explained that the plain language of the FCA and the Supreme Court's interpretation of two similar statutes supported its approach.[155] The Eleventh Circuit affirmed dismissal of the case on summary judgment, as the plaintiff had conceded at oral argument that he would lose under a "but-for" causation standard.

In April, the Eighth Circuit held that the causation standard for FCA retaliation claims is more stringent than other employment-related claims, as "the retaliation [must be] motivated solely by…protected activity."[156] The plaintiff, an oncologist employed by the defendant, experienced numerous conflicts with physicians and staff during his tenure and at one point reported to clinic management that another doctor was engaged in alleged fraudulent billing practices. The defendant sent the plaintiff to a third-party for a fitness-to-practice evaluation, and while the evaluator found that the plaintiff's medical skills were sufficient, the evaluator recommended a

151 963 F.3d at 1101-1102.

152 See 31 U.S.C. § 3730(d)(3), (e)(1), & (e)(2).

153 Speech to the Institute for Legal Reform, U.S. Chamber of Commerce, June 26, 2020, https://www.justice.gov/civil/speech/principal-deputy-assistant-attorney-general-ethan-p-davis-delivers-remarks-false-claims.

154 Nesbitt v. Candler Cty., 945 F.3d 1355 (11th Cir. 2020).

155 945 F.3d 1358-1359 (discussing Univ. of Tex. Sw. Med. Ctr. v. Nassar, 570 U.S. 338 (2013) and Gross v. FBL Fin. Servs., Inc., 557 U.S. 167 (2009)).

156 Bharadwaj v. Mid Dakota Clinic, 954 F.3d 1130 (8th Cir. 2020).

three-week treatment program aimed at dealing with the plaintiff's interpersonal relationship issues. While the plaintiff attended the program, the defendant's legal counsel met with several nurses, some of whom complained about the plaintiff's behavior and not wanting to work with him. Upon the plaintiff's return, the defendant's board decided to suspend and then terminate him, citing his conflicts with co-workers. The plaintiff alleged that he was forced to resign as a result of the defendant's actions. The district court dismissed the plaintiff's FCA retaliation claims on summary judgment, and the Eighth Circuit affirmed.[157] Because there was "simply no evidence, direct or otherwise, that his decision to report the allegedly fraudulent billing practices of a colleague caused—much less solely caused—[the defendant] to force him out," the Court ruled that the plaintiff's FCA retaliation claim must be dismissed.[158]

In June, the Eighth Circuit affirmed the dismissal of a physician relator's allegations that he was terminated because of complaints he made internally on two different occasions about another physician performing medically unnecessary surgeries.[159] The court observed that the relator's allegations showed "his concern was with the medical propriety and ethical ramifications" of those unnecessary surgeries, but that the plaintiff did "not allege that he connected his complaint to a concern over improper billing or the submission of false claims to the government."[160] Because the relator's complaints only related to ethical concerns and not fraud, the Eighth Circuit held that his internal complaints did not constitute protected activity, which a plaintiff must show to establish liability under the FCA's anti-retaliation provision.[161]

In December, the First Circuit addressed for the first time the standard for causation for FCA retaliation claims and joined the Third, Fourth, Fifth, and Eleventh Circuits in holding that it is a "but-for" standard.[162] The plaintiff alleged her employer retaliated against her by placing her on indefinite administrative leave after learning she filed a *qui tam* action against the defendant. The defendant allowed her to return from administrative leave after it settled the *qui tam* matter, and then allegedly retaliated against the plaintiff again by providing her less favorable account assignments. The case went to a jury trial, and the plaintiff was awarded $765,525.[163] On appeal, the First Circuit ruled that the jury had erroneously been instructed that the "protected activity" need only be a "substantial motivating factor" for the retaliation. The First Circuit affirmed the jury verdict, though, because the employer did not object to the erroneous jury instruction before the district court, the jury instruction was not plain error as it was an issue of first impression, and the evidence was sufficient to sustain the jury verdict.[164]

11. HEALTHCARE FRAUD—CRIMINAL ENFORCEMENT

11.1 Updated Guidance for Evaluating Corporate Compliance Programs

In June, with a record number of companies receiving funding from the federal government to help cover pandemic-related losses, the Department of Justice updated its internal guidance for evaluating corporate compliance programs.[165] For years, DOJ attorneys have factored in the existence and adequacy of a corporate compliance program when considering charges to bring against a company and how to resolve investigations. Originally published in 2017, the 2020 update included the following revisions and clarifications, among others:

157 954 F.3d at 1134.

158 954 F.3d at 1137.

159 U.S. ex rel. Benaissa v. Trinity Health, 963 F.3d 733 (8th Cir. 2020).

160 963 F.3d at 742.

161 963 F.3d at 742.

162 Lestage v. Coloplast Corp., 982 F.3d 37 (1st Cir. 2020).

163 982 F.3d at 41-43.

164 982 F.3d at 45-46.

165 See Dept. of Justice Criminal Division, Evaluation of Corp. Compliance Programs (Updated June 2020), https://www.justice.gov/criminal-fraud/page/file/937501/download.

- **Specifically tailored –** Companies should tailor their compliance programs to the company's specific needs and risks. The update instructed government counsel "to understand why the company has chosen to set up the compliance program the way that it has, and why and how the company's compliance program has evolved over time." This may include considering "the company's size, industry, geographic footprint, regulatory landscape, and other factors, both internal and external to the company's operations, that might impact its compliance program."

- **Review and revise –** The updated guidance advised government attorneys to consider whether a company periodically reviews its compliance program and the depth of that review. It also implied that companies should not be afraid to learn from their mistakes, advising government attorneys to ask whether the company has "a process for tracking and incorporating into its periodic risk assessment lessons learned either from the company's own prior issues or from those of other companies operating in the same industry and/or geographical region" and whether the company "review[s] and adapt[s] its compliance program based upon lessons learned from its own misconduct and/or that of other companies facing similar risks?"

- **Adequate resources & accessibility –** As one of three "fundamental questions," the prior version of the guidance instructed government attorneys to ask: "Is the program being applied earnestly and in good faith? In other words, is the program being implemented effectively?" The updated guidance shifted the focus of the second part of this question, instead asking: "Is the program being applied earnestly and in good faith? In other words, is the program adequately resourced and empowered to function effectively?" This and several other changes emphasized that a company must adequately invest in its compliance program, both financially and functionally, in order to receive meaningful credit.

- **Due diligence of third parties –** In addition to closely reviewing their own policies and behaviors, the updated guidance promoted a company's due diligence of other entities with which it does business. In the context of third party vendors, the updated guidance instructed government attorneys to consider whether a company understands the associated risks of engaging a third party in their transaction and whether the company engages in risk management throughout the "lifespan of a relationship," or only during the "onboarding process?" In the context of mergers and acquisitions, the updated guidance encouraged government attorneys to ask whether the company conducts post-acquisition audits at newly acquired entities and whether the company was "able to complete pre-acquisition due diligence," or if not, why?

11.2 Charges & Enforcement

On September 30, 2020, DOJ announced that it charged 345 people in various healthcare fraud schemes nationwide in what it described as the largest "takedown" in history.[166] Altogether, the defendants were charged with submitting more than $6 billion in false claims to federal healthcare programs and private insurers. The enforcement actions, coordinated among multiple DOJ task forces and other agencies, were largely connected to three sectors: telemedicine, substance abuse treatment facilities, and opioid distribution.

The largest portion of fraud losses charged in connection with these cases stemmed from telemedicine fraud, with $4.5 billion in allegedly false claims submitted by more than 86 defendants. DOJ alleged that the defendants paid physicians and nurse practitioners to order unnecessary durable medical equipment, genetic and other diagnostic testing, and pain medication without patient interaction or after only brief phone calls with new patients. The companies, laboratories, and pharmacies then allegedly purchased those orders in exchange for illegal kickbacks. While DOJ touted this takedown as an extension of its 2019 "Operation Brace Yourself," focused

166 See Press Release, U.S. Dept. of Justice, National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses (Sept. 30, 2020), https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants.

on telemedicine and durable medical equipment, enforcement actions related to telemedicine are unlikely to abate with the rise of the use of telemedicine during the COVID-19 pandemic. One telemedicine executive, indicted in April, filed with the District Court for the Middle District of Florida a plea deal just one day before DOJ's announcement.[167] Prosecutors accused that defendant of helping to operate a $1.2 billion telehealth scheme to procure unnecessary joint braces. He agreed to plead guilty to one count of conspiracy and one count of soliciting and receiving healthcare kickbacks, to forfeit $13.595 million in proceeds and a number of properties, and to cooperate with prosecutors.

Charges against more than a dozen defendants relating to "sober homes" accounted for more than $845 million of allegedly false claims.[168] The defendants included physicians, owners and operators of substance abuse treatment facilities, and patient recruiters known in the industry as "body brokers," who allegedly participated in schemes involving the payment of illegal kickbacks for referrals of patients to the treatment centers, where patients were subjected to medically unnecessary testing and therapy sessions that were not provided. Notably, DOJ stated that these false claims were submitted to private insurers, not federal or state healthcare programs. DOJ also alleged that patients who were discharged were often then admitted to other treatment centers or referred to other labs and clinics in exchange for more kickbacks.

The last category of charges, accounting for more than $800 million in false claims, came from "more traditional" healthcare fraud charges and charges related to illegal prescription and/or distribution of opioids. DOJ charged more than 240 defendants, with many cases involving allegations that patient recruiters, beneficiaries, and other co-conspirators were paid cash kickbacks for supplying beneficiary information to providers so that the providers could then submit fraudulent bills to Medicare. This category also included charges against medical professionals involved in the distribution of "more than 30 million doses of opioids and other prescription narcotics." In June, DOJ charged the president of a medical technology company with one count of conspiracy to commit healthcare fraud and one count of securities fraud in one of DOJ's first notable healthcare fraud prosecutions related to the pandemic.[169] The company purported to provide allergy testing using microarray technology. DOJ alleged that the defendant conspired with patient recruiters and physicians to promote its blood test for a panel of 120 allergens, without regard for the need for a blood test instead of a less expensive skin test or the clinical relevance of such a sweeping allergen panel, in exchange for bribes and kickbacks. DOJ alleges that since 2018, the company has submitted or caused the submission of over $5.9 million in claims to Medicare and $63 million in claims to private insurers that were kickback-tainted, medically unnecessary, and/or otherwise not provided as represented. DOJ alleged that during the spread of the COVID-19 virus in early March 2020, the company began promoting its microarray technology for both allergy and COVID-19 testing, instructing patient recruiters and clinics to bundle the tests together even when not medically necessary in order "to capitalize on a national emergency" for "financial gain." The government's investigation allegedly revealed there was little medical basis for bundling COVID-19 testing with blood tests for 120 allergens.

DOJ's enforcement efforts this year indicated that the pandemic did not divert prosecutors' attention from opioid-related enforcement efforts. At the start of the year, the seven defendants in the highly-publicized 2019 Insys Therapeutics prosecution were sentenced to prison sentences of varying lengths for racketeering conspiracy.[170] Prosecutors had argued that the pharmaceutical executives orchestrated a nationwide kickback

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167 Carolina Bolado, Telemedicine CEO Inks Plea Deal in Kickback Scheme Case, Law360 (Oct. 1, 2020), https://www.law360.com/health/articles/1315474/telemedicine-ceo-inks-plea-deal-in-kickback-scheme-case?nl_pk=6373141b-32ab-4c1b-a7fa-e6089f4ed235&utm_source=newsletter&utm_medium=email&utm_campaign=health&read_more=1&attachments=true.

168 See Press Release, U.S. Dept. of Justice, National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More than $6 Billion in Alleged Fraud Losses (Sept. 30, 2020), https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants.

169 See Press Release, U.S. Dept. of Justice, Medical Technology Company President Charged in Scheme to Defraud Investors and Health Care Benefit Programs in Connection with COVID-19 Testing (June 9, 2020), https://www.justice.gov/opa/pr/medical-technology-company-president-charged-scheme-defraud-investors-and-health-care-benefit.

170 See Dept. of Justice, United States v. Michael Babich, Alec Burlakoff, Richard Simon, Sunrise Lee, Joseph Rowan, and Michael Gurry, John Kapoor (Updated May 7, 2020), https://www.justice.gov/usao-ma/victim-and-witness-assistance-program/united-states-v-michael-babich-alec-burlakoff-richard-simon-sunrise-lee-joseph-rowan-and.

ring to increase prescriptions of its fentanyl drug Subsys by bribing high-prescribing physicians through payments disguised as sham speaker fees.[171] Prosecutors also argued that Insys lied to insurance companies in order to obtain prior authorizations for drug coverage, including misleading insurers into thinking patients had a cancer diagnosis, for which insurance companies were more likely to approve use of Subsys.[172] The founder and former chairman of Insys received the longest sentence—66 months in prison plus three years of supervised release, forfeiture, and restitution. Prosecutors recommended a sentence of fifteen years in prison. The District Court for the District of Massachusetts ordered all seven defendants jointly and severally liable for the entire restitution amount of $59,755,362.[173]

Other physicians pled or were found guilty in multiple opioid distribution prosecutions outside those associated with the government's September announcement as well. For example, in August, after a six-day trial, a federal jury found a West Virginia doctor guilty of seventeen counts of unlawfully distributing opioids to his patients.[174] The government presented evidence that the defendant prescribed a host of different opioid drugs to several patients outside the usual course of practice and without a legitimate medical purpose. As to one patient, the government presented evidence that he prescribed more than 150 opioid pills in order to establish a sexual relationship with her. As to another, the government presented evidence that the defendant prescribed more than seven times the dosage recommended by the Centers of Disease Control. The same day, DOJ announced that a Kentucky physician and his wife/former assistant pled guilty to unlawfully distributing opioids and other controlled substances while the defendants did not have a legitimate medical practice.[175] The defendants admitted to using Facebook messenger to sell prescriptions where the physician did not perform any examination that justified the prescriptions and his assistant would exchange the prescriptions for cash in parking lots. Opioid-related prosecutions are likely to continue despite the potential for the government to shift its focus more to telemedicine and other COVID-related fraud schemes.

12. OTHER FRAUD AND ABUSE UPDATES

12.1 DOJ Increases FCA Civil Penalties

Under the False Claims Act ("FCA"), any person who knowingly submits a false claim to the government is subject to a civil penalty of "not less than $5,000 and not more than $10,000."[176] Similarly, following a violation of the Anti-Kickback Statute ("AKS"), the federal government may impose a penalty of "not more than $10,000 for each occurrence of prohibited conduct."[177]

The Balanced Budget Act of 2015 requires the DOJ to make yearly inflationary adjustments to those civil monetary penalties imposed on conduct occurring after November 2, 2015.[178] The DOJ's short history in following this statutory requirement, however, has been unpredictable. From 2016 through 2018, the DOJ made the requisite inflationary adjustments.[179] In 2019, however, the DOJ inexplicably issued no adjustment. That inactivity continued through almost half of 2020.

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171 Gabrielle Emanuel, Pharmaceutical Executives Face Prison Time In Case Linked To Opioid Crisis, NPR (Jan. 13, 2020), https://www.npr.org/2020/01/13/795200200/pharmaceutical-executives-face-prison-time-in-case-linked-to-opioid-crisis.

172 See Dept. of Justice, Founder and Former Chairman of the Board of Insys Therapeutics Sentenced to 66 Months in Prison (Jan. 23, 2020), https://www.justice.gov/usao-ma/pr/founder-and-former-chairman-board-insys-therapeutics-sentenced-66-months-prison.

173 United States v. Babich, 2020 WL 1235536, at *10 (D. Mass. Mar. 13, 2020).

174 See Dept. of Justice, West Virginia Doctor Found Guilty of Unlawfully Distributing Opioids (Aug. 10, 2020), https://www.justice.gov/opa/pr/west-virginia-doctor-found-guilty-unlawfully-distributing-opioids.

175 See Dept. of Justice, Eastern Kentucky Doctor and Assistant Plead Guilty to Unlawfully Distributing Opioids (Aug. 10, 2020), https://www.justice.gov/opa/pr/eastern-kentucky-doctor-and-assistant-plead-guilty-unlawfully-distributing-opioids.

176 31 U.S.C. § 3729(a)(1).

177 41 U.S.C. § 8706(a)(1)(B).

178 The Balanced Budget Act of 2015 was signed into law on November 2, 2015.

179 See Civil Monetary Penalties Inflation Adjustment, 84 Fed. Reg. 13,520 (Apr. 5, 2019); Civil Monetary Penalties Inflation Adjustment, 82 Fed. Reg. 9,131 (Feb. 3, 2017); Civil Monetary Penalties Inflation Adjustment, 83 F.R. 3,944 (Jan. 29, 2018).

Not until June 19, 2020, did the DOJ issue its final rule again increasing the civil penalties assessed under the FCA and the AKS.[180] For the FCA, the DOJ increased the minimum penalty from $11,181 to $11,665 per claim and the maximum penalty from $22,363 to $23,331 per claim. As to the AKS, the DOJ increased the per-occurrence penalty from $22,363 to $23,331. These revised civil monetary penalties apply to all assessments of FCA and AKS penalties imposed after June 19, 2020, including assessed penalties associated with violations predating the June 19, 2020, adjustment. The DOJ's June 2020 rule also retroactively increased the FCA and AKS penalties assessed prior to June 19, 2020.

The current FCA penalties are as follows:

	DOJ Penalty Assessed after August 1, 2016	DOJ Penalty Assessed after February 3, 2017	DOJ Penalty Assessed after January 29, 2018	DOJ Penalty Assessed after June 19, 2020
Minimum Per-Claim Penalty	$10,781	$10,957	$11,181	$11,665
Maximum Per-Claim Penalty	$21,563	$21,916	$22,363	$23,331

The AKS penalties also increased as follows:

	DOJ Penalty Assessed after August 1, 2016	DOJ Penalty Assessed after February 3, 2017	DOJ Penalty Assessed after January 29, 2018	DOJ Penalty Assessed after June 19, 2020
AKS Per-Occurrence Penalty	$21,563	$21,916	$22,363	$23,331

12.2 COVID-Testing and EKRA Enforcement Risk

Given the billions of healthcare dollars already spent in response to the COVID-19 pandemic, the DOJ has raised concerns about the heightened risks of fraud and abuse related to distributed funds, instructing U.S. Attorneys' offices to "prioritize the detection, investigation, and prosecution of all criminal conduct related to the current pandemic."

One of those heightened risks is non-compliance with the Eliminating Kickbacks in Recovery Act ("EKRA"). Enacted in 2018, EKRA makes it a federal crime to knowingly and willfully (1) solicit or receive any remuneration in return for referring a patient to a recovery home, clinical treatment facility, or laboratory, or (2) pay or offer any remuneration either to induce such a referral or in exchange for an individual using the services of a recovery home, clinical treatment facility, or laboratory.[181] An EKRA violation is punishable by a fine of up to $200,000, imprisonment for up to 10 years, or both.

Non-compliance with EKRA is of particular concern given the increases in laboratory testing related to COVID-19. To date, clinical laboratories across the United States have processed approximately 80 million specimens for COVID-19-related diagnostic tests. Some important aspects of EKRA include:

- **EKRA extends to three types of healthcare providers.** EKRA's prohibition reaches recovery homes, clinical treatment facilities, and laboratories. Crucially, EKRA defines the term "laboratory" broadly to essentially capture all CLIA-certified clinical laboratories, regardless of the type of testing. As a result, even arrangements related to COVID-related testing may implicate EKRA.

180 See Civil Monetary Penalties Inflation Adjustment, 85 Fed. Reg. 37,004 (June 19, 2020).

181 18 U.S.C. § 220.

- **EKRA applies even when no federal dollars are involved.** Importantly, EKRA applies to all payors and prohibits arrangements based on the value or volume of referrals even if no federal dollars are involved.[182] While the AKS only applies to services paid for by federal healthcare programs, EKRA applies even if the testing or services are reimbursed by private or commercial insurance. EKRA thus expands federal oversight to transactions previously out of reach.

- **EKRA's exceptions are narrower than those under the AKS.** Although EKRA provides for seven statutory exceptions, those exceptions are limited and narrower in scope than the AKS safe harbors that healthcare providers have relied upon to structure their compensation and marketing arrangements. For example, while the AKS provides an exception for any payments to an employee as long as there is a *bona fide* employment relationship, the EKRA parallel exception does not permit volume- or value-based compensation to employees. This means that payments to employees may not vary based on the number of individuals referred, tests or procedures performed, or amounts billed to or received. Thus, common and historically accepted business practices—such as sales employees' commission-based compensation—are potentially within EKRA's scope.

Despite the breadth of EKRA's statutory reach and clinical laboratory industry lobbying efforts to limit ERKA's scope to urine drug testing, there remains uncertainty regarding how DOJ will apply this law. So far, DOJ has used EKRA sparingly, and it is difficult to predict whether DOJ will use it as a tool for prosecuting COVID-19-related fraud. DOJ has announced only two enforcement actions under EKRA to date. The first involved an office manager of a Kentucky substance abuse clinic who allegedly solicited kickbacks from a toxicology lab CEO in exchange for urine drug test referrals, and the second charged two individuals, one of whom directed recruiters to bribe drug-addicted individuals to enroll in drug rehabilitation and the other paid referral fees in exchange for those patient referrals. While DOJ has not aggressively pursued EKRA's enforcement to date, the increases in laboratory testing spurred by the COVID-19 pandemic may elevate EKRA as a potential enforcement tool.

182 EKRA applies to any "services covered by a health care benefit program." 18 U.S.C. § 220(a). EKRA defines "health care benefit program" to include "any public or private plan or contract affecting commerce, under which any medical benefit, item, or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item, or service for which payment may be made under the plan or contract." 18 U.S.C. § 220(e)(3); 18 U.S.C. § 24(b).