VOLUME I | 2021

HEALTHCARE ENFORCEMENT ROUNDUP

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INTRODUCTION

Stay current on the healthcare enforcement issues impacting your business' compliance strategies. In this installment of the Healthcare Enforcement Roundup, we address:

- Key areas of enforcement scrutiny in 2021, including growing numbers of relator complaints under the False Claims Act, COVID-19-related enforcement, and ongoing attention to private equity;
- Timely updates on Section 1135 waivers, telemedicine-related issues, and further interpretation regarding the enforceability of sub-regulatory guidance;
- The Office of Inspector General's Special Fraud Alert, which provides important guidelines for pharmaceutical and medical device speaker programs; and
- Pertinent developments in cases and other enforcement matters covered in prior issues.

ENFORCEMENT PREDICTIONS FOR 2021

False Claims Act

On January 14, 2021, the US Department of Justice (DOJ) issued a press release announcing that during the fiscal year ending September 30, 2020, it obtained more than $2.2 billion in settlements and judgments from civil cases involving fraud and false claims against the government under the federal False Claims Act (FCA). These amounts do not reflect monies recovered for state Medicaid programs. DOJ's press release also stated that it did not include settlements totaling billions of additional dollars that are not yet final or did not become final before the end of the fiscal year, specifically highlighting large settlements related to allegations of false claims related to opioids.

As previously reported, DOJ recorded more than $3 billion in settlements and judgments in 2019, meaning that the 2020 figures show a decline year-over-year. Further, the 2020 figures are the lowest settlement numbers since 2009, at $2.4 billion.[1] Several factors may have impacted the lower 2020 settlement figure, including delays occasioned by, and other effects of, the COVID-19 pandemic. As DOJ noted, several settlements in principle were reached but not finalized in fiscal year 2020 that would have increased the total recovery. Perhaps as a harbinger of things to come, 2020 also saw a considerable increase in relator complaints (672, 34 more than in 2019) and the largest number of DOJ-filed FCA cases since 1994 (250, 102 more than in 2019).

As noted in the press release, of the more than $2.2 billion in settlements and judgments recovered by the DOJ this past fiscal year, more than $1.8 billion relates to matters that involved the healthcare industry, including drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories and physicians. The largest recoveries in 2020 came from the drug industry. For example, following years of litigation, a large pharmaceutical manufacturer paid almost $600 million to resolve claims that it paid kickbacks to doctors to induce them to prescribe its drugs, including alleged selection of high-volume prescribers to serve as paid "speakers" to induce prescriptions. See below for an in-depth look at a Special Fraud Alert regarding speaker programs that was issued by the US Department of Health and Human Services (HHS) Office of Inspector General (OIG) not long after DOJ announced this settlement.

The press release identified settlements related to alleged violations of the federal Anti-Kickback Statute totaling $1 billion in the aggregate, or about half of the total recoveries for 2020.

In February 2021 in remarks delivered at the Federal Bar Association's annual Qui Tam Conference, Senator Chuck Grassley criticized courts for applying a more stringent materiality standard under the FCA than he believes is supported by the statute. He also criticized the DOJ's practice of seeking to dismiss certain non-intervened *qui tam* cases. The crux of Senator Grassley's criticism was based on his view that the government needs to "come down with a sledgehammer" on those who commit fraud, and that these developments are contrary to the aims of the FCA. To correct this, Senator Grassley promised to enact relator-friendly FCA amendments.

[1] https://www.justice.gov/opa/press-release/file/1354316/download.

Brian Boynton, the acting assistant attorney general of the DOJ's Civil Division, also spoke at the Conference and outlined the Biden administration's priorities for FCA enforcement, including fraud relating to the COVID-19 pandemic, opioids, electronic health records and telehealth. Although the massive outlay of federal funding has not yet resulted in a large wave of COVID-19-related enforcement activity (at least, not that is available in the public domain), there likely will be a marked increase as 2021 progresses, especially under the FCA. Providers, especially those that accept and/or retain COVID-19 relief funding, should ensure that their corporate compliance programs are well-functioning, and should specifically incorporate and monitor conditions tied to any relief funding.

COVID-19 Enforcement

One year into the COVID-19 pandemic, the federal government has already authorized approximately $5.4 trillion for COVID-19 relief through legislation such as the Coronavirus Aid, Relief, and Economic Security (CARES) Act, the Coronavirus Response and Relief Supplemental Appropriations (CRRSA) Act, the Consolidated Appropriations Act of 2021 and the American Rescue Plan Act of 2021.

Under the CARES Act alone, Congress appropriated $175 billion to healthcare providers under the Provider Relief Fund (PRF). Congress appropriated an additional $3 billion to the PRF under the CRRSA. PRF recipients are subject to ongoing government scrutiny and, in many cases, must fulfill specific audit requirements. For example, providers that receive more than $10,000 are subject to reporting requirements. Those that receive $750,000 or more in federal funding (including PRF payments and other federal financial assistance) during the fiscal year are subject to "single audit" requirements. While the PRF Reporting Portal's deadline has been delayed and audits have not begun yet, the government has already initiated enforcement actions and reviews to prevent fraud, waste and abuse with other COVID-19 response funding programs.

The CARES Act also established the Paycheck Protection Program (PPP), which provides small businesses with payroll funding support.[2] By January 31, 2021, the PPP had approved more than six million loans totaling almost $600 billion.[3] And, in January 2021, the Small Business Administration distributed more than 82,000 loans for almost $7.5 billion to the healthcare and social assistance industries alone.[4]

[2] *See The CARES Act Provides Assistance to Small Businesses*, US Dept. of the Treasury, https://home.treasury.gov/policy-issues/cares/assistance-for-small-businesses (last visited Feb. 10, 2021).
[3] *Paycheck Protection Program (PPP) Report Approvals through 01/31/2021*, US SBA, https://www.sba.gov/sites/default/files/2021-02/PPP_Report_Public_210131-508.pdf.
[4] *Id.*

In 2020, DOJ commenced enforcement actions against several companies that sought or used PPP funds.[5] DOJ alleged that some companies falsified the number of employees and payroll expenses, submitted false documentation and used the funds for ineligible expenses.[6] We anticipate an increase in similar enforcement activity in 2021 under the Biden administration, which is likely to re-examine the PPP, and is also likely to more closely scrutinize uses of any program funds that appear to be inconsistent with permitted uses, such as payment of significant compensation to owners or key personnel.

In addition, on January 12, 2021, DOJ announced its first civil FCA settlement related to the PPP. An internet retail company and its president and CEO agreed to pay $100,000 in damages and penalties to resolve civil fraud allegations for making false statements to obtain a $350,000 PPP loan. According to DOJ, the company, through its president and CEO, knowingly represented on its loan application that it was not in bankruptcy when, in fact, it was. This mattered because the PPP loan application provided that the loan could not be approved if the applicant was in bankruptcy proceedings. The company corrected the misrepresentation one day after receiving the loan and eventually returned the money upon demand from the Small Business Administration.

[5] *See* Texas Man Charged with COVID-Relief Fraud, False Statements and Money Laundering, DOJ (June 23, 2020), https://www.justice.gov/opa/pr/texas-man-charged-covid-relief-fraud-false-statements-and-money-laundering; *see also* Texas Man Charged with COVID Relief Fraud, DOJ (June 24, 2020), https://www.justice.gov/opa/pr/texas-man-charged-covid-relief-fraud; *see also* Hollywood Film Producer Charged with $1.7 Million COVID-Relief Fraud, DOJ (May 22, 2020), https://www.justice.gov/opa/pr/hollywood-film-producer-charged-17-million-covid-relief-fraud; *see also* Reality TV Personality Charged with Bank Fraud, DOJ (May 13, 2020), https://www.justice.gov/opa/pr/reality-tv-personality-charged-bank-fraud.

[6] *See id.*

Nonetheless, in the government's view, that was too little, too late.

Given the vast amount of federal funds distributed to date, the United States is gearing up for fraud investigations and enforcement actions.[7] On December 4, 2020, for instance, HHS announced the creation of the False Claims Act Working Group in partnership with the DOJ and OIG. Its purpose is to better coordinate between the departments in identifying potential FCA violations. In a press release announcing the Working Group, HHS noted that the "need for close coordination . . . has taken on even greater salience now, as HHS administers significant supplemental funds to combat a historic pandemic." HHS went on to note that it "has provided billions of dollars for COVID-19 vaccine and therapeutics research, development, distribution, and administration. Through the Provider Relief Fund, HHS has provided over $100 billion to healthcare providers, including many who are on the front lines of the pandemic response."

With the specter of additional investigations and enforcement actions on the horizon, providers should consider taking the following steps in the months and years to come:

- Continue to practice good compliance hygiene at all times. In particular, maintain contemporaneous records regarding the receipt and spending of federal funds.
- Document deviations from policies and demonstrate why such deviations are necessary (*e.g.*, saving lives or no reasonable alternative).

[7] Letter from Norris Cochran, Sec'y of Health & Human Serv., to Governors (Jan. 22, 2021), *available at*: https://ccf.georgetown.edu/wp-content/uploads/2021/01/Public-Health-Emergency-Message-to-Governors.pdf.

- Follow government instructions. When receiving an instruction or answer to a question, document the details of the conversation contemporaneously, including the name of the government official.
- Where program rules are ambiguous or self-contradictory, seek the advice of legal counsel experienced with the program, and contemporaneously document all relevant decisions on how to interpret the rules in either correspondence to the relevant agency (most protective) or in an internal file that can be produced if scrutiny occurs.
- Adhere to proper billing and coding rules when submitting claims for COVID-19 tests and treatments.
- Where necessary, revise policies and procedures to address the changing circumstances of COVID-19.
- Train employees and contractors on proper fraud, waste and abuse compliance.
- Build up the internal audit function to monitor claims for appropriateness before submission, and evaluate audit plans to take into account any changed circumstances.

Such measures will ensure that providers have a roadmap of actions taken and why—information that will prove useful to stave off government investigations and whistleblowers.

Other Trends

OUTLOOK ON HEALTHCARE ENFORCEMENT UNDER THE BIDEN ADMINISTRATION

The Biden administration has already announced that it will likely extend the current public health emergency through the end of 2021, which would extend current waivers and flexibilities, such as telehealth payment regulations and hospitals without walls programs.[8]

PRIVATE EQUITY

We originally reported in the Q4 2019 Report that private equity (PE) was an increasing focus of the government, FCA relators and others. This remains true, and we expect to see continuing enforcement activity in this area, particularly as it relates to healthcare investments.

In November 2020, the DOJ announced it had entered into settlement agreements with Johnson & Johnson's subsidiary Medical Device Business Services, Inc. (MDBS) and a PE firm, the Gores Group (TGG).[9] MDBS agreed to pay $10 million to settle FCA allegations that Therakos, a former Johnson & Johnson subsidiary, engaged in an off-label marketing scheme.[10] TGG agreed to pay an additional $1.5 million to resolve allegations that Therakos continued those alleged practices after TGG acquired Therakos.[11]

Further highlighting the continued focus on PE firms, Principal Deputy Attorney General Ethan

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[8] Letter from Norris Cochran, Sec'y of Health & Human Serv., to Governors (Jan. 22, 2021), *available at*: https://ccf.georgetown.edu/wp-content/uploads/2021/01/Public-Health-Emergency-Message-to-Governors.pdf

[9] Press Release, US Department of Justice, *Former Owners of Therakos, Inc. Pay $11.5 Million to Resolve False Claims Act Allegations of Promotion of Drug-Device System for Unapproved Uses to Pediatric Patients* (E.D. Pa. Nov. 19, 2020). *See also* United States ex rel. Johnson et al. v. Therakos, Inc. et al., No. 12-1454 (E.D. Pa.).[NOTE: I left the "See" capitalized – it either needs to be capitalized, or joined to the previous sentence with a semicolon.]

[10] MDBS Settlement Agreement, 3, Nov. 17, 2020; *see also* Therakos Press Release, *supra.*

[11] The settlement agreement entered into by DOJ and TGG covered conduct that occurred during TGG's ownership of Therakos, between 2013 and 2015. TGG Settlement Agreement, 2-3, Nov. 17, 2020; *see also* Therakos Press Release, *supra.*

Davis of the DOJ gave a speech in June 2020 to the Institute for Legal Reform, US Chamber of Commerce.[12] In his speech, Davis stated:

> Our enforcement efforts may also include, in appropriate cases, private equity firms that sometimes invest in companies receiving CARES Act funds. When a private equity firm invests in a company in a highly regulated space like healthcare or the life sciences, the firm should be aware of laws and regulations designed to prevent fraud. Where a private equity firm takes an active role in illegal conduct by the acquired company, it can expose itself to False Claims Act liability.

PE stakeholders should remain aware of the potential for increased scrutiny and the risk of enforcement actions.

UPDATE ON 1135 WAIVERS

The COVID-19 public health emergency (PHE) has dramatically changed normal operating procedures for healthcare providers. While federal and state governments have taken unprecedented action to waive certain regulatory requirements, hospitals and other providers confronted with an ongoing pandemic have, at times, struggled to remain in compliance with even these modified requirements. The Biden administration has stated that it will likely extend the PHE through the end of 2021, and that it will give providers a transition period before it rescinds any PHE-linked waivers.[13] Nonetheless,

we anticipate increased enforcement focus on section 1135 waivers as the PHE winds down.

What Is a 1135 Waiver?

As reported in the 2020 Mid-Year Roundup, under section 1135 of the Social Security Act, HHS and the Centers for Medicare and Medicaid Services (CMS) may temporarily waive or modify certain Medicare, Medicaid and Children's Health Insurance Program requirements during a PHE to ensure that healthcare items and services meet the needs of individuals enrolled in those programs, and may guarantee that those who provide items and services are exempted from sanctions (except in cases of fraud or abuse).

In response to COVID-19, CMS made changes to coverage, participation, payment and billing requirements for healthcare providers. It also issued a blanket waiver of Stark Law sanctions, giving providers greater flexibility in contracting for office space or professional services between referral sources. This Stark waiver has specific requirements—for example, the purpose of the arrangement must be related to COVID-19

[12] Press Release, US Department of Justice, *Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform* (June 26, 2020).

[13] *See Biden Administration Announces Intent to Extend PHE Through 2021*, MWE (Jan. 28, 2021), https://www.mcdermottplus.com/payment-innovation/biden-

response—and it does not waive all Stark Law exception elements.

WHAT'S NEXT?

While providers can take some comfort in knowing the PHE (and, therefore, the section 1135 waivers and other flexibilities) will not expire soon, they should nonetheless prepare for scrutiny as to how they utilized waivers during the pandemic. For instance, HHS may ask whether the use of a waiver was warranted and whether any associated requirements (i.e., to only use certain waivers in times of a "surge") were satisfied. Managing care during a pandemic is exceedingly difficult. With the passage of time, the potential for a provider to lose track of the changes it has adopted during the pandemic increases, thereby accelerating the risk of compliance and monitoring gaps, and compromising the provider's ability to transition back to normal operations when the PHE ends.

For these reasons, providers should continue to practice good compliance hygiene during the pandemic and plan ahead for a return to normal operations when the PHE ends. Here are a few practical steps that providers can take now:

- Identify actions you will take to return to pre-PHE policies, procedures and processes, and where feasible, plan to shift operations back to pre-PHE policies, procedures and processes so that clinicians and staff are appropriately prepared.
  - » When possible, revise policies and procedures to address the changing circumstances of COVID-19. What was acceptable at the beginning of the PHE may not be as acceptable as a "new normal" emerges.
  - » Determine where modifications are appropriate and permissible to maintain.
- If you made decisions based on government instructions, ensure that there is a "paper trail" to identify those involved in the decision. In the absence of contemporaneous documentation, work with counsel to prepare a memoranda gathering recollections and evidence on hand in case decision-making is subject to scrutiny.
- Make information accessible to employees and contractors on proper fraud, waste and abuse compliance, and provide key compliance training to new providers as needed.
- Support the provider's internal audit function to monitor claims for appropriateness before submission, and evaluate audit plans to take into account any changed circumstances.

HEALTHCARE ENFORCEMENT AND TELEMEDICINE

On February 17, 2021, Acting Assistant Attorney General Brian Boynton addressed the Federal Bar Association's Qui Tam Conference. During his speech, he focused on the DOJ's "False Claims Act enforcement priorities" and noted the DOJ's "continued focus on telehealth schemes, particularly given the expansion of telehealth during the pandemic." In the past several months, DOJ, HHS and OIG have shown that telehealth is a current focus of healthcare enforcement and will continue to be so in the months to come.

administration-announces-intent-to-extend-phe-through-2021/.

The September 30, 2020, Takedown

On September 30, 2020, the DOJ, working with the OIG and state law enforcement agencies, issued a press release describing the largest national healthcare fraud "takedown" in the DOJ's history. The government charged more than 345 defendants with participating in healthcare fraud schemes involving more than $6 billion in alleged losses to federal healthcare programs, including $4.5 billion stemming from telemedicine arrangements.

As DOJ explained in a summary of the takedown, many of the cases involved telehealth executives who allegedly paid healthcare providers to order unnecessary durable medical equipment, genetic and other diagnostic testing, and medications, either without any patient interaction or with only a brief phone call. According to DOJ, these arrangements involved kickbacks to telehealth executives, and the items and services were generally "worthless to patients . . . and delayed their chance to seek appropriate treatment for medical complaints."

In connection with the takedown, OIG issued a fact sheet and a graphic highlighting the fact that since 2016, the OIG has seen a significant increase in telefraud, i.e., schemes that leverage "aggressive marketing and so-called telehealth services."

Recent Criminal Prosecutions

In the first few months of 2021, DOJ has already announced a host of new criminal cases involving telemedicine.

On January 25, 2021, Larry Everett Smith entered the latest guilty plea in an ongoing telefraud conspiracy that involved several other individuals and at least five companies. According to the superseding indictment, Smith and the others hatched a nationwide scheme to defraud pharmacy benefit managers into paying for fraudulent prescriptions for topical creams, vitamins and other products. Smith's guilty plea followed four related pleas in December 2020 from those involved in the same conspiracy.

Two days later, on January 27, 2021, a New Jersey physician received 33 months in prison for his role in a telemedicine scheme to prescribe expensive compounded medications to patients who did not need them. The physician admitted to signing prescriptions for compounded medications without establishing a doctor-patient relationship, speaking to the patient or conducting any medical evaluation. Instead of providing the prescriptions to the patient, the physician would return them to pharmacies involved in the conspiracy. This scheme allegedly resulted in losses to healthcare benefit programs of more than $24 million, including losses to government healthcare programs of more than $7 million.

Then, on February 5, 2021, the DOJ indicted the owners of two telemedicine companies for allegedly orchestrating a nationwide scheme to receive kickbacks in exchange for ordering medically unnecessary orthotic braces for Medicare beneficiaries.

OIG Work Plan

In addition to recent DOJ civil and criminal cases, healthcare providers should take note of the OIG's Active Work Plan, which includes multiple action items specific to telemedicine.

In October 2020, OIG announced a review focused on CMS waivers (and other flexibilities) implemented to provide Medicare beneficiaries with broader access to telehealth services. In this review, OIG is examining Medicare Parts B and C data to determine program integrity risks resulting from the CMS telehealth flexibilities. In particular, OIG is scrutinizing provider billing patterns to determine which characteristics may raise program integrity concerns. In a related Work Plan announcement, OIG said that it is evaluating how telehealth services are being used by Medicare beneficiaries compared to in-person delivery of the same services. Both reports are expected in 2021.

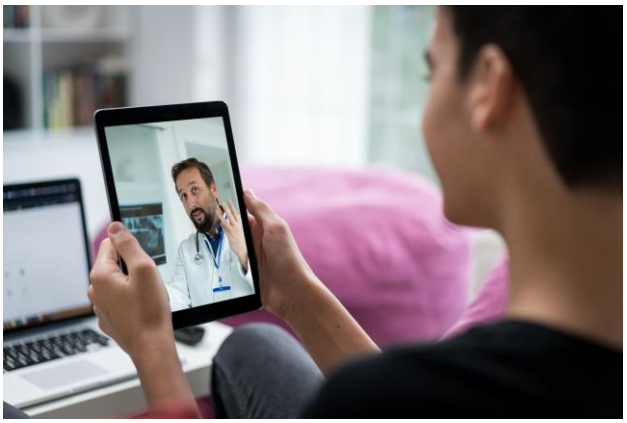
The January 2021 OIG Work Plan picks up on this theme and focuses on other telemedicine-related focus areas. For instance, OIG is evaluating Home Health Agency (HHA) telehealth implementation as it relates to ongoing challenges for HHAs brought on by the COVID-19 pandemic. This evaluation will include findings regarding how well HHA emergency preparedness plans worked during the pandemic. OIG will also look at HHA telehealth services provided in conjunction with section 1135 waivers and skilled services furnished via telehealth. This review will focus on whether those services were provided and billed in compliance with Medicare requirements. OIG will report any improperly billed services as overpayments.

Finally, OIG also announced its plan to conduct a two-phase Medicare Part B audit for the period covering the COVID-19 pandemic. Phase one will ask whether certain telehealth services *(e.g.*, evaluation and management, opioid use disorder, end-stage renal disease and psychotherapy) satisfy Medicare program requirements. In phase two, OIG will evaluate additional telehealth services to determine whether the services meet Medicare requirements. Phase two is expected to include distant and onsite location services, virtual check-in services, electronic visits, remote patient monitoring, use of telehealth technology and annual wellness visits. This report is expected to be released later this year.

Practical Implications of the Focus on Telehealth

The government's growing focus on telehealth arrangements further highlights the need for telehealth providers be vigilant about monitoring compliance. The following are measures telehealth providers may want to consider:

- Be particularly diligent in the design and compliance oversight of marketing strategies to confirm that patients are reached through appropriate channels, which may not include "cold calls."



- Ensure that state-level requirements to establish a legitimate physician-patient relationship are satisfied. This involves evaluating the proposed arrangement under applicable state laws and regulations, some of which have changed in light of COVID-19.
- Ensure that the provider has a robust compliance program that appropriately addresses, among the other elements, review of marketing materials and practices, as well as requirements related to permissible compensation arrangements.
- Carefully evaluate billing and coding practices to ensure such practices are consistent with both government and commercial payor requirements. Again, several of these requirements have changed considerably because of COVID-19 and likely will continue to evolve.

SPECIAL FRAUD ALERT – SPEAKER PROGRAMS

As previously reported in *Special Fraud Alert: OIG Raises Concerns With Speaker Programs*[14], the OIG released a Special Fraud Alert[15] in November 2020 regarding the fraud and abuse risks associated with the offer, payment, solicitation or receipt of remuneration relating to speaker programs by pharmaceutical and medical device companies. Speaker programs are a standard way for pharmaceutical and devices manufacturers to educate and inform healthcare providers about the risks, benefits and expected clinical outcomes of FDA-regulated products. FDA has long recognized certain so-called "bona fide scientific exchanges" among healthcare professionals as beyond the purview of traditional advertising and promotion restrictions when certain guardrails are in place. Nonetheless, these programs have long been the target of DOJ and OIG investigations.

OIG first identified speaker programs as an area of potential risk under the Anti-Kickback Statute (AKS) in the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers[16]. Since then, OIG and DOJ have investigated and resolved many fraud cases involving allegations that

[14] *Special Fraud Alert: OIG Raises Concerns with Speaker Programs*, McDermott Will & Emery (Nov. 17, 2020), https://www.mwe.com/insights/speaker-program-fraud-alert/.
[15] US Dept. of Health & Human Serv., Off. of Inspector Gen., *Special Fraud Alert: Speaker Programs* (Nov. 16, 2020), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/SpecialFraudAlertSpeakerPrograms.pdf
[16] *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, 68 Fed. Reg. 23731 (May 5, 2003), available at https://oig.hhs.gov/authorities/docs/03/050503FRCPGPharmac.pdf.

remuneration offered and paid in connection with speaker programs violated the AKS.

In the Special Fraud Alert, OIG indicated that the following activities "strongly suggest that one purpose of the remuneration to the physician or other health care professional speaker and attendees is to induce or reward referrals:"

- Selecting high-prescribing healthcare professionals as speakers
- Holding speaker programs at expensive restaurants or venues not conducive to an educational presentation
- Allowing attendees at a speaker program who do not have a legitimate reason to attend.

OIG also cautioned that the availability of information provided in a speaker program through other sources that do not involve payment—such as online resources or medical journals—suggests that "at least one purpose of remuneration is often to induce or reward referrals."

OIG provided a list of certain "suspect characteristics" of speaker programs, which, taken separately or together, potentially indicate a violation of the AKS:

- The company sponsors speaker programs where little or no substantive information is actually presented.
- Alcohol is available or a meal exceeding modest value is provided to program attendees (the concern is heightened when the alcohol is free).
- The program is held at a location that is not conducive to the exchange of educational information (*e.g.*, restaurants, or entertainment or sports venues).
- The company sponsors a large number of programs on the same or substantially the same topic or product, especially in situations involving no recent substantive change in relevant information.
- There has been a significant period of time with no new medical or scientific information, nor a new FDA-approved or cleared indication for the product.
- Healthcare professionals attend programs on the same or substantially the same topics more than once (as either a repeat attendee or as an attendee after being a speaker on the same or substantially the same topic).
- Attendees include individuals who don't have a legitimate business reason to attend the program, including, for example, friends, significant others or family members of the speaker or healthcare professional attendee; employees or medical professionals who are members of the speaker's own medical practice; staff of facilities for which the speaker is a medical director; and other individuals with no use for the information.
- The company's sales or marketing business units influence the selection of speakers, or the company selects healthcare professional speakers or attendees based on past or expected revenue that the speakers or attendees have or will generate by prescribing or ordering the company's product(s) (*e.g.*, a return on investment analysis is considered in identifying participants).
- The company pays healthcare professional speakers more than fair market value for the speaking service, or pays compensation that takes into account the volume or value of past or

potential future business generated by the speakers.

Finally, in the Special Fraud Alert, OIG specifically cautioned that parties involved in speaker programs "may be subject to increased scrutiny," raising the likelihood of increased enforcement involving speaker programs in 2021. These parties likely include any drug or device company that organizes or pays remuneration associated with a speaker program, any healthcare professional who is paid to speak, and any healthcare professional attendees who receive remuneration from the company to attend the speaker program.

OIG's alert may be controversial because the PhRMA Code and AdvaMed Code already discuss standards and compliance guardrails for speaker programs. Nevertheless, in light of the potential for increased scrutiny, companies should take the Special Fraud Alert as an opportunity to evaluate their programs and determine whether adjustments could be made. Specifically, companies could review their current "fair market value" databases and compensation models to ensure they have appropriate guidelines and justifications for the compensation models they use for both in-person and virtual speaker programs. Companies should also examine their existing guardrails and requirements surrounding the need for speakers, selecting and paying such speakers, and providing remuneration to healthcare professional attendees, to ensure such policies align with OIG's Special Fraud Alert.

FURTHER INTERPRETATIONS OF THE ENFORCEABILITY OF SUB-REGULATORY GUIDANCE

HHS has continued to interpret when Medicare sub-regulatory guidance (*i.e.*, guidance not promulgated through notice-and-comment rulemaking) is enforceable. In the final days of the Trump administration, HHS promulgated two rules that limit HHS's ability to use sub-regulatory guidance in enforcement actions. Already, President Biden has issued an executive order rescinding the Trump era orders upon which these two HHS rules were based. At the same time, courts continue to provide mixed messages regarding when alleged violations of Medicare sub-regulatory guidance can serve as the hook for FCA liability.

HHS Advisory Opinion

On December 3, 2020, HHS's Office of the General Counsel (OGC) issued Advisory Opinion (AO) 20-05[17] to clarify its interpretations of *Azar, Secretary of Health and Human Services v. Allina Health Services, et al.*[18] Under the Supreme Court's decision, HHS must undergo notice-and-comment rulemaking when making any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility

[17] *See* US Department of Health and Human Services, Office of the General Counsel, "Advisory Opinion 20-05 on Implementing *Allina*" (Dec. 3, 2020). Advisory Opinion 20-05 followed an internal memo, leaked in November 2019, which outlined HHS OGC's initial understanding of the Court's decision. More extensive coverage of the internal memo can be found in our Q4 2019 Report.

[18] 139 S. Ct. 1804 (2019). Notably, several other hospitals and health systems were parties in filing the lawsuit.

of individuals, entities, or organizations to furnish or receive services or benefits under [Medicare]."[19] Key takeaways from AO 20-05 include the following:

- HHS OGC interprets "substantive legal standard" to mean "any issuance that: 1) defines, in part or in whole, or otherwise announces binding parameters governing, 2) any legal right or obligation relating to the scope of Medicare benefits, payment by Medicare for services, or the eligibility of individuals, entities, or organizations to furnish or receive Medicare services or benefits, and 3) sets forth a requirement not otherwise mandated by statute or regulation."
- When guidance should have been promulgated through notice-and-comment rulemaking (but was not), HHS's ability to bring enforcement actions predicated solely on violations of that guidance is "restricted." However, HHS can still bring enforcement actions when guidance documents are "closely tied to statutory or regulatory requirements."
- HHS OGC confirmed its interpretation that local coverage determinations (LCDs) issued by Medicare Administrative Contractors do not "establish or change" a substantive legal standard, but noted that government enforcement actions based solely on LCDs are "generally unsupportable."
- Even if a guidance document cannot be enforced under the Supreme Court's holding, CMS can still enforce it in contracts, as long as the guidance is "expressly and specifically referenced" as an obligation of the party.
- In the future, if HHS intends to create binding rules in preamble text, HHS will signal this intent in the proposed and final rule preamble by using the phrase "HHS intends to bind itself" or by stating that HHS will engage in notice-and-comment rulemaking in order to change the stated preamble policy.

Revocation of Certain Executive Orders Concerning Federal Regulation

On January 20, 2021, President Biden issued an executive order (the Biden order) entitled "Revocation of Certain Executive Orders Concerning Federal Regulation." The Biden order's stated aim is to revoke "harmful policies and directives that threaten to frustrate" the government's ability to confront problems, and it empowers agencies to use appropriate regulatory tools to respond to policy challenges. At this time, the Biden order does not revoke any current rules or guidance documents. Instead, it revokes several Trump administration executive orders that relate to agency regulations, rules, or guidance. Nonetheless, the Biden order raises significant questions about whether certain Trump era rules, regulations or guidance documents remain in effect, particularly because it rescinds the executive orders upon which many regulations were promulgated, including the following: [20]

[19] *Id.* at 1808-09.

[20] The revoked executive orders include: Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs); Executive Order 13777 (Enforcing the Regulatory Reform Agenda); Executive Order 13875 (Evaluating and Improving the Utility of Federal Advisory Committees); Executive Order 13891 (Promoting the Rule of Law Through Improved Agency Guidance Documents); Executive Order 13892 (Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication); and Executive Order 13893 (Increasing Government Accountability for Administrative Actions by Reinvigorating Administrative PAYGO).

- On December 7, 2020, HHS promulgated the final "Department of Health and Human Services Good Guidance Practices" rule [21]via notice-and-comment rulemaking (effective January 6, 2021.) The final rule prohibits HHS from using guidance documents[22] to establish legal obligations not already reflected in duly enacted statutes or regulations. [23] The rule also establishes a new process for issuing guidance documents.[24]
- On January 14, 2021, the *Federal Register* published the "Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions" final rule (effective January 12, 2021).[25] The rule is limited to civil administrative enforcement actions and does not apply to any action related to a criminal investigation or prosecution, or any civil enforcement action or related investigation by the DOJ.[26]

The Biden order further instructs the US Office of Management and Budget director and agency leaders to "take steps to rescind any orders, rules, regulations, guidelines, or policies, or portions thereof, implementing or enforcing the Executive Orders" identified as being revoked.[27]

It remains to be seen whether the Biden administration's HHS will prioritize rescinding the "Good Guidance Practices" rule and/or the "Transparency and Fairness in Civil Administrative Enforcement Actions" rule. Given that the "Transparency and Fairness" rule was promulgated without notice-and-comment, the rule could also be rescinded without notice-and-comment (as long as HHS has good reason for the reversal and appropriately considers reliance interests, under *F.C.C. v. Fox Television Stations, Inc.*)[28] The "Good Guidance Practices" rule, however, was promulgated through notice-and-comment rulemaking and would also need to be rescinded via the notice-and-comment process.

FCA Developments

Recent judicial interpretations have muddied the waters on whether alleged non-compliance with Medicare sub-regulatory guidance can be the basis for FCA liability. As covered in our Q4 2019 Report, two cases in 2019 produced opposite results. More recently, in *United States ex rel. Gray v. Mitias Orthopaedics*, the US District Court for the Northern District of Mississippi signaled its reluctance to hold that *Allina et al.* precludes liability under the FCA in all cases.[29] In *Gray*, the relator's FCA claims were based on alleged non-compliance with LCDs (among other guidance) and on the defendant's billing for brand name drugs used in procedures when generic or compounded drugs

[21] *See* Department of Health and Human Services Good Guidance Practices, 85 Fed. Reg. 78,770 (Dec. 7, 2020) (codified at 45 CFR Part 1).
[22] In the rule, HHS defines "guidance document" as "any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation." *Id.* at 78,785.
[23] *Id.* at 78,785.
[24] *Id.* at 78,786-787.
[25] Department of Health and Human Services Transparency and Fairness in Civil Administrative Enforcement Actions, 86 Fed. Reg. 3,010 (Jan. 14, 2021) (codified at 45 CFR Part 1). HHS did not undertake notice-and-comment rulemaking for the rule, as it implicates internal agency organization, procedure, or practice (exempting the rule from notice-and-comment requirements under the Administrative Procedure Act, 5 USC 551 *et seq*.).
[26] *Id.* at 3,011.
[27] The executive order acknowledges that the rescission of these rules must be done in compliance with applicable law, including the Administrative Procedure Act, 5 USC 551 *et seq*.
[28] *See* F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502 (2009).
[29] United States ex rel. Gray v. Mitias Orthopaedics, No. 15-127, 2021 WL 79615 (N.D. Miss. Jan. 11, 2021).

were actually used.[30] Although the court noted that the relator's strongest claim (*i.e.*, that the defendant billed for more expensive drugs that he did not actually use) did not depend upon the LCD guidance to be alleged, the court also refused to hold that *Allina et al.* would necessarily preclude FCA liability for LCD non-compliance.[31] In denying the defendant's motion to dismiss, the district court expressed doubt that FCA actions are "enforcement actions," and noted that *Allina et al.* should not create a "retroactive get-out-of jail free card for defendants."[32]

UPDATES TO PRIOR REPORTS

UPDATE: Cases Interpreting Materiality Standard Under *Escobar*

Over the past year, courts have continued to grapple with the FCA's materiality standard as interpreted by *Univ. Health Servs., Inc. v. U.S. ex rel. Escobar*.[33]

In *United States ex rel. Scollick v. Narula*,[34] the relator alleged that the defendants violated the FCA by fraudulently registering their construction company as a service-disabled, veteran-owned small business (SDVOSB), then bidding and securing contracts for construction jobs reserved for SDVOSBs.[35] The defendants moved for judgment on the pleadings, which the district court construed as a 12(b)(6) motion. The defendants argued that the relator's second amended complaint did not "meet the rigorous materiality standard set forth by the Supreme Court in Escobar."[36]

The district court disagreed, holding that the Supreme Court in *Escobar* did not intend for the rigorous materiality standard to apply to FCA suits that allege falsity under the fraud in the inducement theory.[37] Under this theory, it is the initial fraud used to procure the contract that taints the claims submitted to the government for payment under the contract.[38] Therefore, the court explained, the relator does not need to allege that the false statements were material because all claims are automatically tainted by the fraudulent procurement of the contract.[39] Furthermore, the fraud in the inducement theory "already has a strict materiality requirement baked in," and for a claim to be false under this theory, "the contract must have been "procured by fraud."[40] Finally, the district court found its analysis consistent with the analysis in *Escobar* because, in that case, the Supreme Court "explicitly recognized that a party can be liable" under the FCA when it secures a government contract "by fraudulent means."[41] Accordingly, the district court held that the relator properly pled materiality and falsity and denied the defendants' motion to dismiss.

Almost a month after *Scollick*, and with a similar fact pattern, the US Court of Appeals for the Second

[30] *Id.* at *1.
[31] *Id.* at *9, *11.
[32] *Id.* at *11-12.
[33] 136 S. Ct. 1989 (2016).
[34] 2020WL6544734, Case No. 14-cv-1339 (D.D.C. Nov. 6, 2020).
[35] *Id.* at *1.
[36] *Id.* at *6.
[37] *Id.* at *8.
[38] *Id.* at *9.
[39] *Id.*
[40] *Id.*
[41] *Id.* at 10.

Circuit held that in an FCA action pursued under a fraudulent inducement theory, the district court should consider both the government's decision to award the contract in the first place and "its ultimate decision to pay under the contract" when evaluating materiality.[42] Like the relators in *Scollick*, the United States brought a claim under the FCA alleging that the defendants fraudulently registered their company as a SDVOSB and received contracts from the US Department of Veterans Affairs (VA), the US Army and the US Air Force as a result of the fraud.[43] The district court dismissed the government's complaint because the government did not plead that the misrepresentation was material to the government's decision to pay.[44] Relying on *Escobar*, the Second Circuit reversed. It first explained that the Supreme Court had "rejected the notion that FCA liability is limited to instances in which a defendant violates an express condition of payment."[45] In fact, "such a rule would 'undercut[ ]' the FCA by imposing no liability for 'misrepresenting compliance with a condition of eligibility to even participate in a federal program when submitting a claim.'"[46]

The analysis did not end there, however. The Second Circuit also noted that Escobar held that the government's behavior after learning about noncompliance was also "highly relevant" to the materiality analysis.[47] The Second Circuit ultimately held that being a SDVOSB was material to the government's decision to award the defendants the contracts and vacated the dismissal.[48] The Second Circuit also held that the individual defendant, Strock, knew that his company was not a SDVOSB and that the status was material to the government's decision to pay under the contract.[49] Therefore, the government sufficiently alleged that "Strock acted in reckless disregard of the materiality of the SDVOSB compliance" to survive the motion to dismiss.[50] The Second Circuit did not attribute similar knowledge to co-defendant Golde and affirmed the district court's dismissal of the case against him.[51]

Just recently, the US Court of Appeals for the Eleventh Circuit issued a ruling that sought to clarify the materiality standard.[52] In that case, the relators brought a *qui tam* action against lenders, claiming that they charged closing fees to veterans in connection with mortgage loans in violation of regulations established by the VA.[53] The lenders would then certify to the VA that they charged only permissible fees in order to induce the VA to guarantee the loans and pay out if a borrower defaulted on the loan.[54]

The district court granted the defendants' motion for summary judgment on the relator's FCA claim and ruled that "no reasonable jury could find [that the defendants'] alleged fraud was material."[55] The district court found that "a lender's truthful certification that it charged only permissible fees was a condition of the government's payment" on the loans it guaranteed and essential to the bargain between the VA and the defendant.[56] Nonetheless, the district court found that the VA continued to pay loans borrowers defaulted on, despite its knowledge

[42] *United States v. Strock*, 982 F.3d 51, 62 (2d Cir. 2020).
[43] *Id.* at 56-57.
[44] *Id.* at 58.
[45] *Id.* at 61.
[46] *Id.* at 61 (quoting *Escobar*, 136 S. Ct. at 2002).
[47] *Id.*
[48] *Id.* at 65.
[49] *Id.* at 66-67.
[50] *Id.*
[51] *Id.* at 67-68.
[52] *United States v. Mortgage Investors Corporation*, No. 19-12736, 2021WL137739 (11th Cir. Jan. 15, 2021).
[53] *Id.* at *2.
[54] *Id.*
[55] *Id.* at *1.
[56] *Id.* at *4-*5.

of the defendants' failure to adhere to the fee regulations.[57] Therefore, adherence to the fee regulations was not material.[58]

The Eleventh Circuit disagreed and held that the government's payment decision, while relevant to the materiality inquiry, was not dispositive.[59] Rather, "the significance of continued payment may vary depending on the circumstances."[60] Here, the VA was required by law to pay the defaulted loans, regardless of any fraud by defendant, suggesting that the VA's actions after becoming aware of the fraud were not dispositive in the materiality analysis.[61] Instead, "[l]ooking at the VA's behavior holistically, the record shows that the VA took a number of actions to address noncompliance with fee regulations."[62] The Eleventh Circuit believed that this evidence rebutted and undercut the "strong evidence of immateriality" established by the VA's decision to honor the loans when a borrower defaulted.[63] Therefore, the Eleventh Circuit reversed the grant of summary judgment because "there is sufficient evidence to support a finding of materiality," and it is up to the factfinder to make the final determination.[64]

UPDATE: Cases Interpreting *Care Alternatives* And Objective Falsity

As reported in the 2020 Mid-Year Roundup, the US Courts of Appeals for the Third Circuit[65] and the Eleventh Circuit[66] have issued arguably conflicting rulings on whether a difference in medical opinion can establish the "falsity" element of the FCA. At its conference on February 19, 2021, the Supreme Court of the United States considered whether to grant certiorari in *Care Alternatives v. United States ex rel. Druding et al.*[67] The question presented was "[w]hether a physician's honestly held clinical judgment regarding hospice certification can be 'false' under the False Claims Act based solely on a reasonable difference of opinion among physicians."[68]

Care Alternatives contended that a good faith difference of medical opinion regarding a hospice patient's life expectancy is not grounds to establish falsity. It argued that the disagreement between the circuits is "both real and practically significant, the [Third Circuit decision] is plainly wrong, and the issue is consequential."[69] By comparison, Druding argued that the FCA does not define "false or fraudulent," and therefore disagreements of opinion can establish legal falsity. In Druding's view, because objectivity is a principle of scienter rather than falsity, the statement of opinion does not itself need to be objectively false.[70] Druding further

[57] *Id.* at *8.
[58] *Id.*
[59] *Id.* at *7.
[60] *Id.*
[61] *Id.* at *7.
[62] *Id.* at *8.
[63] *Id.* at *9.
[64] *Id.*
[65] *United States v. Care Alternatives*, 952 F.3d 89 (3d Cir. 2020).

[66] *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019). For more AseraCare analysis, see McDermott's Q4 2019 *Healthcare Enforcement Quarterly Roundup.*
[67] US Supreme Court Docket #20-371, available at https://www.supremecourt.gov/search.aspx?filename=/docket/docketfiles/html/public/20-371.html.
[68] *Care Alternatives v. United States*, Petition for Writ of Certiorari, Docket #20-371, Sept. 16, 2020 (available at https://www.supremecourt.gov/DocketPDF/20/20-371/154133/20200916115519875_Druding%20Cert%20Petition%209-16-20%20FINAL.pdf).
[69] *Care Alternatives v. United States*, Reply Brief of Petitioner, Docket #20-371, Jan. 26, 2021 (available at https://www.supremecourt.gov/DocketPDF/20/20-371/167192/20210126102658567_20-371%20Reply%20Brief.pdf).
[70] *Care Alternatives v. United States*, Reply Brief of Petitioner, Docket #20-371, Jan. 26, 2021 (available at https://www.supremecourt.gov/DocketPDF/20/20-

argued that the circuits merely characterize the same substantive test in slightly different ways: the Third Circuit separates falsity and scienter into separate elements, whereas the Eleventh Circuit aggregates those elements into the concept of "objective falsity."[71] The difference in formulation does not lead to different outcomes, according to Druding, because both circuits consider the same types of evidence to answer the same questions.

On February 22, 2021, the Supreme Court denied *certiorari*, meaning that the objective falsity question in the context of medical judgments will remain unresolved for the time being. We will continue to monitor this important topic closely.

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[71] *Id.* at 10.

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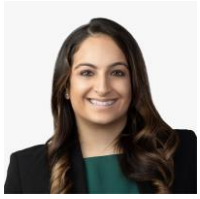

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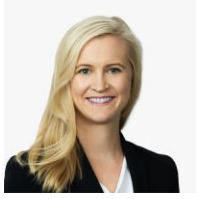

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