MINTZ

HEALTH CARE ENFORCEMENT

2021 Year in Review & **2022** Outlook

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INTRODUCTION

In 2021, health care fraud enforcement authorities directed attention to priorities of recent years while increasing their focus on emerging areas. Perhaps necessarily, enforcement efforts targeted some of the dominant challenges of the day: the COVID-19 pandemic and the worsening opioid epidemic. As we predicted in our **Health Care Enforcement 2020 Year in Review & 2021 Outlook**[1/] (2021 Outlook), the government aggressively pursued many forms of alleged fraud involving COVID-19, which included misuse of COVID-19 relief funds, the promotion and sale of unproven COVID-19 treatments, improper billing for COVID-19 testing, and the peddling of fake vaccination cards. As we also expected, several government enforcement agencies, including the Department of Justice (DOJ) through its Criminal and Civil Divisions and the Federal Trade Commission (FTC), are coordinating to bring COVID-19 related enforcement actions. Opioids also remained a top enforcement priority at the federal level, and a number of closely watched lawsuits against opioid manufacturers are being litigated in states around the country.

We also saw health care enforcement shift to address the increasing importance of technology in health care. As the use of telehealth grew exponentially during the COVID-19 pandemic (and its broad use is expected to continue), the risk of abuse increased as well. DOJ historically has prioritized enforcement against outright telefraud, but we have begun to see enforcement evolve toward investigations and False Claims Act (FCA) cases involving billing for sham telehealth consults. DOJ also geared up in 2021 to target cybersecurity by launching a cyberfraud initiative. Among other things, DOJ widely publicized its intention to use the FCA as a tool to address government contractors' misrepresentations about compliance with cybersecurity requirements. Further, enforcement actions involving electronic health records (EHR) vendors have been ongoing for several years, and we saw additional settlements announced in 2021 that included kickback allegations related to their sales and marketing practices.

The FCA continues to be one of the government's most potent enforcement tools. Despite the pandemic's impact on courts and all types of organizations, FCA cases involving traditional health care providers, such as laboratories, hospices, skilled nursing facilities, and hospitals, as well as Medicare Advantage Organizations (MAOs), remained at the forefront in 2021.

A few additional enforcement trends were notable in 2021. Given the upward trend in private equity investment in health care, enforcement against health care sector investors remains an enforcement priority. DOJ has also shined a spotlight on clinical trial fraud as an area of concern for some time, and it delivered on its warnings in 2021. Finally, the government began to utilize newer laws intended to target health care fraud, such as Eliminating Kickbacks in Recovery Act (EKRA) and the COVID-19 Consumer Protection Act.

Mintz's Health Care Enforcement Defense team[2/] has reviewed criminal enforcement activities, key civil cases and settlements, policy issues, statistics, and court decisions from 2021, and in this report we reflect on those developments and also predict the trends in health care enforcement in 2022 and beyond.

STATISTICAL TRENDS IN FALSE CLAIMS ACT LITIGATION

FCA case activity for 2021 reveals seemingly contrary trends. For the federal fiscal year (FY) that ended September 30, 2021, the DOJ **annual report on FCA enforcement activity**[3/] (FCA FY 2021 Report) touts record recoveries in FCA cases. At the same time, both DOJ-reported statistics and the health care–related *qui tam* litigation activity tracked in our internal Health Care *Qui Tam* Database (the Mintz Database) show a decline in the number of cases being brought.[4/] When we look more closely at data from the Mintz Database for cases unsealed in 2021, we see some subtle changes in rates of government intervention and in the types of defendants, but consistency in who is bringing the cases. Taken together, these trends show that FCA litigation continues to have a substantial impact on the health care industry, even as the total number of new cases has declined.

DOJ Reports Record FCA Recoveries in 2021 (but with a Possible Asterisk)

According to the FCA FY 2021 Report, FCA recoveries in FY 2021 totaled $5.6 billion. Of that amount, a staggering $5 billion relates to the health care sector, particularly opioid manufacturers, as well as drug and medical device manufacturers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians. This amount compares to a previous record for recoveries in health care cases of $3.1 billion in FY 2012 and represents an almost threefold increase from the $1.8 billion in health care–related recoveries in FY 2020.

Now here is the asterisk to denote that this record might not actually be a record.[5/] DOJ's $5 billion tally for its FY 2021 health care haul appears to include DOJ's agreement with Purdue Pharma in connection with Purdue Pharma's global bankruptcy court opioid litigation settlement for an allowed, unsubordinated, general unsecured bankruptcy claim of $2.8 billion. As discussed below, the Purdue bankruptcy plan may not survive review, and if it does, it is unclear how much DOJ might actually recover on this claim. Without counting this $2.8 billion, DOJ's FCA health care recoveries would be $2.2 billion, the same amount recovered in FY 2020.

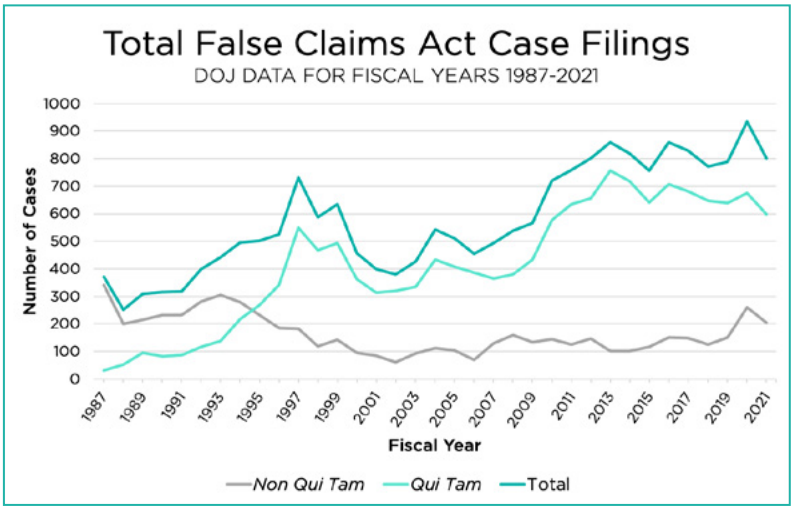
Led by the anticipated recovery in the Purdue Pharma case, the reported $4 billion in recoveries in cases brought by DOJ in FY 2021 significantly outstripped recoveries of $1.6 billion in *qui tam* cases. (For those keeping track, payments to relators in those *qui tam* cases totaled $237 million). By way of comparison, DOJ reported $1.7 billion in *qui tam* recoveries (and $309 million in payments to relators) in FY 2020, compared to roughly $500 million in recoveries in cases brought by DOJ. The fact that the scale tipped toward government cases in FY 2021 is consistent with the increase we have observed in DOJ-initiated actions in recent years and represents a remarkable year for DOJ recoveries in these matters.

Qui Tam Case Volume Decreased in 2021, but the Total Remains High

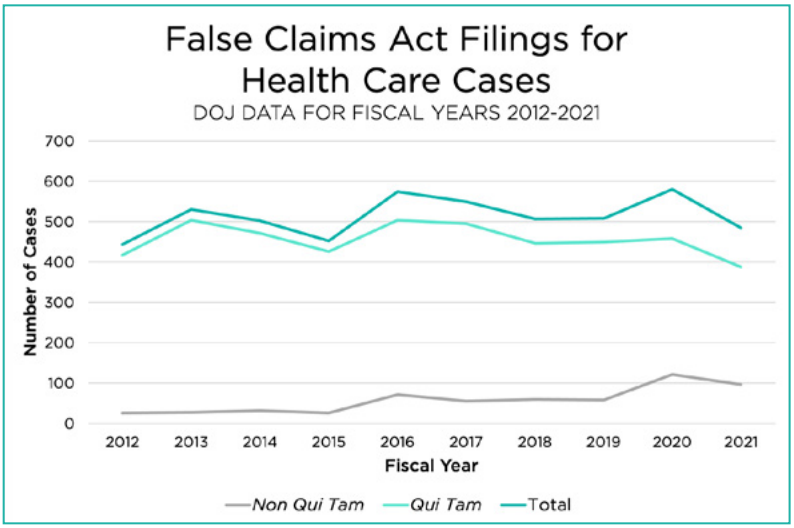
Both the FCA FY 2021 Report and the Mintz Database show declining numbers of *qui tam* cases. According to the FCA FY 2021 Report, which captures all FCA cases, relators filed 598 lawsuits under the *qui tam* provisions of the FCA in FY 2021, which is a decrease from the 672 filings in FY 2020, and the lowest number of *qui tam* filings since FY 2010. Likewise, the total number of unsealed *qui tam* cases brought against health care defendants captured in the Mintz Database decreased significantly from 2020 to 2021. In 2021, we observed 225 unsealed health care *qui tam* cases, compared to 287 unsealed in 2020.

While the data cannot tell us the reasons for the apparent decrease in cases, we can speculate that the ongoing pandemic may have had an adverse effect over the past two years on the volume of investigatory activity by DOJ, the Office of Inspector General for the Department of Health and Human Services (OIG), and relators. Diversion of agency staff to address COVID-19 issues, together with lost time for sick employees, could have diminished DOJ's ability to complete investigations and move to unseal *qui tam* complaints.

Regardless, the total number of filed and unsealed cases remains high. For example, the long-term case volume trend in the FCA FY 2021 Report data show total case filings at levels well above then-record case filings in 2010:



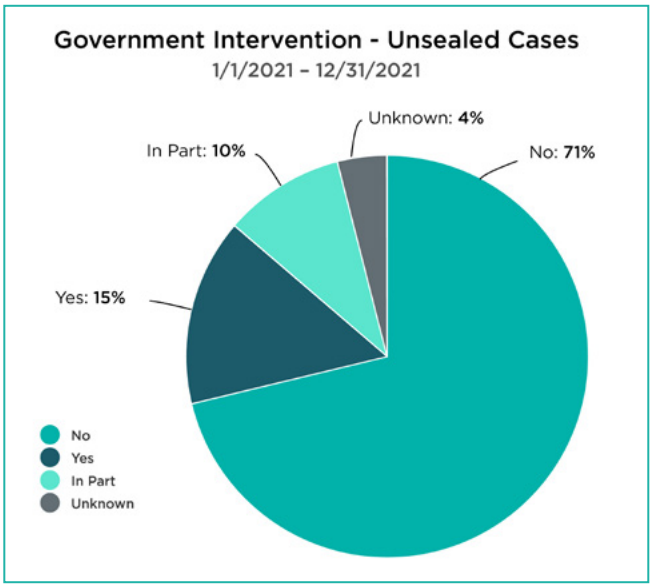
Likewise, the FCA FY 2021 Report data show that total health care–related FCA filings have remained relatively consistent over the past ten years, with increasing DOJ-initiated cases offsetting declines in *qui tam* cases filed by private relators:



STATISTICAL TRENDS IN FALSE CLAIMS ACT LITIGATION *contd.*

Notably, the FCA FY 2021 Report data, which track filed cases, are a leading indicator of FCA case volume, while the Mintz Database data, which track unsealed cases, are a trailing indicator. Because DOJ has exclusive access to cases under seal, it has unique visibility into the pipeline for *qui tam* cases. A declining inventory of relator-filed cases inevitably will drive down future unsealed cases. The reduced number of *qui tam* filings reported in the FCA FY 2021 Report indicates a future reduction in *qui tam* litigation activity. But we anticipate that DOJ-initiated cases will be a driver of FCA investigations and litigation activity for years to come.

Based on our analysis of cases in the Mintz Database, we observed that the rate of government intervention in *qui tam* cases, which was significantly above normal in 2020, receded in 2021. Over the ten years that we have maintained the Mintz Database, the federal government typically has intervened in approximately 20% to 25% of the cases filed in any given year. In 2020, that rate shot up to 31%, which was consistent with the general increase at that time in DOJ litigation of civil FCA cases. In 2021, however, the government intervention rate fell to 25%, which is more in line with historical trends:

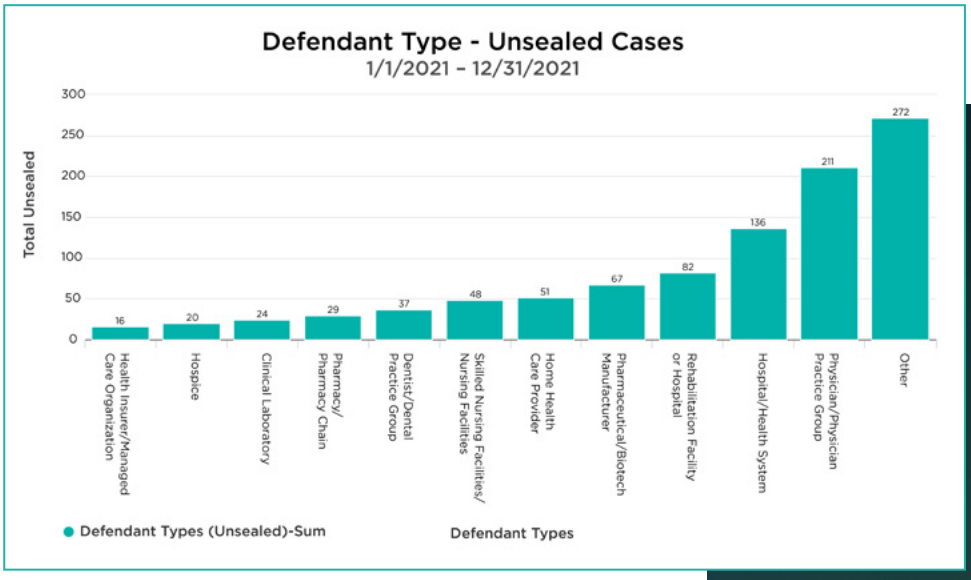


Given that we are looking at just one year of data and that the 2021 intervention rate was at the higher end of the spectrum with respect to the typical intervention range, we cannot conclude that the decline from 2020 to 2021 reflects a diminished government appetite to take on FCA cases. Still, the rate at which DOJ intervenes in *qui tam* cases is a trend that bears watching in 2022.

STATISTICAL TRENDS IN FALSE CLAIMS ACT LITIGATION *contd.*

Hospitals and Physicians Continue to Be the Leading Targets of *Qui Tam* Cases

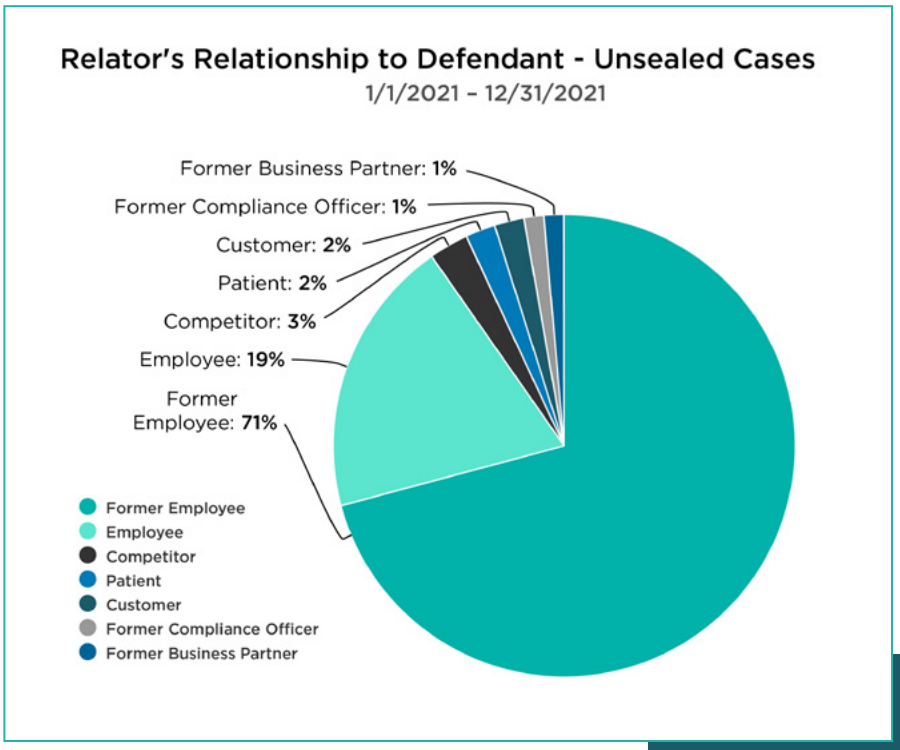
The data from the Mintz Database show, unsurprisingly, that physicians and hospitals continue to be subject to the greatest number of whistleblower claims. This chart shows the top health care sectors targeted for *qui tam* lawsuits unsealed in 2021:



The data[6] mirror what we have seen in the past with respect to hospitals and physicians, who unfortunately are natural targets for *qui tam* litigation because they are at the center of care provided by the health care industry. In recent years, the next most frequently targeted defendant type has been pharmaceutical companies. While a large number of such cases were unsealed in 2021, we observed a notable increase in unsealed cases against rehabilitation hospitals and facilities. The growing number of cases targeting the rehabilitation sector, together with the significant number of cases against home health agencies and skilled nursing facilities, reflects the outsized focus on services provided to the elderly in *qui tam* litigation. The aging of the American population, together with DOJ's recent focus on the quality of care provided to the elderly, indicates that growth in litigation concerning services to the elderly will continue during 2022.

Current and Former Employees Continue to Bring the Vast Majority of Health Care *Qui Tam* Cases

It is no surprise who brought *qui tam* lawsuits unsealed in 2021. Employees have always been the most common source of *qui tam* cases, and, according to the Mintz Database, 2021 was no exception:



Nine out of ten of the cases unsealed in 2021 were brought by former or current employees. Former employees make up almost three-quarters of all *qui tam* litigants. People leaving their employers on bad terms are prone to look for reasons to sue. However, someone who is determined to blow the whistle may find it easier to do so once no longer employed by the defendant. The significant role that employees play in fueling *qui tam* litigation underscores the critical importance of employee relations in mitigating *qui tam* risk. Health care companies should, among other things, maintain a robust compliance structure to respond to employee concerns and a strong human resources function to ensure that employee discipline and termination decisions are well-grounded and are executed with firmness and respect.

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Health Care *Qui Tam* Suits Unsealed in 2021 Were Concentrated in Major Metropolitan Areas in California, the South, and the Northeast

Eighteen courts that unsealed five or more cases apiece in 2021 accounted for almost 60% of the unsealed cases in our database:

Courts Unsealing a High Volume of *Qui Tam* Cases in 2021

Jurisdictions (with locations of main courthouses)	Case Count	% of All Cases
Central District of California (Los Angeles)	19	8%
Northern District of Georgia (Atlanta)	19	8%
District of New Jersey (Newark)	19	8%
Eastern District of Michigan (Detroit)	11	5%
Middle District of Florida (Orlando/Tampa/Jacksonville)	9	4%
Northern District of Texas (Dallas)	9	4%
District of Maryland (Baltimore)	8	4%
Southern District of Florida (Miami)	6	3%
Middle District of Georgia (Macon)	6	3%
Southern District of New York (Manhattan)	6	3%
Eastern District of Pennsylvania (Philadelphia)	6	3%
Eastern District of California (Bakersfield)	5	2%
Eastern District of New York (Brooklyn)	5	2%
District of Arizona (Phoenix)	5	2%
Total Cases in High-Volume Courts	**133**	**59%**

The roster of high-volume courts demonstrates the continued significance of the Florida courts as venues for *qui tam* litigation, consistent with the experienced government and relators' bar in Florida and a growing state population, a large segment of whom are elderly Medicare beneficiaries. The District of New Jersey and the Eastern District of Pennsylvania, both of which have a high concentration of pharmaceutical manufacturers, also continue to be hotbeds for *qui tam* cases. The geographic region conspicuously underrepresented in this list is the Midwest, as *qui tam* activity continues to be low in states such as Illinois, Ohio, Wisconsin, and Minnesota. Only the Eastern District of Michigan had enough unsealed cases to crack this list.

ONGOING AREAS OF ENFORCEMENT FOCUS

Opioids

Opioid-related enforcement remained a top federal and state priority in 2021. As stated in the FCA FY 2021 Report, "[c]ivil enforcement actions against the parties responsible for triggering and fueling the opioid epidemic are a critical part of the department's ongoing efforts to address this crisis." Opioid recoveries constitute the lion's share of reported FCA recoveries this year, but, surprisingly, the total volume of federal opioid enforcement cases declined from prior years. As expected, pharmacies were the main target in new opioid-related federal health care fraud enforcement actions. However, major DOJ resolutions were few and far between, with many of the blockbuster corporate resolutions occurring at the state level. Despite this shift, individuals and entities in the opioid supply chain are likely to remain on the radar of state and federal health care enforcement authorities in 2022 given that drug overdose deaths — including those resulting from opioids — continue to increase.[7]

National Enforcement Action

In September 2021, DOJ announced its **National Enforcement Action (NEA),**[8] which detailed new criminal health care fraud charges filed against 142 defendants. While one of the NEA's priorities was opioid-related enforcement, only $14 million in alleged losses (out of the $1.4 billion total) related to opioid distribution fraud charges. The reasons for this decline are not obvious. COVID-19 may have played a part due to delays in investigations and grand jury empanelments. The transition from the Trump administration to the Biden administration also may have slowed enforcement efforts.

While these isolated causes may offer some explanation, conflating this recent decline with any broader priority shift away from opioid enforcement would be a mistake, given that the opioid epidemic accelerated this past year. Recent data reflect that overdose deaths increased nearly 30% in 2021.[9] Given these facts, increased enforcement is likely to follow.

Further, DOJ has expressly reaffirmed that opioid-related enforcement is a top priority. In announcing the NEA, Assistant Attorney General Kenneth Polite, Jr. opened and closed his **press conference**[10] by discussing opioid-related enforcement. He noted that, in the past year, "drug overdoses killed a record number of Americans," and vowed that DOJ would "reach new milestones" in the fight against opioid abuse, and highlighted the "significant strides" that DOJ's Appalachian Regional Prescription Opioid Strike Force has made since its creation in 2018.[11]

Pharmacies

Last year[12] we forecasted that pharmacies seemed to be "next in line" for opioid-related enforcement. That prediction has proven to be correct, as evidenced by the examples of enforcement actions discussed below.

In February, a Pennsylvania-based pharmacy, McElroy Pharmacy, and its pharmacist agreed to pay $2.9 million to resolve Controlled Substances Act (CSA) allegations related to illegally dispensing opioids without a prescription and FCA allegations for false Medicare billings, whereby the pharmacy filled prescriptions with generics but billed Medicare for more expensive brands. McElroy Pharmacy surrendered its license as part of the resolution.[13/]

In May, AlixaRx LLC, a pharmacy services provider for long-term care facilities, agreed to pay $2.75 million to resolve CSA and FCA allegations relating to the unlawful dispensing and fraudulent billing of opioids. These allegations involved providing opioids to long-term care facilities without a written prescription on an "emergency" basis and then double billing claims for reimbursement under both Medicare Part A and Medicare Part D.[14/]

More recently, in December, two Michigan-based pharmacies and a pharmacist agreed to pay $1 million to resolve FCA and Anti-Kickback Statute (AKS) allegations related to false Medicare claims submitted for the opioid overdose drug Evzio. Evzio is one of the most expensive injectable naloxone medications on the market. A prescription for the drug generally requires prior authorization for coverage. Defendants allegedly falsified prior authorization documentation and failed to collect (or attempt to collect) co-payments for the drug from Medicare beneficiaries. As discussed in more detail below, the settlement also resolved FCA claims brought by a former employee of kaléo Inc., (kaléo), the manufacturer of Evzio.[15/]

Other Opioid Resolutions and Trials

DOJ's opioid-related resolutions in 2021 did not involve many well-known companies, unlike in years prior (e.g., **Insys**,[16/] **Reckitt Benckiser**,[17/] **and Purdue Pharma**[18/]). However, DOJ secured convictions at trial in a few closely watched matters. Section highlights from 2021 are discussed below.

One of the more significant resolutions in 2021 involved kaléo. In November, kaléo agreed to pay $12.7 million to resolve FCA and AKS allegations that it directed physicians to send Evzio prescriptions to specific pharmacies, which then submitted false prior authorizations or failed to collect co-payments from federal health care program beneficiaries. DOJ alleged that the manufacturer knew of or deliberately ignored misconduct by its preferred pharmacies when directing business there and also that kaléo provided kickbacks to physicians and its office staff to induce or reward prescriptions.[19/]

In September, a Michigan pain management physician was convicted of health care fraud, among other charges, for a scheme to defraud Medicare of over $100 million by administering (or at least billing for) expensive and medically unnecessary spinal injections to patients, in exchange for prescribing high doses of opioids to patients. The physician also participated in a kickback scheme with a diagnostic laboratory through which he received payments in exchange for referrals to the laboratory, and he used those funds to promote a fad diet and "lifestyle and wellness" book. Sentencing is scheduled for March 2022.[20/]

Operators of two Florida-based addiction treatment facilities were convicted in November of various health care fraud, kickback, and money laundering counts arising from fraudulent billings of approximately $112 million in addiction treatment services that were medically unnecessary or were never rendered. The operators paid kickbacks to "patient recruiters" — who then gave drugs to patients before their admission to the inpatient facility — and shuffled patients between facilities to fraudulently maximize bills. The jury's guilty verdict is particularly noteworthy because the charges against these two individuals included violations of EKRA, enacted in 2018, which prohibits kickbacks in referrals to recovery homes and treatment centers, among other facilities.[21] This case is an example of how EKRA enforcement is slowly making its way into DOJ's enforcement toolkit, which we discuss in greater detail later in this report. Sentencing is scheduled for March 2022.[22]

One important case to watch in 2022 is the criminal prosecution of the former CEO of Rochester Drug Co-Operative, Inc., a pharmaceutical distributor, on counts of narcotics conspiracy and conspiracy to defraud.[23] On February 2, 2022, after a two-week trial, the jury convicted the former CEO on both counts. Sentencing is expected in June 2022. This case is significant because it involved criminal charges under the Controlled Substances Act (CSA) against an executive of a large drug distributor for allegedly directing opioid sales and shipments to pharmacies filling suspicious prescription orders. When the indictment was first announced in 2019, then–U.S. Attorney Geoffrey Berman called this prosecution the "first of its kind."[24] Though the verdict may be appealed, the trial result may prompt prosecutors to pursue similar theories under the CSA in other cases.

Another important opioid distribution case to watch in 2022 is the criminal prosecution of pharmaceutical distributor Miami-Luken, its former president, compliance officer, and two pharmacists. The indictment alleges that Miami-Luken and the individual defendants conspired to violate the CSA by distributing millions of opioid painkillers to pharmacies in rural towns with small populations in West Virginia, Ohio, Indiana, and Tennessee, and by continuing to distribute these drugs even after the Drug Enforcement Administration (DEA) made accusations of diversion and suspicious orders.[25] Last month, one of the individual defendants — the compliance officer — pleaded guilty to a superseding information of one count of misprision of a felony (i.e., failing to report a known CSA violation to the DEA).[26] That defendant is awaiting sentencing; all other defendants have not pleaded guilty and are awaiting trial.

State-Level Enforcement and Civil Matters

The largest opioid-related resolutions in 2021 came at the state level. In February, a major consulting firm agreed to pay $573 million to resolve numerous investigations by state attorneys general into the company's practices related to its work for opioid companies.[27] A few months later, in July, three pharmaceutical distributors and one manufacturer of opioids agreed to pay $26 billion to resolve numerous state and local investigations into whether the distributors failed to stop suspicious opioid orders and whether the manufacturer misled patients and doctors about the addictiveness of opioids.[28]

On the civil side, government suits against manufacturers, distributors, and pharmacies asserting a "public nuisance" theory have generated mixed early results.[29] Finally, in

bankruptcy, Purdue Pharma remained in the news, even after its $8.34 billion global resolution last year. The Southern District of New York rejected the company's plan of reorganization because that plan included non-debtor releases for members of the Sackler family.[30] The company has appealed the decision to the U.S. Court of Appeals for the Second Circuit on an expedited basis, with oral argument set for April 2022.[31] No matter how the Second Circuit rules, it is likely that this case may reach the Supreme Court.

COVID-19 Fraud

As was the case in **2020,**[32] the COVID-19 public health emergency continued to provide fertile ground for fraud schemes in 2021, and much of the conduct subject to enforcement over the past year was similar to the schemes targeted in 2020. For example, the government continued in 2021 to prosecute fraudsters accused of unlawfully obtaining Paycheck Protection Program (PPP) loans and using them for personal enrichment (e.g., **gambling**[33] or buying a **Lamborghini Urus**[34]), hawking fake and unproven COVID-19 remedies (e.g., **"Virus Shut Out Cards"**[35]), and selling **fake vaccine cards**.[36] As we anticipated, 2021 also ushered in some new areas of focus for the government's COVID-19 related fraud enforcement efforts, as well as some new tools to aid in these undertakings.

The Prominent Role of DOJ's Consumer Protection Branch in COVID-19 Enforcement

DOJ's Consumer Protection Branch (CPB), which enforces the Food, Drug & Cosmetic Act and other federal laws that protect Americans' health and safety, played a key role in COVID-19 related fraud enforcement in 2021. In **December,**[37] Deputy Assistant Attorney General Arun Rao reflected on this branch's COVID-19 related work over the past year and emphasized that COVID-19 related fraud remains a top enforcement priority for DOJ and the CPB. The CPB has utilized civil and criminal authorities and partnered with various federal agencies to root out pandemic-related misconduct. For example, the CPB worked with the Food and Drug Administration (FDA) to use the Food Drug and Cosmetic Act to address fake and unapproved COVID-19 treatments and cures and also collaborated with the FTC based on referrals from the FTC for civil penalty matters.[38]

In April, **the CPB and FTC undertook their first joint enforcement action under the COVID-19 Consumer Protection Act,**[39] which Congress enacted in December 2020 to prohibit deceptive acts or practices associated with the treatment, cure, prevention, mitigation, or diagnosis of COVID-19. Violations of the COVID-19 Consumer Protection Act also constitute unfair or deceptive acts or practices under the FTC Act and are subject to substantial civil penalties. In this joint enforcement effort, the agencies accused

the defendants of advertising vitamin D and zinc nutritional supplements as being able to prevent or treat COVID-19 as well or better than available vaccines without reliable scientific evidence to support those claims.[40] We expect, as Deputy Attorney General Rao has indicated, that as COVID-19 related fraud continues to evolve, so too will the work of the CPB to combat such schemes.

Creation of the COVID-19 Fraud Enforcement Task Force

In May 2021, Attorney General Merrick Garland announced the **creation of the COVID-19 Fraud Enforcement Task Force,**[41] which is composed of various entities within DOJ, including its U.S. Attorneys, the Executive Office for United States Attorneys, and DOJ's Office of the Inspector General, as well as the Federal Bureau of Investigation (FBI) and other key interagency partners.[42] In comments given in June 2021, Principal Deputy Inspector General for the OIG Christi Grimm announced that the OIG is working with this Task Force, with the goal of holding bad actors accountable and putting others on notice that COVID-19 fraud "will be caught by OIG and our friends."[43]

Just over a week after the formation of the Task Force, DOJ announced that the Task Force had executed a significant coordinated **takedown**[44] targeting telemedicine executives, physicians, marketers, and medical business owners for COVID-19 related fraud schemes causing losses in excess of $143 million to federal health care programs. One such scheme involved the provision of COVID-19 testing to Medicare beneficiaries at senior living facilities, at drive-through COVID-19 testing sites, and at medical offices. Defendants were accused of using the Medicare data and specimens they collected for purported COVID-19 testing to instead conduct and bill Medicare for unrelated and medically unnecessary testing, including cancer genetic testing, allergy testing, and respiratory pathogen panels, the results of which were often not provided to the targeted patients. In addition, when defendants did provide COVID-19 test results to their Medicare-beneficiary victims, these results were often unreliable or were not timely.

DOJ also reported that a man who **owned and/or managed**[45] two diagnostic laboratories was indicted on charges of health care fraud and money laundering after allegedly using his access to beneficiary and provider information contained in test orders to submit fraudulent Medicare claims amounting to more than $100 million. These fraudulent claims were for testing services not ordered or performed, including COVID-19 testing and respiratory pathogen panels (among other services), as well as hundreds of claims for testing allegedly provided to beneficiaries who were already deceased.

The May takedown also included a string of prosecutions involving alleged exploitation of telehealth policies that the Centers for Medicare & Medicaid Services (CMS) had relaxed during the pandemic to allow a wider range of services to be offered via telehealth so that patients could avoid in-person interactions. Marketers, medical business owners, physicians, and telemedicine executives allegedly submitted false and fraudulent claims to Medicare for sham telemedicine encounters that never occurred. Providers also were accused of receiving kickbacks from marketers and laboratory owners to refer medically unnecessary testing as a result

of these fictitious encounters. This report covers enforcement developments related to telehealth in greater detail below.

DOJ announced another takedown in September[46] that built upon the success of the May takedown. This coordinated effort targeted 138 defendants, including multiple providers, for alleged health care fraud schemes that resulted in approximately $1.4 billion in losses[47] to the government, about $29 million of which was attributed to COVID-19 related fraud. DOJ charged nine defendants with engaging in COVID-19 related schemes to exploit relaxed telehealth policies and misuse of patient information to submit claims to Medicare for medically unnecessary and expensive testing, including cancer genetic testing.

COVID-19 Relief Programs

In addition to new enforcement tools, 2021 also brought new enforcement priorities, including rooting out fraud against the Provider Relief Fund (PRF) (as we predicted in the 2021 Outlook[48]). The PRF offers financial relief to providers suffering the economic effects of the COVID-19 pandemic and allows them to maintain patients' access to medical care.[49] One unique aspect of the PRF is that certain providers received funds without having to apply for them because the federal agency responsible for administering the program, the Health Resources & Services Administration (HRSA), deposited funds directly into the accounts of providers who met applicable criteria. Any provider who decided to retain those funds had to sign an attestation indicating acceptance of the terms and conditions associated with payment.

To date, we are aware of only criminal (not civil) enforcement actions against those who misappropriated PRF funds. The first indictment related to PRF fraud was announced in February 2020. In that case, the owner of a home health company faced charges for intentional misuse of PRF funds.[50] The home health company was not operational when the PRF funds were disbursed (it had closed after Medicare issued an overpayment demand for over $1.6 million for patients who did not qualify for home health services). The owner, who was accused of distributing the PRF funds to her family for personal use, was charged with embezzling government property. Many similar prosecutions have followed.[51]

We expect that civil enforcement of suspected PRF fraud will soon follow these criminal prosecutions. In fact, in comments made in June 21, Principal Deputy Inspector for the OIG Christi Grimm announced that the OIG is "conducting several audits" related to the PRF and other relief funds.[52] Providers who received and improperly retained PRF funds may be subject to liability under the reverse false claims provision of the FCA, which prohibits "knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government."[53] Likewise, a provider who misuses PRF funds may violate the terms and conditions set forth in the attestations it submitted to retain those funds and likewise incur FCA liability. In the coming years, we expect to see civil actions brought by the government and *qui tam* relators alleging these and other theories of fraud. In particular, we expect that DOJ will assert FCA violations based on allegedly false certifications on PPP loan applications, including allegations that FCA violations present at the time of the loan certification led to a false certification.

The OIG also recently announced[54] that it will perform a nationwide audit to determine whether hospitals that received PRF payments and attested to the associated terms and conditions complied with the "balance billing" condition, which prohibits providers from pursuing collection of out-of-pocket payments from presumptive or actual COVID-19 patients in excess of what the patients otherwise would have paid for care provided by an in-network provider.[55] This OIG initiative will likely garner significant enforcement attention, particularly in light of the fact that the No Surprises Act recently took effect and the entire health care industry, including enforcement agencies, are attuned to issues relating to balance billing and surprise bills to patients.[56]

COVID-19 Related Health Care Services

While criminal prosecutions of COVID-19 fraud dominated in 2021, we expect to see a ramp-up in 2022 of civil enforcement actions under both the COVID-19 Consumer Protection Act and the FCA, with the latter category of civil actions stemming from both *qui tam* cases and cases filed directly by DOJ. As we noted in the 2021 Outlook,[57] Deputy Assistant Attorney General Michael Granston commented[58] that the FCA would play a central role in DOJ's civil enforcement efforts related to COVID-19, and Acting Assistant Attorney General Brian Boynton echoed these remarks[59] in February 2021. We also expect that the work of DOJ's CPB in this area will also continue to expand and evolve.

In addition, we expect that the government will be taking a harder look at COVID-19 related health care services, including laboratory testing. For example, on December 30, 2021, the OIG published a report[60] setting forth the details of the agency's review of COVID-19 testing, as well as non-COVID-19 testing, paid for by Medicare Part B in 2020. In short, the OIG found that while overall spending on clinical diagnostic laboratory testing rose to $8 billion in 2020 (from $7.7 billion in 2019), this increase was driven by new spending on COVID-19 testing ($1.5 billion), while overall spending on non-COVID-19 tests *decreased* by about $1.2 billion. Given the high amount of Medicare dollars spent on COVID-19 testing, the OIG and other federal agencies may very well start taking a closer look at the services being billed to federal health care programs, as well as the recipients of those reimbursements.

> [W]e expect to see a ramp-up in 2022 of civil enforcement actions under both the **COVID-19 Consumer Protection Act** and the **FCA**, with the latter category of civil actions stemming from both ***qui tam*** cases and cases filed directly by DOJ.

In fact, we have already started to see some enforcement attention focused on the laboratories performing and billing for COVID-19 related testing. In early January 2022, a Florida man pled guilty to one count of conspiracy to commit health care fraud,[61] stemming from a $6.9 million scheme that involved paying kickbacks to patient brokers who referred Medicare beneficiaries and physician orders authorizing medically unnecessary testing to his laboratory. The laboratory would then bundle COVID-19 testing with other more expensive

(and medically unnecessary) testing, including respiratory pathogen panel testing, as well as genetic testing for a wide variety of conditions, such as cardiovascular disease, cancer, diabetes, Parkinson's, Alzheimer's, and dementia, among others.

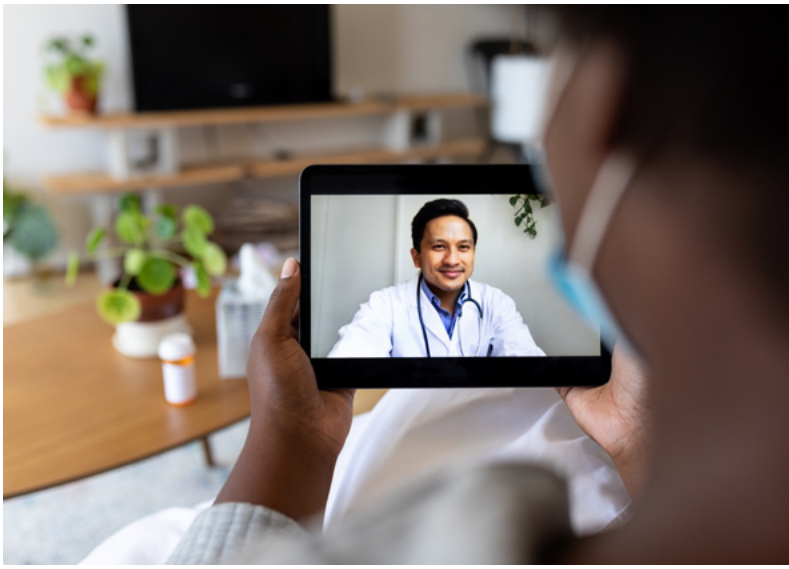
State attorneys general also have begun to pursue enforcement related to COVID-19 testing performed by providers. For example, the Minnesota Attorney General **announced**[62] on January 19, 2022, that he has **filed suit**[63] against the Center for COVID Control, LLC (the Center) and Doctors Clinical Laboratory, Inc., which allegedly failed to provide test results or reported false or inaccurate results to Minnesota residents. According to **news reports**,[64] multiple states, as well as CMS, are conducting their own investigations because the Center was operating 300 pop-up locations nationwide.

In the face of billions of dollars spent on COVID-19 related aid and services, we expect that state and federal governments will continue to prioritize COVID-19 related fraud enforcement in 2022 and beyond. With many enforcement tools at their disposal, we foresee many such enforcement actions at the state and federal levels across different segments of the health care landscape.

Telehealth

While telehealth-related enforcement in 2021 was largely a continuance of the telefraud initiatives discussed in the **2021 Outlook**,[65] certain enforcement actions may be a harbinger of things to come in 2022. We expect that enforcement will follow the massive growth of telehealth during the COVID-19 pandemic.

The telefraud schemes that began to emerge in 2019, such as Operation Brace Yourself and Operation Double Helix, resulted in more criminal prosecutions in 2021. To be clear, there is a distinction between alleged "telefraud" and "telehealth fraud." The former involves utilizing fraudulent telemarketing schemes to falsely bill for genetic and other diagnostic tests, durable medical equipment, and prescription drugs. The latter involves, for example, falsely submitting claims for sham or inadequate telehealth visits.



Telefraud schemes remained the subject of enforcement in 2021. For example, last May **DOJ announced**[66] indictments of three telemarketing company owners in an alleged telefraud scheme involving the referral of medically unnecessary genetic testing to laboratories through a chain of kickbacks. Two of the individuals allegedly conducted a telemarketing campaign to convince Medicare beneficiaries to accept genetic tests that these beneficiaries did not need. According to the indictment, the telemarketing company owners paid kickbacks to telemedicine companies, who contracted with physicians in

exchange for physician orders for the expensive genetic tests. The physicians, however, had no prior relationship with and were not treating the beneficiaries for cancer or cancer symptoms, and they did not conduct proper telemedicine visits with these beneficiaries. All three indicted individuals then sold the orders to laboratories, one of which allegedly submitted $46 million in claims to Medicare and received $27 million in reimbursements. The laboratory paid the telemarketing company $14 million in kickbacks for those test orders.

A new type of enforcement involving telehealth emerged in mid-2021. **DOJ announced**[67] charges against individuals engaged in various health care fraud schemes — including telehealth fraud — that caused over $143 million in false billings. This announcement marked a significant change in telehealth enforcement because certain defendants billed for sham telehealth consults that did not occur, in contrast to the telefraud schemes involving fraudulent orders for ancillary services ordered through telehealth consults. DOJ described the indictments as "first in the nation charges" that exploited CMS's decision to allow flexibilities in billing for telehealth visits. In September 2021, DOJ **announced**[68] charges against numerous defendants, including telemedicine providers, who submitted more than $1.1 billion in false and fraudulent claims.[69] While the alleged scheme primarily involved telefraud, DOJ did state that "in some instances, medical professionals billed Medicare for sham telehealth consultations that did not occur as represented."[70]

A continued shift in enforcement activity toward fraud involving telehealth consults seems inevitable given the marked increase in telemedicine users among Medicare beneficiaries during the pandemic. From March 1, 2020 through February 28, 2021, over 28 million Medicare beneficiaries received at least one telemedicine service, as compared to just over 910,000 from March 1, 2019 through February 29, 2020.[71] While this extraordinary level of usage is unlikely to continue, Medicare beneficiaries and other patients will undoubtedly continue to avail themselves of the conveniences offered by telemedicine services. In light of the increased use of telemedicine services by Medicare and Medicaid beneficiaries, the OIG is "conducting significant oversight work assessing telehealth services during the public health emergency."[72] The OIG Work Plan includes several telehealth-related reviews and audits, with a particular focus on providers' billing patterns for telehealth services.

Public evidence of an uptick in civil FCA cases related to telehealth fraud has yet to materialize, perhaps because these matters are still under seal given that the increased telehealth flexibilities took effect in early 2020. Even so, telehealth providers should take steps to mitigate risk, such as closely monitoring state and federal requirements as waivers come and go, conducting internal and external billing and coding audits, and implementing a robust compliance program that meets state and federal agency expectations and constantly evaluating its effectiveness.

Medicare Advantage

As discussed in the **2021 Outlook,**[73] DOJ has scrutinized Medicare Advantage (MA) risk adjustment activities for a number of years, and its focus on MAOs intensified in 2021. The FCA FY 2021 Report states that "investigating and

litigating a growing number of matters related to the Medicare Advantage program" is an "important priority" for DOJ.

By way of background, CMS adjusts capitated payments to MAOs based on members' demographic information and health conditions, as captured by diagnosis codes. Generally speaking, MAOs receive higher payments for sicker members because the cost of care for these members is typically higher. CMS requires MAOs to submit data, including diagnosis codes, to enable CMS to adjust payments to MAOs in accordance with the risk adjustment system. MAOs obtain diagnosis codes through claims submitted by providers, Health Risk Assessments (HRAs), and the review of members' medical records (i.e., chart reviews) and then submit this data to CMS.

The increased payments to MAOs caused by capturing and adding diagnosis codes have sharpened the government's focus on enforcement against both MAOs and their vendors. In recent years, the OIG and DOJ have expressed concern that MAOs may be receiving overpayments as a result of improperly utilizing chart reviews and HRAs to identify additional diagnosis codes or otherwise submitting unsupported diagnoses to CMS to increase member risk scores, and thus capitation payments. OIG issued a report detailing concerns that MAOs use chart reviews and HRAs to drive up risk-adjusted payments without beneficiaries receiving care for the diagnoses submitted.[74] DOJ has emphasized that MA enforcement is a top priority, and the enforcement activity in 2021 bears that out.[75]

DOJ intervened in several FCA lawsuits in 2021, alleging that defendants defrauded the United States by adding unsupported diagnoses to risk adjustment data submitted to CMS to increase their risk-adjusted payments. These lawsuits have targeted several types of risk adjustment activities, alleging that various MAOs:

- mined patient medical records to identify lucrative diagnoses;
- added diagnoses to patient encounters through medical record addenda from providers after the patient encounter occurred;
- submitted diagnoses for conditions previously documented but that were not addressed or treated during the patient encounter;
- failed to delete unsupported diagnosis codes; and
- gathered diagnosis codes through home visits without going through the clinical steps necessary to diagnose those conditions, such as testing or imaging.

For example, in July 2021 DOJ intervened in six *qui tam* cases filed against several MAO members of the Kaiser Permanente consortium. There, the government alleged that Kaiser pressured its physicians to create addenda to medical records after patient encounters to add risk-adjusting

diagnoses that patients did not have or that were not considered or addressed during the patient encounter.[76] The case is notable because DOJ increasingly appears to be arguing that even if a member has a condition (e.g., diabetes), MAOs can only submit diagnosis codes for conditions that affected patient care during the encounter with the physician.

DOJ also continued to litigate several ongoing FCA cases against MAOs in 2021, and these cases remain hotly contested. A long-running and closely watched FCA case against an MAO, *United States ex rel. Poehling v. UnitedhealthGroup, Inc.*, is in discovery, and trial is currently set for 2023. In addition, DOJ and Anthem, Inc. (Anthem) continue to litigate a case DOJ filed against Anthem last year.[77] There, DOJ alleged that Anthem implemented a retrospective chart review program using a vendor called Medi-Connect to identify additional diagnosis codes that Anthem submitted to CMS and that Anthem allegedly failed to delete unsupported diagnosis codes. The case is also notable because DOJ filed the case directly, without the apparent involvement of any relator.

Further, DOJ intervened in 2021 in a case against an MAO and a diagnosis coding vendor that conducted reviews of patient medical charts and identified additional diagnosis codes.[78] DOJ has alleged that the vendor caused the MAO to submit unsupported diagnosis codes to CMS, in violation of the FCA. This case demonstrates a trend we have observed where DOJ and relators have alleged that the vendors to MAOs caused the MAOs to submit false claims. We expect more cases to emerge that rely on this theory of FCA liability.

In addition to enforcement actions against MAOs and vendors, DOJ also has pursued providers involved in risk adjustment activities. For example, DOJ and Sutter Health, with several of its affiliated entities, reached a $90 million settlement in *United States ex rel. Ormsby v. Sutter Health* in August 2021.[79] Sutter Health agreed to pay $90 million to resolve allegations that it knowingly submitted unsupported diagnosis codes for certain patient encounters submitted for risk-adjustment purposes. The government specifically alleged that even once Sutter Health became aware of the unsupported diagnosis codes, it failed to correct the medical records and delete the additional unsupported diagnosis codes. In addition to the settlement, Sutter Health also entered into a five-year Corporate Integrity Agreement (CIA) requiring that it implement a centralized risk assessment program as part of its compliance program and hire an Independent Review Organization to annually review a sample of its MA patient medical records and diagnosis data.

In September 2021, the United States intervened in a *qui tam* case and filed a complaint against the University of Pittsburgh Medical Center (UPMC) and its head cardiothoracic surgeon, alleging that defendants submitted hundreds of false claims related to the surgeon's performance of concurrent surgical procedures in violation of the appropriate standard of care and regulations that prohibit teaching physicians from performing and billing for concurrent procedures.[80] In its complaint, the United States contended that the cardiothoracic surgeon's actions directly caused his patients to undergo medically unnecessary procedures, hospital stays, therapy, and other medical treatments. These additional services caused UPMC to submit additional diagnosis codes that increased the MAOs' capitation payments.

In light of continuing enforcement activities in this area, MAOs and providers who serve MA beneficiaries should closely review their practices related to the use of chart reviews and HRAs for risk adjustment. They also should monitor developments in the ongoing FCA lawsuits, as we anticipate court decisions will bring more clarity to the unsettled risk adjustment landscape being litigated by MAOs and the government.

Fraud Targeting Seniors

Fraud related to elder care also is an ongoing enforcement priority. For many years, federal and state enforcement agencies have taken aim at providers furnishing substandard care to nursing home residents or engaging in fraud related to services provided to the elderly (e.g., billing federal health care programs for allegedly medically unnecessary services,[81] for services not provided, or for services of such poor quality that they were alleged to be worthless.[82])

2021 was no different, but the COVID-19 pandemic has taken these enforcement efforts in a new direction as the virus has taken a particularly serious toll on nursing homes and other elder care facilities.[83] In June, a representative of the OIG noted in public comments that the OIG is "prioritizing improving the quality of care and safety of nursing home residents," particularly in light of the devastating impact on Medicare beneficiaries residing in nursing homes during the pandemic.[84] A number of states also took significant enforcement action in 2021 against nursing homes and elder care facilities that allegedly provided substandard care during the pandemic.[85]

In February 2021, Acting Assistant Attorney General Brian Boynton **stated**[86] that DOJ "currently has open investigations across the country focused on nursing homes that are providing deficient care" and "will continue to pursue these matters actively and aggressively." We expect fraud targeting seniors to remain a significant state and federal enforcement priority for years to come.

Health Care Industry Investors

The government continued to turn up the heat on private equity firms and other health care industry investors in 2021, as evidenced by an FCA settlement **announced**[87] in July. Alliance Family of Companies LLC (Alliance), a diagnostic testing company, and Ancor Holdings LP (Ancor), a Texas-based private investment company, paid a total of $15.3 million to settle six *qui tam* actions. Ancor, a minority investor that managed Alliance, paid $1.8 million of the settlement amount.

Unlike **earlier settlements**[88] involving investors in health care companies, this matter did not focus on the investor's post-acquisition participation in or acceptance of a fraud scheme but instead highlighted the fact that Ancor learned of Alliance's improper conduct during due diligence but failed to take action after closing. Ancor thus caused the filing of false claims for diagnostic testing services.

Another notable development occurred in ***United States ex rel. Martino-Fleming v. South Bay Mental Health Centers,***[89] a long-running *qui tam* case in which the government declined to intervene against a mental health services provider and its private equity firm owner. Back in May, the

court rejected the private equity firm's motion for summary judgment in part based on a finding that a genuine dispute of material fact exists as to whether the firm knew of the provider's alleged non-compliance during due diligence but failed to take action. The court relied in part on documents provided to the firm during the due diligence process.

While FCA settlements that include investors as defendants are rare and typically involve unusual fact patterns, investors in the health care sector should nonetheless take steps to avoid being held liable for a portfolio company's activities. The importance of a robust due diligence process is becoming increasingly important, and, if diligence identifies risky or fraudulent conduct, swift post-closing corrective action should be taken, and self-disclosure should be considered. Further, investors should take steps to help ensure that portfolio companies have adequate resources to support an effective compliance program.

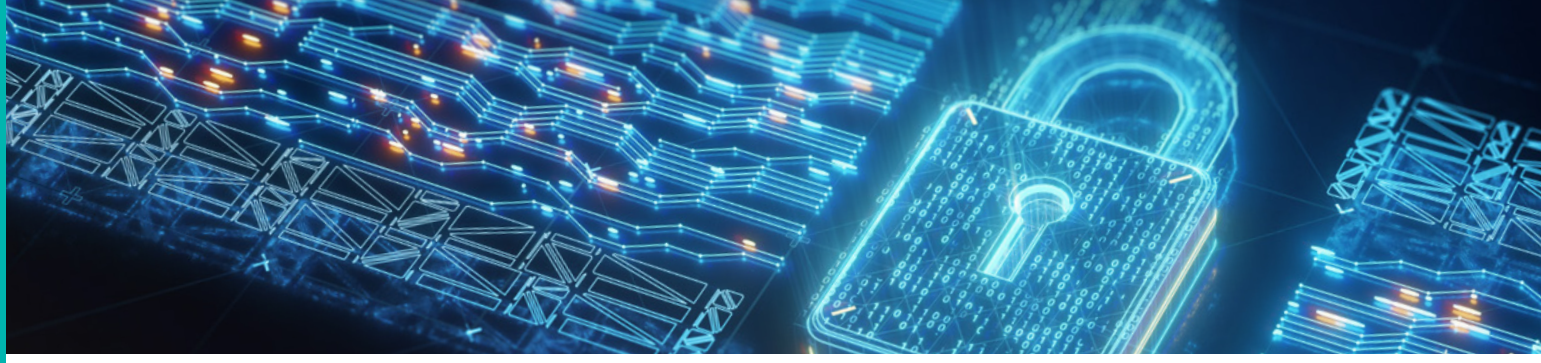
Enforcement activity involving **electronic health records (EHR)** vendors also continued in 2021, with the sales and marketing practices of those companies taking center stage.

Electronic Health Records Vendors

Enforcement activity involving electronic health records (EHR) vendors also continued in 2021, with the sales and marketing practices of those companies taking center stage. These allegations differ from early enforcement actions alleging that EHR vendors violated the FCA by supplying EHR technology that did not meet federal standards, thereby causing providers who used those products to submit false attestations to the federal government when they certified to using EHR technology that met applicable requirements when seeking related incentive payments.[90]

In January, athenahealth, Inc., (athenahealth) one of the country's largest and best-known EHR vendors, agreed to pay $18.25 million to resolve allegations that it paid illegal kickbacks in the form of entertainment to prospective and current customers, payments of up to $3,000 per individual to providers for lead generation, and payments to competing companies exiting the EHR market that successfully converted their customers into athenahealth customers.[91] Similarly, in April, CareCloud Health Inc. (CareCloud) agreed to pay $3.8 million to resolve allegations that its marketing referral program, which paid cash bonuses and percentage success payments to CareCloud's existing customers to recommend CareCloud's EHR products to prospective clients, violated the AKS.[92] CareCloud allegedly paid existing clients $550 to host on-site visits from prospective clients and $250 for 60-minute calls with prospective clients.

Given the seemingly steady pace of these enforcement actions over the last several years, we expect to see similar settlements announced in 2022, especially in light of DOJ's focus on fraud related to telehealth in 2021 and the announcement of its new cybersecurity initiative, which is discussed below.



EMERGING ENFORCEMENT PRIORITIES

Cybersecurity and DOJ's Cyber-Fraud Initiative

In addition to opioid-related enforcement, another area in which we expect to see increased enforcement efforts in 2022 relates to cybersecurity obligations applicable to federal contractors and grant recipients. In October 2021, DOJ announced that it was launching a Civil Cyber-Fraud Initiative[93] that would use the FCA to combat "new and emerging cyber threats to the security of sensitive information and critical systems." In particular, this initiative will target federal contractors and grant recipients and examine whether they are meeting applicable cybersecurity obligations to which they agree or certify when accepting federal funds. While this initiative is not health care–specific, health care companies and providers that contract with (or receive grant money from) the federal government might be subject to FCA enforcement under this new initiative.

According to DOJ, this initiative "will hold accountable entities or individuals that put U.S. information or systems at risk by knowingly providing deficient cybersecurity products or services, knowingly misrepresenting their cybersecurity practices or protocols, or knowingly violating obligations to monitor and report cybersecurity incidents and breaches." In remarks made at the Cybersecurity and Infrastructure Security Agency Fourth Annual National Cybersecurity Summit,[94] Acting Assistant Attorney General Brian Boynton explained three common cybersecurity failures that are "prime candidates for potential [FCA] enforcement through this initiative":

1. **Knowing failure to comply with cybersecurity standards.** When government agencies acquire cyber products and services, they often require contractors and grantees to meet specific contractual requirements, such as taking measures to protect government data or restricting non-U.S. citizen employees from accessing systems. The government views the knowing failure to meet these cybersecurity standards as depriving the government of what it bargained for.

2. **Knowing misrepresentation of security controls and practices.** In seeking or performing under a government contract, contractors often make representations to the government about their products, services, and cybersecurity practices (e.g., representations about a system security plan and the security controls it has in place, practices for monitoring its systems for breaches, or password and access requirements). The government takes the position that such misrepresentations might cause the government to choose a contractor it might otherwise not have, or to structure a contract differently than it otherwise would have and thus deprive the government of what it paid for.

3. Knowing failure to timely report suspected breaches. Government contracts for cyber products, goods, and services often require the timely reporting of cyber incidents that could threaten the security of agency information and systems. Prompt reporting by contractors often is crucial for agencies to respond to a breach, remediate the vulnerability, and limit the resulting harm.

Acting Assistant Attorney General Brian Boynton also emphasized the benefits that DOJ hopes to achieve through this initiative:

1. Improving overall cybersecurity practices and helping to prevent cybersecurity intrusions across the government, the public sector, and key industry partners. Because the federal government is one of the largest purchasers of cyber products and services, the cybersecurity requirements it sets for the companies it does business with can set the standard for the industry as a whole, to the benefit of both the government and the public.

2. Holding contractors and grantees to their commitments to protect government information and infrastructure. As the government increasingly refines its cybersecurity requirements for contracts and grants, enforcement of adherence to these requirements can also bolster the efforts of those trying to promote compliance within an organization.

3. Ensuring a level playing field. Companies that follow the rules and invest in meeting cybersecurity requirements will not be at a competitive disadvantage for doing so.

4. Supporting the work of government experts to timely identify, create, and publicize patches for vulnerabilities in commonly used information technology products and services.

5. Reimbursing taxpayers for the losses incurred when entities or individuals fail to satisfy their cybersecurity obligations. The DOJ Civil Division's Commercial Litigation Branch Fraud Section, which is responsible for FCA enforcement, will lead this initiative and partner with Inspector General Offices from numerous federal agencies. We expect to see the Initiative's first enforcement action in 2022.

Clinical Trials Fraud

DOJ has made its focus on clinical trial fraud known for some time now, and it certainly delivered on its previous warnings in 2021. Given the threat to health and safety posed by this type of scheme, enforcement authorities vigorously pursue reports of clinical trial fraud.

A clinical trial is a research study conducted in humans designed to help clinical investigators evaluate the safety and effectiveness of a new drug. It is governed by a protocol that describes the objectives, design, methodology, statistical considerations, and organization of the clinical trial. The FDA then relies on the truthfulness and accuracy of the data from the clinical trial to make regulatory decisions regarding the approval of the new drug. The FDA conducts inspections of clinical investigators and clinical trial records to ensure compliance with the clinical trial protocol and applicable laws and regulations. Pharmaceutical companies seeking to launch new drugs sponsor the clinical trials but do not conduct them directly; instead, they engage trial sites and principal investigators to enroll subjects and conduct the trials. These sites may be

academic medical centers, community hospitals, physician practices, or entities established specifically to conduct clinical research. Often, pharmaceutical companies engage a clinical research organization (CRO) to help them manage clinical trials, including the selection and oversight of trial sites.

While clinical trial fraud is often detected first by the FDA, DOJ handles the resulting enforcement actions through the Criminal Division's **Health Care Fraud Unit**[95] or the CPB. As mentioned above, in the context of COVID-19 fraud enforcement, the CPB enforces federal laws that protect Americans' health and safety through affirmative civil and criminal cases. Deputy Assistant Attorney General Arun Rao **spoke in December 2021**[96] about the CPB's continuing emphasis on clinical trial fraud and described enforcement efforts related to clinical trial fraud as "aggressive." He referenced two particular cases as examples.

In March 2021, DOJ announced criminal charges against a physician and three others who allegedly participated in a scheme to falsify clinical trial data for profit while working at Tellus Clinical Research (Tellus), a medical clinic based in Miami. The indictment alleged that, among other things, the defendants — who included the primary investigator, Tellus's owners, and two of its senior employees — knowingly enrolled subjects who did not meet the study's eligibility criteria, falsified laboratory results and medical records, and falsely represented that the subjects were taking the drugs being studied. As of December 2021, a total of eight individuals have been charged in connection with this scheme.

> These enforcement actions point to the need for clinical research sponsors and CROs to ***carefully select*** and ***closely monitor*** clinical trial sites and principal investigators.

Similarly, multiple individuals have been charged in another clinical trial fraud scheme allegedly carried out at Unlimited Medical Research (UMR), which is also located in Florida. According to the charging documents, the individuals falsified medical records in connection with a clinical trial designed to investigate a pediatric asthma medication. Specifically, they are accused of falsifying subjects' medical records to make it appear that they had made scheduled visits and taken study drugs even though they had not done so. Activity in this case has continued into 2022 with the **announcement**[97] that one of the owners of UMR pleaded guilty to one count of obstruction of justice after she knowingly lied to an FDA investigator during a 2017 regulatory inspection.[98]

These enforcement actions point to the need for clinical research sponsors and CROs to carefully select and closely monitor clinical trial sites and principal investigators. Further, principal investigators should critically review all data that is collected. All parties should evaluate the effectiveness of their respective compliance programs in an effort to prevent and detect any wrongdoing.

Given the health and safety threat posed by clinical trial fraud, it undoubtedly will remain an enforcement priority in 2022. The CPB is growing, and Deputy Assistant Attorney General Rao reported in his recent speech that it has 90 prosecutors and more than 100 support personnel and that it is a "large and sophisticated enforcement component of the DOJ" with criminal as well as civil enforcement authority.

Eliminating Kickbacks in Recovery Act

EKRA, which was signed into law in October 2018, is a criminal statute designed to prevent individuals from referring substance abuse disorder patients covered by any "health care benefit program" to recovery homes, clinical treatment facilities, and laboratories in return for illegal kickbacks.[99] Since its passage, EKRA has caused concern and confusion among entities to which it applies because its prohibitions overlap with, but in some cases extend beyond, the prohibitions of the AKS. For example, while the AKS contains a safe harbor provision that protects payments made by an employer to a bona fide employee,[100] the requirements for meeting the EKRA exception for payments to employees are different than those for meeting the AKS safe harbor.

Moreover, while EKRA empowers DOJ in consultation with HHS to issue regulations to clarify EKRA's exceptions, DOJ has not issued any such regulations, which has left recovery homes, clinical treatment facilities, and laboratories with little guidance, except for what can be gleaned from EKRA enforcement efforts.

Since its passage, EKRA has caused concern and confusion among entities to which it applies because its prohibitions overlap with, but in some cases extend beyond, the prohibitions of the AKS.

The first widely known EKRA enforcement action came to light in January 2020 when the **office manager of a substance abuse treatment clinic pleaded guilty to violating EKRA by soliciting kickbacks**[101] from a laboratory in exchange for urine drug testing referrals, among other charges. Since that time, EKRA enforcement actions have increased in frequency and have often focused on patient brokering schemes through which defendants are accused of paying bribes (in the form of cash, illegal drugs, or other items of value) directly to drug-addicted individuals to enroll in drug rehabilitation programs or paying bribes to others to secure patient referrals to similar facilities or programs.[102]

In some of these same cases, the government has also alleged that part of the scheme involved toxicology laboratories paying for patient referrals. These allegations suggest that we may see more government attention on, and investigation of, the role of toxicology laboratories in arrangements suspected of violating EKRA, including the medical necessity (or lack thereof) of testing performed. While the government's interest in the medical necessity of toxicology

testing is not necessarily new, we expect to see more EKRA enforcement that includes similar allegations, if not others, against laboratories.

We also have seen at least one case where a federal district court has interpreted EKRA in commercial litigation.[103] In that case, a former sales employee of a laboratory sued the laboratory to enforce his employment agreement and to obtain the money he believed he was owed thereunder. The laboratory argued that the employment agreement was unenforceable because the commission-based compensation arrangement with the ex-employee violated EKRA's prohibition on paying remuneration "to induce a referral of an individual" to a laboratory.[104] In this context, the court decided that because the sales representative was paid to obtain client *accounts* for the laboratory and because "there was no evidence that [the former employee's] client accounts included individuals who self-paid" for testing, the "compensation [the laboratory] paid him was not paid to induce him to refer individuals" to the laboratory and thus did not violate EKRA.[105]

While this court decision seemingly clarifies that EKRA does not apply to compensation paid to sales force employees, it does not bind DOJ. Whether DOJ will (or will not) take this decision into account when making enforcement decisions remains to be seen.

REGULATORY AND POLICY DEVELOPMENTS

DOJ Developments

Renewal of DOJ's Focus on Individual Accountability

DOJ's focus on pursuing individual liability and accountability in corporate criminal matters has ebbed and flowed over the last several years. In 2015, the "Yates Memo"[106] announced the Obama administration's focus on individual liability in corporate criminal cases. In particular, the policy reflected in the Yates Memo required companies, in order to receive cooperation credit, to identify all relevant facts related to individuals responsible for misconduct. In 2018, then–Deputy Attorney General Rod Rosenstein tempered the "all or nothing" approach[107] that required companies to identify "every person involved in alleged misconduct in any way."

Deputy Attorney General Lisa Monaco recently announced DOJ's reinvigorated efforts[108] to hold accountable the individuals responsible for corporate crime. Deputy Attorney General Monaco stressed that prosecution of individuals prevents recidivism and strengthens corporate compliance and issued a related memorandum.[109] These efforts have manifested themselves in several policy changes. DOJ reinstated former guidance that a company seeking to obtain cooperation credit in an investigation must provide DOJ with ***all*** non-privileged information about individuals involved in or responsible for the alleged corporate misconduct, rather than just individuals who were "substantially involved," as has been the case. In addition, DOJ amended its Principles of Federal Prosecution of Business Organizations to direct prosecutors to consider the criminal, civil, and regulatory record of a company that is the subject of a criminal investigation when deciding an appropriate resolution. DOJ also signaled increased willingness to impose independent monitors on companies as part of a deferred prosecution or non-prosecution agreement.

DOJ's shift back toward requiring broad disclosures to obtain cooperation credit and potential increased use of monitors has important consequences for companies. Of course, companies should implement and monitor robust compliance programs to prevent wrongdoing and perhaps even allow the company to argue that a monitor is not necessary. During investigations, counsel will have to structure their investigations and discussions with DOJ to provide sufficient information to meet DOJ's standard for cooperation credit if the company wants the benefit of such credit.

DOJ's Rescission of Prior Memoranda Limiting Reliance on Guidance Documents

In July, Attorney General Merrick Garland issued a memorandum regarding "Issuance and Use of Guidance Documents by the Department of Justice" (July 2021 Memorandum),[110] which rescinded two previously issued DOJ memoranda

regarding the agency's ability to issue guidance documents and to rely on them in affirmative civil enforcement actions, respectively.[111] The July 2021 Memorandum described these previous memoranda as having "substantially changed [DOJ's] traditional approach to guidance documents by establishing new review and approval conditions, and by placing additional restrictions and requirements on both publishing and relying on agency guidance." Moreover, the procedures set forth in the now-rescinded November 2017 and January 2018 memoranda were "overly restrictive," and they, along with their implementing regulations, "discouraged the development of valuable guidance" and "also generated collateral disputes and otherwise hampered [DOJ] attorneys when litigating cases where there is relevant agency guidance."[112]

The July 2021 Memorandum also sets forth principles that govern DOJ's issuance of guidance documents, as well as its use of guidance documents issued by DOJ and other agencies, which include the following:

- DOJ's guidance documents should be drafted with the recognition that they do not bind the public (except in limited circumstances) or have the force and effect of law. Guidance documents may, however, set forth DOJ's interpretation of binding regulations, statutes, and constitutional provisions.
- In the enforcement context, an agency guidance document by itself does not form the basis for an enforcement action because these documents do not impose legally binding requirements on private parties. Enforcement actions must instead be based on a failure to comply with a binding obligation (e.g., an obligation imposed by the Constitution, a statute, a legislative rule, or a contract). However, DOJ attorneys handling enforcement actions or other litigation may rely on relevant guidance documents in any appropriate and lawful circumstances (e.g., when a guidance document may be entitled to deference or otherwise carry persuasive weight with respect to the meaning of the applicable legal requirements). DOJ attorneys may also cite or rely on guidance documents where they are relevant to claims or defenses in litigation.
- DOJ's guidance documents should be clear, transparent, and readily accessible to the public. DOJ components are free to post guidance and other public-facing materials on their own websites.
- DOJ's guidance documents should reflect the breadth of expertise within DOJ and should be drafted in a way that does not create inconsistencies among different components.

Notably, DOJ reaffirmed that "[i]n the enforcement context, an agency guidance document by itself "never forms 'the basis for an enforcement action'" because such documents cannot "impose any 'legally binding requirements' on private parties."[113] Whether this action results in more aggressive use of guidance documents in 2022 and beyond remains to be seen.

OIG Developments

Revisions to the OIG Self-Disclosure Protocol

In November,[114] the OIG revised its Self-Disclosure Protocol[115] (SDP) and renamed it the "Health Care Fraud Self-Disclosure Protocol," presumably to make clear than the SDP is available to any "person," not just health care providers.

Generally speaking, the purpose of the SDP is to allow providers and other entities to voluntarily

disclose to and resolve with OIG instances of possible fraud involving federal health care programs, such as violations of the AKS. OIG first published the SDP in 1998 and has amended it several times, most recently in 2013 and then in 2021. The purpose of the OIG's 2021 revisions, like previous revisions, presumably is to make sure that the SDP is an appealing option for providers and other entities.

One of the most noteworthy aspects of the 2021 amendments was the statistical information on SDP settlements provided by the OIG. Between 1998, when the OIG first published the SDP, and 2020, the OIG resolved over 2,200 disclosures resulting in recoveries of over $870 million to federal health care programs. In the five years preceding the 2013 SDP amendments (2009 to 2013), the OIG settled 235 disclosures, while in the five years preceding the 2021 amendments (2016 to 2020), the OIG settled 330 disclosures. These statistics seem to suggest either that the OIG received a higher volume of disclosures in the latter period or that it processed the disclosures at a faster pace — or both. Notably, the OIG reported that in all cases, it released the disclosing parties from permissive exclusion without requiring a Corporate Integrity Agreement or similar measures, which should offer some encouragement for anyone considering submission of a self-disclosure to the OIG.

One major drawback to the SDP is that it only results in settlement of matters under the OIG's CMP authorities, and thus it does not release a disclosing party from liability under the FCA. The SDP has long included a section noting that the OIG coordinates with DOJ on matters disclosed under the SDP and "advocates that the disclosing party receives a benefit from disclosure under the SDP." But, ultimately, DOJ determines the outcome with respect to the FCA. While the OIG's policy with respect to civil matters has not changed, the revised SDP does include minor changes regarding OIG's coordination with DOJ in criminal matters. Most notably, OIG no longer will encourage disclosure of potential criminal conduct through the SDP process or advocate to DOJ for leniency in criminal cases. The OIG seems to be taking a more hands-off approach when it comes to criminal conduct.

Other changes worth mentioning include an increase in the minimum settlement amounts required to resolve a matter through the SDP from $50,000 to $100,000 for AKS-related matters and from $10,000 to $20,000 for all other matters, as well as clarification that a disclosure must include itemized damages for each affected federal health care program.

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These statistics seem to suggest either that the OIG received a **higher volume** of disclosures in the latter period or that it processed the disclosures at a **faster pace** — or ***both.***

Congressional Developments

Proposed FCA Amendments and Expansion

In August,[116] a bipartisan group of Senators led by Senator Chuck Grassley (R-Iowa) introduced two pieces of proposed legislation that would revise the FCA and provide remedies for small procedural claims:

1. the False Claims Amendments Act of 2021 (FCA Amendments Act),[117] proposes to amend the FCA to make it harder for defendants to assert a lack of materiality defense and to strengthen relators' ability to object to dismissals of FCA *qui tam* cases by DOJ; and

2. the Administrative False Claims Act of 2021 (AFCA)[118] seeks to amend the Program Fraud Civil Remedies Act of 1986,[119] which allows certain agencies to impose civil penalties and assessments through administrative adjudication for the submission of false claims or statements, to (i) expand potential claims thereunder and the officials who can review those claims, and (ii) allow for recoupment of government costs for investigating and enforcing these matters.

The FCA Amendments Act includes a number of notable features, such as:

1. Adding a new section 3729(e) that would require a higher burden of proof applicable solely to defendants rebutting materiality. This new section was proposed to address purported concerns that the Supreme Court weakened the FCA in 2016 when it issued its *Escobar* decision and thereby made it too easy for FCA defendants to argue that their alleged fraud was not material because the government continued payment.[120]

2. Adding section 3730(c)(2)(A), which would require DOJ to demonstrate its reasons for moving to dismiss a *qui tam* case and provide relators with a statutory standard for challenging DOJ's decision. These changes would effectively hinder DOJ's ability to enforce the FCA by restraining its Executive Branch authority to dismiss cases.

3. Amending section 3730(h)(1), the FCA's anti-retaliation provision, to state that "[a]ny current or former employee, contractor, or agent" is entitled to relief if that person is subject to retaliation based on their acts as a whistleblower, for the purpose of protecting against "post-employment retaliation." This amendment would clarify the definition of "employee" as used in section 3730(h), as at least one federal judicial circuit has found that this section includes former employees in its protection, while another circuit has found that former employees are excluded.[121]

4. Adding a new subsection 3731(f), which would allow the government in declined cases to move that any party requesting discovery from the government be required to "pay the Government's expenses, including costs and attorneys' fees… unless the party can demonstrate that the information sought is relevant, proportionate to the needs of the case, and not unduly burdensome on the Government." The press release posted on Senator Grassley's website suggests that this last provision is intended to "make[ ] fraudsters liable for reimbursing the government for costs associated with a burdensome discovery process," but, as written, this provision would apply to any party that requested discovery in a declined case.

Senator Grassley indicated[122] both proposed bills are intended to "help recoup even more money by clarifying confusion after the *Escobar* case" and are needed more than ever "to fight the significant amounts of fraud we are already seeing" related to the trillions of dollars Congress has appropriated for COVID-19 relief.

While the fate of the proposed measures remains unclear, stakeholders should nonetheless monitor developments related to these bills, particularly the FCA Amendments Act, given Senator Grassley's longstanding interest in the FCA and the bipartisan support, including from the Senate Judiciary Committee leadership, for the proposed changes.

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CONCLUSION

While 2021 ushered in a new president and attorney general, health care fraud enforcement activities largely remained consistent with recent years. In 2022, we expect COVID-19 fraud to remain in the spotlight, especially given the new tricks and tools available to DOJ, including the COVID-19 Consumer Protection Act enacted in December 2020 and the COVID-19 Fraud Enforcement Task Force created in 2021. As the pandemic (hopefully!) begins to wane, DOJ will just be getting started as FCA enforcement activities related to the PPP, the PRF, and other COVID-19 relief programs are likely to increase.

Even though state and federal governments have brought all their weight to bear in recent years when it comes to opioid-related enforcement, these activities are sure to continue in 2022 given that reported overdose deaths are higher than ever, likely due in part to the stress of the pandemic. With the Biden administration's renewed interest in individual accountability, we may start to see more individuals held responsible for corporate wrongdoing.

Finally, the increasing importance and use of health care technology will likely result in increased enforcement activity related to telehealth, EHR, and cybersecurity in 2022 and beyond. Cybersecurity, in particular, is a growing concern for the federal government, and DOJ undoubtedly will use all available resources to prevent cyberattacks by making sure that government contractors inside and outside of the health care sector comply with required cybersecurity standards. We also anticipate that enforcement actions will continue to target EHR vendors, given the broad and significant use of EHRs in all aspects of health care, as well as companies involved in the provision of telehealth, given that flexibilities extended to telehealth services by Medicare over the course of the pandemic will mostly continue through 2023.

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