MINTZ

HEALTH CARE ENFORCEMENT

2020 Year in Review & **2021** Outlook

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INTRODUCTION

Despite the threat of COVID-19 paralyzing much of the country in 2020, government health care fraud enforcement continued even though the government had the added burden of investigating and pursuing allegations of COVID-19 related fraud. While criminal enforcement actions involving opioids continued as a top enforcement priority, the civil False Claims Act (FCA) still remains one of the government's most powerful enforcement tools. In 2020, the total volume of FCA cases brought against health care companies continued to grow, but the dollar amount of recoveries under the FCA was down compared to recent years.

Mintz's Health Care Enforcement Defense team has reviewed the key policy issues, statistics, settlements, and court decisions from 2020, and in this report we reflect on those developments and also predict the trends in health care enforcement in 2021 and beyond.

> While criminal enforcement actions involving opioids continued as a top enforcement priority, the civil False Claims Act still remains one of the government's *most powerful* enforcement tools.

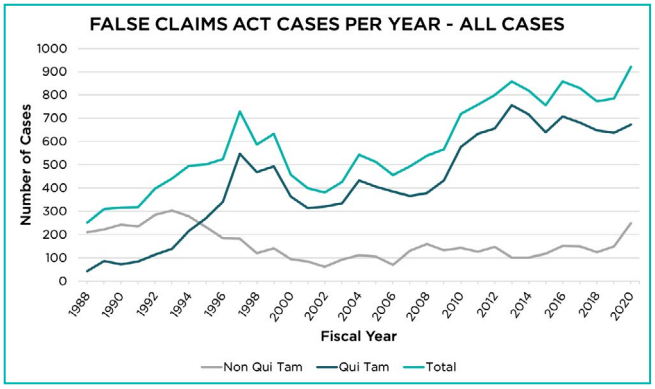
STATISTICAL TRENDS IN CIVIL FALSE CLAIMS ACT LITIGATION IN 2020

While overall recoveries resulting from FCA cases decreased in 2020, the health care industry should view this development as an aberration resulting in part from the upheaval of COVID-19 rather than a long-term trend. However, we did observe growth in the total volume of FCA cases brought against health care companies in 2020 based on our review of the statistical data published by DOJ on January 14, 2021, and the qui tam case activity that Mintz monitors and compiles for our internal Health Care Qui Tam Database (the Mintz Database).[1/] We analyzed both data sets to see how many cases were filed, who filed them, where they were filed, and who the defendants are. Our findings are described in this section of the report.

Qui Tam Case Volume Decreased While Government-Initiated Matters Increased

Since 2015, we have closely tracked changes in the volume of health care qui tam litigation, as reflected in the annual statistics published by DOJ. See, e.g., The Twenty-Year Ascendancy of Health Care Qui Tam Litigation in Five Simple Graphs (Dec. 8, 2015). Our initial findings in 2015 showed a twenty-year rise in the volume of FCA cases, predominantly driven by growth in health care–related qui tam cases. Case counts peaked in 2013 and then declined over the next two years, which begged the question whether health care qui tam filings were headed for a long-term decline.

In 2020, DOJ reported a total of 922 new FCA matters, 672 of which were qui tam cases. DOJ also reported a total of $2,231,454,855 in recoveries, $1,686,124,824 of which was recovered in qui tam cases. While health care companies might feel like the barrage of qui tam cases and related government investigations is endless, qui tam volume has actually continued to decline since 2015. Even so, overall FCA case volume has grown, as illustrated in the following chart, which graphs overall FCA case volume from 1988 to 2020:

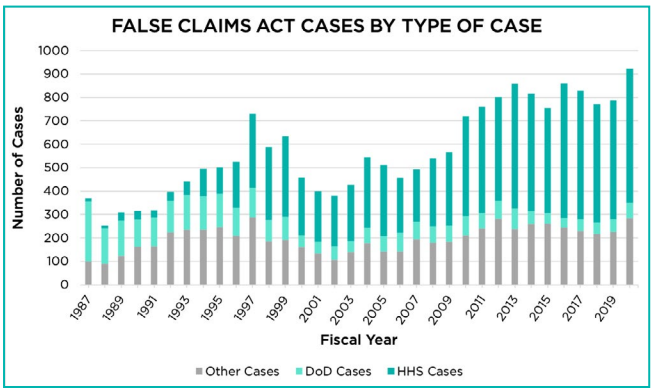


Total FCA volume has increased as a result of a surprising increase in government-initiated enforcement actions. Federal civil enforcement activity typically declines during a Republican presidency, but DOJ's statistics unexpectedly show that cases brought by DOJ doubled over the course of the Trump administration. This development is particularly surprising given that during the Trump presidency DOJ issued the Granston memo, which established guidelines for the more frequent exercise of the government's

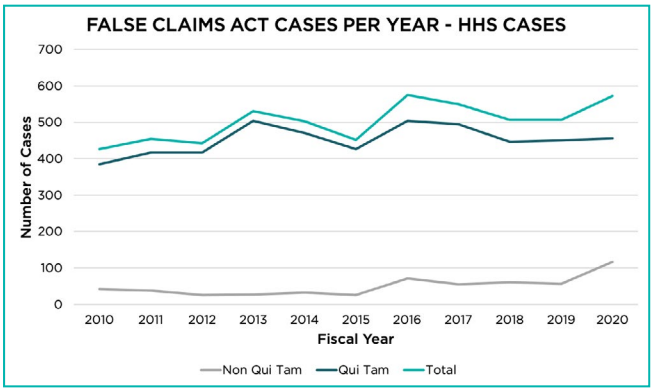
power to dismiss meritless qui tam cases. But policies directed toward potentially abusive private whistleblower actions do not foreclose the government from pursuing its own cases, which is what seems to have happened over the past five years. As Deputy Assistant Attorney General Michael Granston himself observed in a December 2, 2020 speech to the ABA Civil False Claims and Qui Tam Enforcement Institute, "Since fiscal year 2017, the Civil Division opened a record number of new matters," which reflects "the Department's continued commitment to broadly protect federal programs and operations" and the use of "the False Claims Act to target a number of specific enforcement priorities." Specifically, Granston noted that the Civil Division has been "undertaking sophisticated analyses of Medicare data to uncover potential fraud schemes that have not been identified by whistleblower suits" and should be expected to "expand its reliance on data analysis." Not mentioned by Granston, but also potentially contributing to increased government case volume, are sealed FCA cases addressing alleged fraud in connection with COVID-19 related relief programs.

> In 2020, DOJ reported a total of **922** new FCA matters, **672** of which were qui tam cases. DOJ also reported a total of **$2,231,454,855** in recoveries, **$1,686,124,824** of which was recovered in qui tam cases.

Health care cases continue to be the largest component of FCA litigation, as shown in this breakdown of annual FCA case volume between health care, defense, and other cases:



Again in 2020, health care cases made up the majority of FCA cases. The following chart tracks the volume of health care cases over the past 10 years:



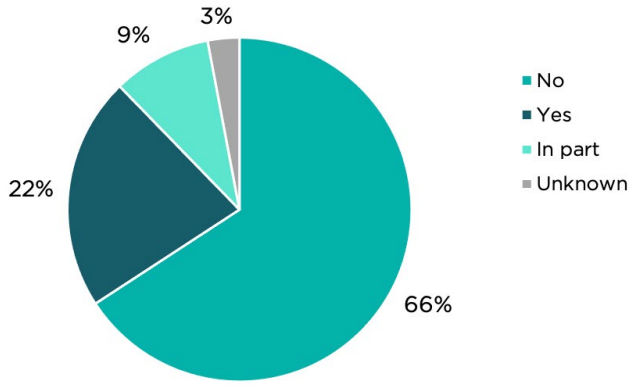
Here again, the data show overall volume increasing, despite a slight downward trend in qui tam cases since 2013, with growth almost entirely attributable to an increasing number of government cases.

The increase in government enforcement activity can be seen not only in DOJ statistics, but also in the cases collected in the Mintz Health Care Qui Tam Database. Our database overlaps with, but

> ...the government intervention rate shot up to **31%** in 2020, a significant increase over prior years.

does not match, the DOJ data set. However, for the calendar year 2020, the data concerning government intervention in lawsuits filed by whistleblowers also show growing federal enforcement activity. Based on the case activity in our database, in a typical year, the government intervenes, in whole or in part, in 20% to 25% of unsealed qui tam cases. In 2020, the intervention rate was significantly higher:

GOVERNMENT INTERVENTION - UNSEALED CASES
12.31.2019 - 12.31.2020



As demonstrated by this chart, our statistics show that the government intervention rate shot up to 31% in calendar year 2020, a significant increase over prior years. That said, the growth in the government intervention rate observed through review of our own data is consistent with a continued — and perhaps growing — DOJ focus on health care fraud.

DOJ political appointees never announced an intent to double government FCA enforcement activity during the Trump administration, but the increased case count could reflect institutional priorities rather than political objectives. This trend is likely to continue after Merrick Garland assumes command at DOJ, particularly given the significance of health care spending in the federal budget and the small likelihood that the Biden administration will reduce the volume of enforcement activities directed toward health care companies.

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

The data from the Mintz Health Care Qui Tam Database show, unsurprisingly, that hospitals and physicians continue to be subject to the greatest number of whistleblower claims. Figure A shows the top health care sectors targeted for qui tam lawsuits unsealed in 2020.

These data mirror what we have seen in the past with respect to hospitals and physicians. Qui tam lawsuits against pharmaceutical manufacturers, a frequent target of such cases, followed close behind. Industry sectors seeing increased activity over prior years include hospices, mental health providers, treatment and rehab centers, and pain clinics. The aging of the American population and DOJ's focus on the quality of care provided to the elderly (which is discussed elsewhere in this report) makes it likely that, in the coming years, services focused on the elderly, including long term care, home health care, and hospice care, will increasingly be subject to qui tam litigation.

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

Looking at who brought qui tam lawsuits unsealed in 2020, there are no surprises. Employees have always been the most common source of whistleblower lawsuits. The data from the Mintz Health Care Qui Tam Database show that 2020 was no exception (see Figure B).

Just over three-quarters of the cases unsealed in 2020 were brought by former or current employees. As is typical, former employees make up the lion's share, as people leaving their employers on bad terms are prone to look for reasons to sue. The continuing outsized role that employees play in fomenting 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 executed with firmness and respect.

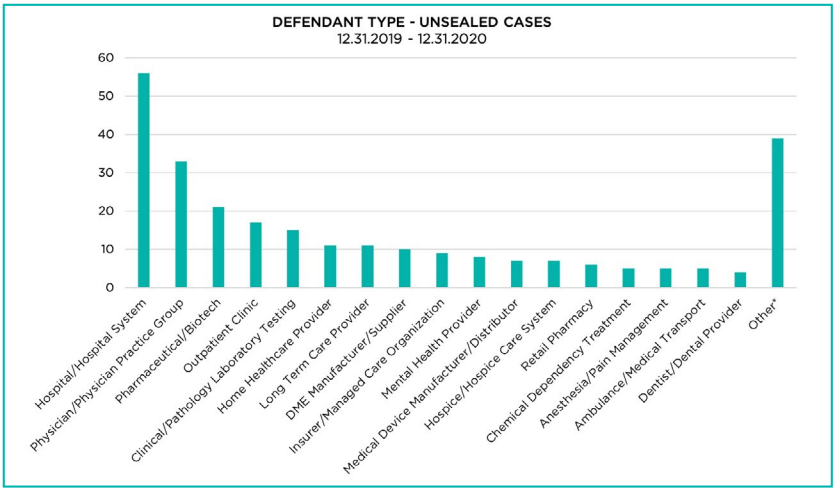


Figure A

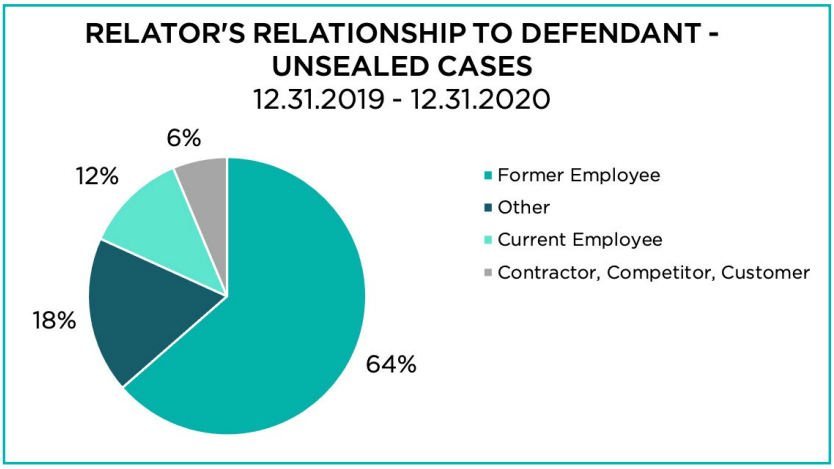


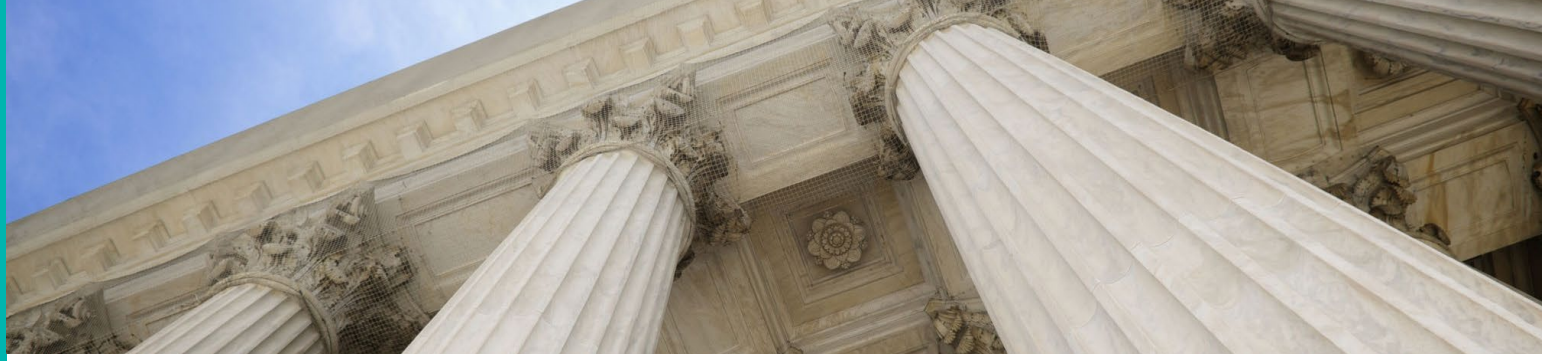
Figure B

Health Care Qui Tam Suits Are Concentrated in Major Metropolitan Areas

Eighteen courts that unsealed five or more cases apiece in 2020 accounted for 68% of the unsealed cases in our database:

Courts Unsealing a High Volume of Qui Tam Cases in 2020		
Jurisdictions (with locations of main courthouses)	**Case Count**	**% of All Cases**
Middle District of Florida (Orlando/ Tampa/Jacksonville)	32	12%
Eastern District of Pennsylvania (Philadelphia)	28	10%
Middle District of Tennessee (Nashville)	15	6%
Northern District of Texas (Dallas)	14	5%
Central District of California (Los Angeles)	12	4%
District of New Jersey (Newark)	9	3%
Northern District of Georgia (Atlanta)	9	3%
Southern District of New York (New York City)	8	3%
Southern District of Florida (Miami)	7	3%
District of Maryland (Baltimore)	7	3%
District of Massachusetts (Boston)	6	2%
District of South Carolina (Charleston)	6	2%
Eastern District of Tennessee (Knoxville)	6	2%
Eastern District of Virginia (Richmond/Alexandria)	5	2%
Southern District of California (San Diego)	5	2%
Northern District of California (San Francisco/Oakland)	5	2%
Eastern District of Michigan (Detroit)	5	2%
Southern District of Texas (Houston)	5	2%
Total Cases in High Volume Courts	**184**	**68%**

The roster of high-volume courts demonstrates the continued significance of the Florida courts as venues for qui tam litigation, consistent with the growing state population, a large segment of which is the elderly. The Eastern District of Pennsylvania, one of the country's centers for pharmaceutical manufacturing and a historical hotbed of qui tam cases, also continues to have a high volume of cases. Surprisingly, the Chicago-based Northern District of Illinois did not make the cut, but, otherwise, this list consists of most large U.S. metropolitan areas, centers for medical and life sciences business, or a combination of the two.



HEALTH CARE FRAUD ENFORCEMENT PRIORITIES IN 2020

Opioids

DOJ's continued focus on opioid-related enforcement activity should come as no surprise. We have covered this trend in our year-end reports (which are available here, here, and here) for the past three years. Last year, we correctly forecasted that 2020 would bring continued opioid prosecutions against both corporations and individual executives. DOJ's enforcement actions against opioid manufacturers, distributors, and prescribers continued in 2020, and DOJ also expanded the reach of its enforcement efforts to include opioid marketers and pharmacies. The message here is clear: any individual or company in the opioid supply chain is subject to DOJ scrutiny.

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Purdue Pharma

The largest opioid enforcement matter in 2020 was undoubtedly the culmination of the long-running investigation of Purdue Pharma, the Connecticut-based manufacturer of OxyContin. On October 21, 2020, DOJ announced an $8.34 billion settlement and global resolution of the criminal and civil investigation of Purdue Pharma and its individual shareholders from the Sackler family. The resolution included $3.54 billion in criminal penalties, $2 billion forfeiture, and a $2.8 billion civil settlement. Additionally, in a separate settlement, the Sackler family shareholders, who have been harshly criticized for contributing to the opioid crisis, agreed to pay $225 million in damages to resolve their civil liability under the FCA.

These were the largest penalties DOJ has ever recovered from a pharmaceutical manufacturer. Purdue's admissions in the criminal pleas were notable for the substance, scale, and duration of the admitted wrongdoing. Purdue admitted that, for over a decade, it falsely represented to the DEA that it maintained an anti-diversion program when, in fact, Purdue marketed its opioids to over one hundred providers that Purdue had reason to believe were diverting opioids. Purdue also admitted to violating the federal Anti-Kickback Statute (AKS) by making payments to two physicians through Purdue's speaker program to induce them to write more opioid prescriptions.

Also as part of the resolution, Purdue Pharma will be reorganized as a public benefit company. This

new company will aim to prevent future patient harm by safely distributing opioids, subsidizing overdose rescue drugs, and funding opioid abatement programs. These initiatives show DOJ's continued focus on preventing patient harm. Additionally, the global resolution does not prohibit future criminal or civil penalties against executives or employees of Purdue Pharma.[2/] We expect to see additional enforcement actions brought against individuals related to Purdue Pharma in the future, which would be consistent with DOJ's ongoing focus on prosecuting individuals deemed responsible for corporate wrongdoing related to opioids.

Indivior Solutions

In **July 2020, DOJ announced** the resolution of criminal and civil charges brought against Indivior Solutions, the Virginia-based marketer of the opioid-addiction treatment drug Suboxone. Indivior Solutions is the marketing subsidiary of Indivior Inc. (the manufacturer of Suboxone) and former subsidiary of past DOJ target Reckitt Benckiser Group.[3/] Indivior Solutions pled guilty to one felony charge of making false statements to MassHealth in marketing and promoting Suboxone Film's purported safety.[4/] Specifically, Indivior Solutions marketed and sought approval for Suboxone Film based on data that falsely suggested it was less susceptible to "accidental pediatric exposure" than other buprenorphine addiction treatment drugs. In other words, Indivior Solutions claimed its product was safer around children without data to support its claim. In total, Indivior Solutions paid $600 million to resolve the civil and criminal charges brought against it.

In addition to the company's plea, two of Indivior's former executives each pleaded guilty to one-count misdemeanor informations relating to the same conduct (falsely marketing Suboxone Film as safer around children, when it was not). Two aspects of these pleas are particularly noteworthy. First, the plea documents reflect the government's use of the "responsible corporate officer" doctrine, through which an executive may be held responsible for failing to prevent or correct illegal corporate acts, even absent the executive's direct involvement.[5/] Second, the sentence for Indivior's former CEO included a six-month term of imprisonment.[6/]

These resolutions were pleas, and thus we do not know much about the underlying facts, which means that the actual level of the executives' involvement in Indivior Solutions's false statements is unknown. However, after sentencing, DOJ representatives stressed in the media that the executives were "significantly involved and aware of the company's activities" and highlighted the message of deterrence for high-level individuals at pharmaceutical companies.[7/] Accordingly, the Indivior Solutions case should serve as a warning to health care executives that charges stemming from failure to act can result in jail time.

Practice Fusion

In January 2020, DOJ announced the resolution of criminal and civil charges brought against Practice Fusion, a California-based developer of a cloud-based electronic health records (EHR) system.[8/] DOJ alleged Practice Fusion violated the AKS by receiving kickbacks for its work with an unnamed opioid company (which we **subsequently learned** was Purdue Pharma) to "influence" physicians to prescribe opioid pain medications through clinical decision support alerts sent to physicians using its EHR system.

DOJ described the alerts as "abhorrent" for a variety of reasons, including the fact that the parties considered clinical guidelines but failed to draft the alerts consistent with them. The resolution of the charges involved a deferred prosecution agreement, admission of guilt, and Practice Fusion's payment of $26 million in criminal fines and almost $1 million in criminal forfeiture. This case broke new ground as the first-ever criminal action against an EHR vendor. Separately, the civil settlement involved a payment of $118 million to federal and state authorities to resolve related kickback allegations giving rise to FCA liability.

> Civil (or even criminal) enforcement actions against ***major national pharmacies*** are on the horizon.

Pharmacies

Pharmacies appear to be the next in line for opioid-related DOJ inquiry. For example, two North Carolina–based pharmacies entered into consent decrees in the past year to resolve civil charges relating to high-volume opioid prescriptions. In February, Farmville Discount Drug and its owner agreed to a $600,000 civil penalty and a permanent prohibition on dispensing opioids and other controlled substances.[9/] Similarly, in December, Seashore Drugs and its owner entered a consent decree and agreed to pay over $1 million in civil penalties and to cease dispensing controlled substances.[10/] In both cases, defendants allegedly ignored "red flags" of drug diversion and drug-seeking behavior in filling prescriptions, amounting to alleged violations of the Controlled Substances Act. Further, in the **2020 National Health Care Fraud and Opioid Takedown**, DOJ announced numerous charges against pharmacy defendants for schemes to defraud insurance programs of millions of dollars, which included allegations of kickbacks paid by pharmacies to marketers in exchange for prescriptions ordered regardless of medical need, and unlawful dispensing of opioids.

Civil (or even criminal) enforcement actions against major national pharmacies are on the horizon.[11/] In October, Walmart brought a declaratory judgment action against federal government agencies (including DOJ) seeking a ruling that Walmart cannot be held civilly or criminally liable for the opioid prescription practices of Walmart's pharmacies. Just two months later, DOJ announced a civil enforcement action against Walmart, alleging Controlled Substances Act violations by Walmart in its pharmacy and distribution operations.[12/] In the Complaint, DOJ alleges Walmart "abdicated" its "critical gatekeeping responsibilities" as a nationwide distributor and dispenser of opioids in (a) pressuring pharmacists to fill prescriptions as quickly as possible; (b) filling prescriptions from identified "pill-mill" prescribers; and (c) failing to monitor and ignoring red flags on suspicious prescription orders.[13/] It remains to be seen whether DOJ will bring criminal charges relating to these allegations.

State AG Actions

State Attorney General (AG) offices have continued to bring opioid enforcement actions as well. For example, the Missouri AG, along with many other state AGs, announced a $1.6 billion

global settlement resolution of claims against Mallinckrodt, a generic opioid manufacturer whose U.S. operations are based in Missouri.[14/] Recently, Massachusetts AG Maura Healey intervened in civil false claims brought against a Tennessee-based addiction treatment center accused of ordering medically unnecessary drug testing and submitting over $50 million in fraudulent health insurance claims.[15/]

In 2021, we expect more of the same with respect to opioid enforcement. The entire opioid supply chain ecosystem is likely to remain under DOJ scrutiny, and pharmacies appear to be the next major DOJ target. High-level executives should be on notice that individuals deemed by DOJ as "responsible corporate officers" face the risk of serious penalties for corporate wrongdoing, and even possible jail time.

COVID-19 Related Fraud

The pandemic created fertile ground for fraud schemes in 2020, and DOJ took criminal as well as civil action against the alleged perpetrators. Generally speaking, these enforcement efforts targeted allegedly fraudulent products as well as individuals and small businesses accused of alleged misuse of Paycheck Protection Program (PPP) funds, but we may see a shift in focus in 2021 toward civil investigations of companies that accepted COVID-19 relief funding through the Provider Relief Fund (PRF), the PPP, and other sources of federal grants and loans.

As mentioned, allegedly fraudulent products related to COVID-19 were the subject of intense enforcement efforts. In a recent speech, the Deputy Assistant Attorney General for DOJ's Consumer Protection Branch noted that, since the start of the pandemic, DOJ has sought to protect the public from "fraudulent and unlawful products" and "fake cures" in the market.[16/] DOJ brought multiple civil actions and advanced numerous criminal prosecutions arising from marketing of allegedly fraudulent products related to COVID-19, including ineffective ozone therapies, a fake vaccine, and the use of "industrial bleach" as a cure for COVID-19. DOJ also **shut down an allegedly fraudulent website** claiming to offer consumers access to World Health Organization COVID-19 vaccine kits in exchange for the cost of shipping and handling, which consumers would pay via credit card on the website.

Alleged schemes related to COVID-19 testing were the target of enforcement efforts as well. In June 2020, **federal prosecutors charged Mark Schena, President of Arrayit Corporation**, a publicly traded medical technology company, in the first securities fraud prosecution related to COVID-19. **Arrayit allegedly submitted or caused the submission** of over $5.9 million in Medicare claims and over $63 million in private insurance claims for allergy and COVID-19 tests that were not medically necessary, were not provided as claimed, or were tainted by the payment of kickbacks and bribes. According to DOJ, Schena "used the COVID-19 pandemic as an opportunity… to capitalize on a national emergency for his own financial gain." Among other things, Arrayit allegedly promoted the ordering of its allergy test panel with every COVID-19 test even though it was not medically necessary. In addition, Arrayit's COVID-19 test kit allegedly failed to meet FDA standards. DOJ charged Schena with conspiracy to commit health care fraud as well as securities fraud because, among other things, he and others allegedly concealed information about the accuracy of Arrayit's COVID-19 testing.

In another securities fraud action involving COVID-19 testing, **the CEO of Decision Diagnostics, Inc. was indicted** for an alleged scheme to defraud investors regarding the development of a finger-prick COVID-19 test. The CEO purportedly knew the test was merely a concept, but he told investors that FDA was on the verge of approving the test. Meanwhile, the CEO reportedly hired lobbyists to persuade FDA to grant emergency-use authorization without the necessary clinical testing and also adopted an alias to broadcast misleading claims to investors on Internet message boards about the demand for the test — and lied to the SEC about it.

Finally, DOJ also expended considerable effort pursuing recipients of loans and other economic relief made available through COVID-19 relief programs, including those created by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). The federal government has made over $2 trillion in loans and other financial support available to individuals, small businesses, health care providers, and others through the PPP, the PRF, and a variety of other programs. Given that the COVID-19 relief programs constitute the largest emergency assistance package in American history, it is not surprising that DOJ prioritized pursuit of fraud related to the COVID-19 relief programs. Early criminal prosecutions targeted individuals and small businesses for making false statements in connection with PPP loans, and they included **two individuals in Rhode Island**, **a software engineer in Washington**, **a Hollywood film producer**, and the **owner of an IT services company**. DOJ will likely initiate more civil as well as criminal actions involving the PPP in 2021, especially since the federal government has expanded the PPP on two occasions since passage of the CARES Act. While DOJ has yet to announce any enforcement actions involving the PRF, which was created to assist health care providers facing unexpected financial challenges due to COVID-19, we expect that relators have already or will soon begin to file qui tam cases alleging, among other things, false representations related to eligibility, other false statements, failure to comply with the program's terms and conditions, and misuse of funds.

Telemedicine Fraud

DOJ's September 30, 2020 announcement of the National Healthcare Fraud and Opioid Takedown (2020 Takedown) sent a clear signal to telemedicine companies. Of the $6 billion in alleged fraud losses in the 2020 Takedown, $4.5 billion was connected to telemedicine fraud. The charges related to, among other things, alleged payment and kickback schemes whereby telemedicine companies and executives prevailed upon health care providers to order medically unnecessary testing, durable medical equipment, and pain medication prescriptions, either after a short phone call or no patient interaction at all.[17] Ordering providers allegedly received kickbacks in exchange for these referrals, which resulted in false claims submitted to federal health care programs. For example, a case charged in the District of New Jersey involved defendants who allegedly submitted over $522 million in false genetic testing claims to Medicare as part of a telemedicine scheme involving patients in all 50 states, D.C., and the Virgin Islands, while another in Illinois resulted in charges against a physician who worked for more than 10 telemedicine

companies and prescribed the highest number of genetic tests across the country, involving $145 million in alleged fraud-related loss.[18]

The fact that these fraud schemes involved genetic testing is not surprising given that **an OIG report** published in 2020 revealed that Medicare has steadily increased its spending on laboratory testing and, in particular, genetic testing. For this same reason, we expect to see DOJ continue to focus on genetic testing fraud in 2021. In addition, the dramatic expansion of telemedicine due to COVID-19 will undoubtedly lead to increased enforcement. Before the pandemic, Medicare and Medicaid covered telemedicine services only in very limited circumstances, but state and federal agencies, including the Centers for Medicare & Medicaid Services (CMS), have waived many of the applicable restrictions to limit in-person visits during the pandemic. The resulting increase in telemedicine services will likely intensify DOJ's already close scrutiny of telemedicine services in 2021.

Consistent with the trend in recent years, 2020 saw substantial investigation and litigation activity related to Medicare Advantage risk adjustment activities, which involve verifying and capturing members' diagnosis codes.

Medicare Advantage

Consistent with the trend in recent years, 2020 saw substantial investigation and litigation activity related to Medicare Advantage risk adjustment activities, which involve verifying and capturing members' diagnosis codes. These diagnosis codes generally reflect members' health status and affect the amount that a Medicare Advantage Organization (MAO) is paid to cover each member. This area will continue to be a priority for DOJ in 2021, given that about one-third of all Medicare beneficiaries are covered by Medicare Advantage, at an annual cost of over $230 billion. In fact, at the December 2, 2020 ABA Civil False Claims Act and Qui Tam Enforcement Institute, Deputy Assistant Attorney General Michael D. Granston gave **remarks** underscoring DOJ's continued focus on the Medicare Advantage risk adjustment processes.

U.S. v. Anthem, Inc.

As discussed in a **previous blog post**, in March 2020, the U.S. Attorney's Office for the Southern District of New York (SDNY) filed suit against **Anthem, Inc.**, alleging that the MAO violated the FCA when it knowingly failed to delete inaccurate diagnosis codes submitted to CMS for risk-adjustment purposes, which thus allegedly inflated payments. Specifically, SDNY alleges that from 2014 to 2018 Anthem purportedly used its "retrospective chart review" program — which it marketed as an "oversight activity" to ensure diagnosis codes were accurately reported to CMS — only to find additional diagnosis codes and increase risk scores and revenue. Where Anthem, working with a medical chart review vendor, identified unsupported diagnosis codes, it allegedly failed to delete those codes and retained higher payment amounts. The government also claims that Anthem made false attestations to CMS when it annually certified that its data submissions were "accurate, complete, and truthful" to its "best knowledge,

information and belief." This case is notable because SDNY, rather than a qui tam relator, filed the case directly against Anthem. The fact that SDNY identified, developed, and filed the claims without the involvement of a relator underscores DOJ's intense scrutiny of MAOs and, in particular, their risk adjustment activities.

Medicare Advantage Settlements

DOJ announced two settlements involving Medicare Advantage in 2020. On September 3, 2020, the U.S. Attorney's Office for the Eastern District of Pennsylvania **announced** that Keystone Health Plan East, Inc. and QCC Insurance Company, Inc., on behalf of parent company Independence Blue Cross, LLC, an operator of Medicare Advantage plans, agreed to pay a total of $2,250,000 plus interest to resolve FCA allegations that the companies incorrectly calculated anticipated plan costs, resulting in inflated Medicare Advantage plan bids to CMS. This settlement is of interest because it focused on the MAOs annual bid to CMS (reflecting the MAOs estimated costs to provide care to its members), rather than on risk adjustment activities. Reflecting DOJ's long-standing concern related to allegedly inflated diagnosis codes, DOJ **announced on** November 16, 2020 that Kaiser Foundation Health Plan of Washington (formerly known as Group Health Cooperative) agreed to pay $6,375,000 to resolve allegations that it submitted invalid diagnoses for Medicare Advantage beneficiaries and received inflated payments from Medicare as a result.

UnitedHealth Medicare Advantage Litigation

A series of long-running lawsuits involving Medicare Advantage continued in 2020. In *U.S. ex rel. Poehling v. UnitedHealth Group Inc.*[19] the government alleged that UnitedHealth Group (UnitedHealth) had fraudulently inflated patient risk scores to obtain higher reimbursements from Medicare Advantage. In March 2019, the court denied the government's motion for partial summary judgment, declining to rule as a matter of law that UnitedHealth was required to delete codes known to be inaccurate. The case is still pending, and currently in discovery. The outcome of the case may have a substantial impact on whether one of the key theories of MAO liability — the failure to delete unsupported diagnosis codes — is deemed non-viable.

Another closely watched case, *UnitedHealthcare Insurance Company v. Azar*, remained ongoing. In September 2018, the District Court for the District of Columbia granted summary judgment in favor of UnitedHealthcare in a case where UnitedHealthcare challenged the 60-day overpayment rule with respect to Medicare Advantage. The court held that the rule violated Medicare Advantage's "actuarial equivalence" and "same methodology" requirements; was arbitrary and capricious because it diverged from CMS's prior policy of recognizing key differences between Medicare Advantage and traditional Medicare; and impermissibly created a "negligence" standard under the FCA by requiring MAOs to exercise "reasonable diligence." The government moved for reconsideration, and, in January 2020, the court denied the government's motion. The government then appealed that decision to the U.S. Court of Appeals for the D.C. Circuit, and **oral argument took place in November 2020**. The case remains pending and will be closely watched in 2021 to see if the D.C. Circuit affirms the district court's decision to invalidate the 60-day overpayment rule.

The manner in which courts apply the *Azar* decision will continue to be an area to monitor in 2021. In March 2020, the District Court for the Northern District of California in ***United States ex rel. Ormsby v. Sutter Health*** rejected a motion to dismiss an FCA theory based on the alleged failure to delete diagnosis codes. The defendants' argument relied substantially on the *Azar* court's "actuarial equivalence" decision.

In *Ormsby*, the government (and a relator) alleged that Sutter Health (Sutter) and its affiliate, Palo Alto Medical Foundation (PAMF), knowingly submitted to CMS unsupported diagnoses codes, which resulted in inflated payments to Sutter. Relying on *Azar*, Sutter and PAMF argued that requiring Medicare Advantage participants to return payments predicated on purportedly unsupported diagnosis codes violated the statutory mandate of "actuarial equivalence" because it would cause CMS to pay less for beneficiaries enrolled in Medicare Advantage Plans than it would pay for those beneficiaries if they were enrolled in traditional Medicare. The court rejected this theory because (1) Sutter and PAMF had not demonstrated that CMS inevitably pays less for Medicare Advantage plan beneficiaries than for traditional Medicare beneficiaries, and (2) "actuarial equivalence" is not a defense to FCA claims. We will continue to monitor how the *UnitedHealth* decisions are being implemented as they make their way through the appeals process.

Pharmaceutical Manufacturers and Patient Assistance Programs

Over the past few years, the Boston U.S. Attorney's Office has entered into settlements with multiple pharmaceutical manufacturers alleged to have violated the FCA by paying kickbacks to Medicare beneficiaries through their patient assistance programs (PAPs), and it did not break the streak in 2020. Three pharmaceutical manufacturers, including **Novartis** and **Gilead Sciences**, paid a combined total of over $170 million to resolve claims that they improperly supported patient assistance programs run by charitable foundations that helped patients afford copayments for their prescription drugs. The settlements are notable for at least two reasons. First, only one of the three press releases mentions a qui tam case; instead, the Boston U.S. Attorney's Office apparently initiated these high-profile investigations, which was the case in many of the settlements announced in previous years. Second, only one of the announced settlements (Novartis) involved a **Corporate Integrity Agreement** (CIA), which was surprising given that some of the other settlements involved CIAs that specifically addressed the implementation of controls and monitoring activities designed to ensure that the PAPs to which the manufacturers donate operate independently. This long-running investigation should be close to completion and may have even concluded already.

Nursing Homes & Elder Care

On a number of occasions in 2020, DOJ representatives indicated an ongoing enforcement focus on nursing homes and related service providers. In March, DOJ **launched a National Nursing Home Initiative**, which coordinates civil and criminal enforcement efforts against nursing homes suspected of providing wholly deficient care to residents (e.g., consistent failure to provide adequate nursing staff, food, and medication and/or to adhere to basic hygiene and infection control protocols, among other practices). Then, in public comments made in **June** and **December**, DOJ representatives

included the use of the FCA to combat schemes designed to take advantage of the elderly among the agency's 2020 enforcement priorities, and they referred specifically to nursing homes and rehabilitation contractors as potential enforcement targets.

Despite the implementation of new enforcement tools and statements that elder care fraud is an enforcement priority, DOJ's focus in this area is nothing new. For many years, DOJ and other federal enforcement agencies, as well as qui tam relators, have focused on nursing homes and other elder care providers. (Mintz has likewise tracked many such cases over the years, including, for example, the ***AseraCare* hospice FCA case** recently settled by DOJ after nearly five years of litigation.) Given DOJ's long-standing focus in this area, the most important lesson to draw from DOJ's new and sustained efforts is likely that providers and companies in this space should sustain and renew their efforts to provide quality care in a manner that complies with applicable regulatory requirements.

There is no time like the present given that nursing homes have been among the facilities hardest hit by the pandemic. Regulatory requirements are already changing to adapt to these unprecedented challenges, and enforcement authorities are already pursuing perceived wrongdoers. In Massachusetts, for example, the Attorney General filed criminal charges against a group of nursing home operators in connection with a COVID-19 outbreak that killed dozens of residents. While this case was the first of its kind, it likely will not be the last. Another state to watch for action in this area is New York, where the Attorney General just released a **report** on nursing homes' response to COVID-19. This report was just issued on January 28, 2021, but it has already sparked controversy because it claims that the New York State Department of Health may have undercounted the number of nursing home residents who died from COVID-19.

> Despite the implementation of new enforcement tools and statements that elder care fraud is an **enforcement priority**, DOJ's focus in this area is nothing new.

AGENCY GUIDANCE AND ACTIONS

OIG's Special Fraud Alert on Speaker Programs

As discussed in a **prior post**, on November 16, 2020, the OIG issued a **Special Fraud Alert** concerning in-person educational programs for health care professionals (HCPs), known as "speaker programs." In OIG's first Special Fraud Alert in six years, OIG warned that parties involved in speaker programs may be subject to "increased scrutiny" under the federal AKS. In-person speaker programs have been a long-standing area of health care fraud enforcement.

The OIG expressed skepticism about the educational value of in-person speaker programs and even went a step further by questioning whether *any* speaker program arrangement is permissible. The concern is that one purpose of any speaker program is to induce HCPs to refer or prescribe their product in violation of the AKS by offering speakers and attendees remuneration that could "skew their clinical decision making." According to the OIG, whether a speaker program violates the AKS depends on the facts and circumstances and the intent of the parties. The Special Fraud Alert identified a non-exhaustive list of "**suspect characteristics,**" which, taken separately or together, may indicate when a speaker program arrangement violates the AKS.

The Special Fraud Alert encouraged companies and HCPs alike to consider the risks involved in participating in speaker programs in light of less risky alternative means for conveying or gathering information. In particular, the OIG noted that HCPs may access the same or similar information provided in a speaker program through online and print resources and third-party educational conferences.

The timing of the Special Fraud Alert is notable given that the pandemic has severely limited in-person activities across the country. The OIG cautioned that the risks associated with speaker programs "will become more pronounced if companies resume in-person speaker programs or increase speaker program–related remuneration to HCPs" when people are able to reconvene in person. Interestingly, the Special Fraud Alert did not discuss whether OIG has the same concerns if speaker programs are held online or by "remote" means, a format to which many events generally have shifted during the pandemic. We expect, however, that virtual speaker programs implicating the same concerns that the OIG voiced in the Special Fraud Alert likely would be the subject of enforcement.

> In OIG's first Special Fraud Alert in six years, OIG warned that parties involved in speaker programs may be subject to "*increased scrutiny*" under the federal AKS.

Enforcement activity regarding speaker programs made headlines earlier this year with the sentencing of the founder of **Insys Therapeutics** and other company executives in connection with the company's kickback scheme related to its high-dose fentanyl sublingual spray, Subsys. Insys previously agreed to pay $225 million to resolve its criminal and civil liability for paying kickbacks to physicians based primarily on its alleged use of speaker programs to bribe HCPs to increase the number and dosages of Subsys prescriptions, often in circumstances where the drug was not medically necessary. The criminal case proceeded under the Racketeer Influenced and Corrupt Organizations statute, and it offers an extreme example of the fraud and abuse risks associated with speaker programs. In another 2020 settlement, **Novartis paid over $642 million** to resolve claims that it bribed physicians with honorariums and lavish meals to prescribe its anti-hypertensive drugs.

In the past, the OIG has often issued a Special Fraud Alert in connection with, or as a precursor to, increased enforcement in a specific area. The Special Fraud Alert leaves no doubt that OIG will continue to scrutinize speaker programs carefully, particularly when gatherings can resume safely after the pandemic. We expect enforcement authorities to make use of data related to payments to HCPs available through **CMS's Open Payments system,** which, incidentally, is even referenced in the Special Fraud Alert.

HHS's Anti-Kickback Statute and Stark Law Final Rules

On November 20, 2020, HHS **finalized** significant changes to regulations implementing AKS, the Physician Self-Referral Law (commonly known as the Stark Law), and the civil monetary penalty rules regarding beneficiary inducements (Beneficiary Inducements CMP). The sweeping changes came through corresponding final rules — **one issued by the OIG addressing changes to the AKS and the Beneficiary Inducements CMP,** and **one issued by CMS addressing changes to the Stark Law**. HHS promulgated the industry-friendly final rules in connection with HHS's Regulatory Sprint to Coordinated Care, and they are designed to offer the health care industry more flexibility and to reduce the regulatory burden associated with the AKS and the Stark Law. Because DOJ and relators often bootstrap violations of the AKS and the Stark Law to allege FCA liability, we expect these rules to have a significant effect on health care fraud enforcement.

Both final rules focus heavily on addressing the potentially chilling impact of the AKS, the Beneficiary Inducements CMP, and the Stark Law on care coordination and value-based care. The OIG implemented three new AKS safe harbors, all designed to protect certain arrangements entered into with or by a value-based enterprise (VBE), which is broadly defined to capture any number of network arrangements where the participants have agreed to collaborate for value-based purposes. Similarly, CMS implemented four new exceptions to the Stark Law for value-based arrangements that apply based on the level of risk assumed by the VBE or the physician.

To address the growing threat of cyberattacks impacting the health care industry, CMS and the OIG finalized a new Stark Law exception and a new AKS safe harbor, respectively, to protect non-monetary donations of certain cybersecurity technology and related services. This new safe

harbor permits individuals or entities, such as large health systems, to donate cybersecurity technology to physician groups or other providers that may otherwise lack the resources to procure cybersecurity technology, as long as the technology is "necessary and used predominantly to implement, maintain, or reestablish cybersecurity."

Other highlights include critical guidance and clarification related to fundamental Stark Law terminology and requirements, such as commercially reasonable, the volume or value standard, and fair market value, and a new Stark Law exception for limited compensation paid to a physician.

The changes discussed above merely scratch the surface of these historic final rules. More in-depth analysis can be found in our **extensive blog series**.

DOJ Civil Division's Inability-to-Pay Memo

Consistent with DOJ's recent efforts to be more transparent about its decision-making processes, Ethan Davis, then Acting Assistant Attorney General for the Civil Division, published an internal memorandum on September 4, 2020 (**Civil Division Memorandum**), addressing the Civil Division's process for assessing an entity's assertion of an inability to pay. DOJ has always entertained requests from defendants to reduce the amount owed based on an inability to pay, but, until now, defendants in civil cases did not necessarily know how DOJ made these decisions. In the past, a defendant would submit DOJ's Financial Disclosure Form, and DOJ would inform the defendant the amount it believed the defendant could pay without providing much, if any, detail regarding the basis for its decision, which made it difficult for the defendant to negotiate a lower amount. The memorandum provides helpful guidance regarding the "analytical framework" used by DOJ when evaluating inability-to-pay claims. The memorandum is well-timed, given that many health care providers suffered financially in 2020 as a result of the pandemic and may need to avail themselves of the inability-to-pay process in FCA cases in 2021.

The process still begins with the defendant's submission of the Financial Disclosure Form, along with relevant documentation, including tax returns and audited financial statements. The defendant bears the burden of establishing the inability to pay and thus should be prepared to respond to a variety of follow-up requests. However, the defendant should be mindful of the fact that any information provided can be used in litigation by the government and may be provided to relators' counsel unless the parties agree otherwise. The information also could be subject to discovery in other proceedings.

The memorandum lists a variety of factors that DOJ will consider when evaluating the request, including background related to the defendant's current financial condition, alternative sources of capital, and collateral consequences. The factors are mostly — but not entirely — consistent with those articulated in a similar memorandum published last year by DOJ's Criminal Division (**Criminal Division Memorandum**). DOJ typically uses "qualified financial experts" to review the documentation, and the process employed is very rigorous.

One important difference between the two guidance documents is that the Criminal Division

makes clear that the parties must first agree upon the amount of the fine before DOJ will consider an inability-to-pay claim while the Civil Division does not mention this issue. Any defendant claiming an inability-to-pay in a FCA case should consider whether it might be advantageous to come to an agreement on the settlement amount before moving forward with this process. DOJ often requires such an agreement in the civil FCA context before it will engage in the inability-to-pay analysis.

HHS Rule Restricting Use of Guidance Standards in Civil Enforcement

Given the extensive use of sub-regulatory guidance in federal health care programs to implement and interpret statutes and regulations, the health care industry has closely monitored several recent developments related to the use of sub-regulatory guidance in enforcement actions.

> A new rule, "promoting *transparency and fairness* in civil enforcement actions," that took effect on January 12, 2021 is one of many now subject to a **60-day pause** imposed by the Biden administration.

A **new rule**, "promoting transparency and fairness in civil enforcement actions," that took effect on January 12, 2021 is one of many now subject to a 60-day pause imposed by the Biden administration. Generally speaking, the rule limits HHS's ability to use guidance documents in enforcement actions. If the rule takes effect after the 60-day period, it would, among many other things, curtail HHS's ability to use standards set forth solely from sub-regulatory guidance documents as the basis for civil enforcement actions. The rule states that HHS "may not treat noncompliance with a standard or practice announced solely in a guidance document as itself a violation of applicable statutes or regulations except as expressly authorized by law."

The rule followed a **December 3, 2020 Advisory Opinion** in which HHS's General Counsel discussed implementing *Azar v. Allina Health Services*,[20] a recent Supreme Court decision where the Court held that under Social Security Act Section 1871, any Medicare issuance that establishes or changes a "substantive legal standard" governing the scope of benefits, payment for services, eligibility of individuals to receive benefits, or eligibility of individuals, entities, or organizations to furnish services, must go through notice-and-comment rulemaking.

The Advisory Opinion explained that, under *Allina*, HHS and CMS cannot bring enforcement based only on guidance that establishes a substantive legal standard. Where HHS or CMS issued guidance that, under *Allina*, should have been promulgated through notice-and-comment rulemaking, DOJ's ability to bring enforcement actions predicated solely on violations of those policies is restricted.

However, enforcement actions can be based on Internet–Only Manuals, and other CMS-issued guidance (including preamble text published with proposed or final rules), where the guidance is closely tied to statutory or regulatory requirements. The sub-regulatory guidance in these circumstances is not establishing or changing a substantive legal standard, but rather is "aid[ing] in demonstrating that the standards in the relevant statutory and regulatory

requirements have been or have not been satisfied." *See* Justice Manual § 1-20.202.

The advisory opinion also addressed the substantial use of preamble language in rulemaking. According to the Advisory Opinion, when HHS engages in notice-and-comment rulemaking through preamble language only, DOJ must be sufficiently clear to separate binding legal obligations from the rest of the preamble text that contains nonbinding interpretive statements.

Given the pervasive reliance on sub-regulatory guidance in federal enforcement actions, we expect the extent to which the government can rely upon sub-regulatory guidance in FCA cases will be hotly contested, and the law in this area will continually develop in the coming years.

HHS's Announcement of a False Claims Act Working Group

On December 4, 2020, HHS **announced** the creation of a FCA Working Group to strengthen the relationship between the HHS, OIG, and DOJ. While the structure and operations of the working group remain to be seen in practice, it is intended to "combat fraud and abuse by identifying and focusing resources on those who seek to defraud the American taxpayers." This working group will seek to identify potential FCA actions and refer them to DOJ and OIG. Additionally, the working group will provide HHS's views on the "legal frameworks of the agency's numerous funding programs."

The working group will purportedly focus on "preventing fraud and abuse" and administering resources to identify "bad actors" while trying not to burden those acting in "good faith" to comply with the law. Additionally, the group expects to provide targeted training to HHS programs that are most vulnerable to fraud and abuse. The purpose of this effort is to improve HHS attorneys' and officials' ability to detect potential false claims and refer them to DOJ and OIG. Moreover, the working group hopes to serve a major role in consultation about legal requirements pertaining to FCA violations.

The announcement did not specify the composition of the working group aside from generally stating that it will be comprised of "former DOJ False Claims Act and healthcare fraud prosecutors, former private counsel for healthcare and life science companies, and HHS attorneys." The statement also provided few details about the group's anticipated operations. The reason for creating the working group is not entirely clear, but we speculate that it relates to the expected increase in government enforcement related to COVID-19 relief programs administered by HHS.

With the Biden administration's arrival in 2021, it is unclear if this working group will be implemented or abolished. If it does survive, its mission and role will be an area to watch. Although DOJ has the sole authority to file FCA cases after obtaining input from the affected agency, this working group could impact what matters CMS and OIG refer to DOJ. The involvement of HHS leaves many questions about the practical function of the working group and its potential impact.

2021 OUTLOOK

With 2020 in the rearview mirror and processes in place to address disruption caused by COVID-19, DOJ will likely be back to normal and actively investigating FCA allegations, whether in response to qui tam cases filed by relators or upon its own initiative. In addition, 2021 brings a new president and attorney general. While both parties typically support health care fraud enforcement, the expectation is that **regulatory and enforcement activity, particularly FCA enforcement, will increase under the Biden administration**. However, we anticipate that DOJ will review and assess FCA policies implemented during the Trump administration, including the so-called **Granston memo** addressing DOJ's dismissal authority in declined qui tam cases under 31 U.S.C. § 3730(c)(2)(a). While we do not expect that the Granston memo will be revised or revoked, the use of dismissal authority likely will be more closely scrutinized at DOJ and thus may be used less often.

Opioid-related enforcement will remain a key area of focus in 2021. We expect that the government will continue to hotly pursue individuals and companies that have allegedly contributed to the opioid epidemic and will use both the criminal laws and the FCA to target additional opioid manufacturers as well as physicians who are accused of improperly prescribing opioids. We also anticipate that the scope of opioid enforcement will expand to include more pharmacies and other entities in the drug supply chain. And it is possible DOJ will once again use the responsible corporate officer doctrine in seeking to hold executives responsible, as it did in the Indivior settlement.

As noted in DOJ's past statements, **including on December 2, 2020,** enforcement related to Medicare Advantage will continue to be a priority for DOJ in 2021. Investigations and litigation will remain focused on risk adjustment activities where MAOs either allegedly add unsupported diagnosis codes or fail to delete codes they later determine are unsupported. We also predict that enforcement activity will be directed at vendors that conduct risk adjustment activities or other support services for MAOs. As MAOs continue to litigate FCA lawsuits involving risk adjustment, and as courts issue more decisions and cases proceed further in litigation, the landscape of Medicare Advantage enforcement will continue to evolve.

COVID-19 undoubtedly will generate substantial enforcement activity in 2021 in several respects. Given the massive amount of COVID-19 relief

funding disbursed through the PPP, the PRF, and other programs over the last year, we expect DOJ and other agencies to closely scrutinize allegations that companies fraudulently obtained or misspent relief funds. By way of comparison, enforcement related to the Troubled Asset Relief Program (TARP), enacted in 2008, still remains ongoing today. And, **as we discussed**, that effort may be a model for COVID-19 enforcement, particularly the coordination and collaboration among a variety of agencies with enforcement authority. While most of the COVID-19 related enforcement actions in 2020 were criminal matters, we expect to see a wave of civil FCA cases involving the PRF and PPP emerge in 2021.

COVID-19 also dramatically accelerated the adoption of telemedicine. Even after the pandemic, we anticipate telemedicine will remain embedded in the health care delivery system. As a result, telemedicine, which was the subject of fraud takedowns and enforcement operations even before the pandemic, will remain a target of enforcement authorities. We expect these enforcement efforts will be directed at countless health care providers and suppliers who provide testing, drugs, durable medical equipment, and other products and services.

The pandemic also put nursing homes under the spotlight, given COVID-19's deadly toll on the elderly. We anticipate that DOJ and state AGs will escalate enforcement against nursing homes, building upon its National Nursing Home Initiative launched in 2020. DOJ will vigorously pursue wide-ranging allegations of deficient care, substandard services, and billing for unnecessary services.

In a year unlike any in recent memory, health care enforcement authorities quickly pivoted to address the emergence of alleged COVID-19 related fraud as the pandemic escalated. At the same time, they continued to pursue matters in many of the same areas that have traditionally been enforcement priorities. While we all hope the pandemic fades away in 2021, COVID-19 related enforcement is likely just beginning.

ENDNOTES

1. The annual statistical report from the Civil Division of the United States Department of Justice includes all civil False Claims Act cases, whether brought by the government or by qui tam relators, in federal fiscal years 1988 through 2020. Each federal fiscal year commences on October 1 and ends on September 30. The Mintz Database includes only unsealed qui tam cases brought against health care companies and related entities. We report data in the Mintz Database on a calendar year basis.

2. U.S. Department of Justice, Remarks by Deputy Attorney General Jeffrey A. Rosen on the Resolution of Civil and Criminal Investigations into Purdue Pharma and the Sackler Family, October 21, 2020, https://www.justice.gov/opa/speech/remarks-deputy-attorney-general-jeffrey-rosen-resolution-civil-and-criminal.

3. In the summer of 2019, Reckitt Benckiser resolved the criminal and civil charges against it for $1.4 billion. We covered that resolution in our 2019 Year in Review (available here).

4. Although the case concerned Indivior Solution's statements to MassHealth, the criminal investigation was brought in the Western District of Virginia, which has led a number of cross-agency investigations into Suboxone and other opioid-related drugs.

5. *See, e.g.*, *United States v. Shaun Thaxter*, Case No. 1:20-cr-00024-JPJ-PMS (W.D. Va. filed June 30, 2020), ECF No. 5.

6. U.S. Department of Justice, "Indivior Solutions Sentenced to Pay $289 Million in Criminal Penalties for Unlawful Marketing of Opioid Drug," Press Release, November 12, 2020, https://www.justice.gov/opa/pr/indivior-solutions-sentenced-pay-289-million-criminal-penalties-unlawful-marketing-opioid.

7. Jeff Overley, DOJ Attys Dish on Indivior Opioid Case as Sentencing Wraps, *Law360*, January 4, 2021, https://www.law360.com/articles/1338969/doj-attys-dish-on-indivior-opioid-case-as-sentencing-wraps.

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

9. U.S. Department of Justice, "Federal Court Orders North Carolina Pharmacy and Pharmacist to Pay $600,000 and to Permanently Cease Dispensing Opioids or Other Controlled Substances," Press Release, February 3, 2020, https://www.justice.gov/opa/pr/federal-court-orders-north-carolina-pharmacy-and-pharmacist-pay-600000-and-permanently-cease.

10. U.S. Department of Justice, "Federal Court Orders North Carolina Pharmacy, Pharmacy Owner, and Pharmacist-in-Charge to Pay More Than $1 Million and Stop Dispensing Opioids," Press Release, December 16, 2020, https://www.justice.gov/opa/pr/federal-court-orders-north-carolina-pharmacy-pharmacy-owner-and-pharmacist-charge-pay-more-1.

11. Jeff Overley, Where DOJ's Opioid Blitz Stands After Purdue's Criminal Case, *Law360*, October 21, 2020, https://www.law360.com/articles/1321712/where-doj-s-opioid-blitz-stands-after-purdue-s-criminal-case.

12. *See* Compl., *United States v. Walmart Inc.*, Case No. 1:20-cv-01744-UNA (D. Del. filed Dec. 22, 2020), ECF No. 1.

13. *Id.*

14. Missouri Attorney General's Office, "Attorney General Schmitt Announces Updated Settlement with Opioid Manufacturer Mallinckrodt," Press Release, October 12, 2020, https://www.ago.mo.gov/home/news/2020/10/12/attorney-general-schmitt-announces-updated-settlement-with-opioid-manufacturer-mallinckrodt.

15. Massachusetts Attorney General's Office, "AG Healey Sues National Addiction Treatment Center Chain for Ordering Medically Unnecessary Drug Tests and Violating Self-referral Laws," Press Release, October 20, 2020, https://www.mass.gov/news/ag-healey-sues-national-addiction-treatment-center-chain-for-ordering-medically-unnecessary.

16. U.S. Department of Justice, Deputy Assistant Attorney General Daniel Feith Delivers Remarks at the FDLI Enforcement, Litigation, and Compliance Conference, December 15, 2020, https://www.justice.gov/opa/speech/deputy-assistant-attorney-general-daniel-feith-delivers-remarks-fdli-enforcement.

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

18. U.S. Department of Justice, Acting Assistant Attorney General Brian C. Rabbitt Delivers Remarks at Health Care Fraud Takedown Press Conference, September 30, 2020, https://www.justice.gov/opa/speech/acting-assistant-attorney-general-brian-c-rabbitt-delivers-remarks-health-care-fraud-0.

19. *See United States ex rel. Poehling v. UnitedHealth Group Inc. et al.*, Case No. 2:16-cv-08697 (C.D. Cal.).

20. *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).

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