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False Claims in Healthcare
Chapter 8. Cutting-Edge Topics in the FCA

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Like seemingly everything else in 2020, False Claims Act (FCA) enforcement and the development of FCA case law was heavily affected by the COVID-19 pandemic. With courts closed and much of the U.S. Department of Justice's (DOJ) attention turned to COVID-19–related issues, much of the action on what were then the FCA's cutting-edge topics stalled. Late in 2020, though, activity on these issues began to pick back up. This chapter covers three (non-COVID-19) topics that are likely to have a significant impact on enforcement and litigation going forward.

First, the chapter covers federal enforcement actions related to the opioid epidemic, which are important for compliance officers to note because of the increasing focus on individual prescribers and organizations.

Second, the chapter summarizes how federal courts have grappled with the U.S. Supreme Court's decision in *Azar v. Allina Health Services* (*Allina*), which held that Medicare cannot change a "substantive legal standard" without notice and comment rulemaking.[4] This is important because of the frequency with which the Centers for Medicare & Medicaid Services (CMS) uses subregulatory guidance (including, among other things, Internet-Only Manuals, local coverage determinations, and preambles to final rules). The *Allina* decision materially affects potential FCA exposure for violation of subregulatory guidance in some situations and will likely require CMS to increasingly rely on regulations.

Finally, the chapter covers DOJ guidance and case law surrounding settlements of FCA actions over the objection of a qui tam relator (i.e., whistleblower). In an era of ever-increasing qui tam actions, often brought by for-profit, outsider relators, whether courts uphold DOJ's moves to dismiss meritless cases stands to have a material impact on the risk profile for many providers.

The Opioid Epidemic

The opioid crisis over the past 20 years has magnified the need for treatment, and along with that comes increased scrutiny. (Note: While this section generally refers to the "opioid crisis," we recognize that this current public health crisis includes issues related to illicit fentanyl and other synthetic opioids, and heroin use, as well as the abuse of prescription opioids.) This section provides a brief overview regarding recent federal initiatives and efforts targeting healthcare fraud related to opioid manufacturing, prescribing, and dispensing. While much of the current focus is on actions that clearly cross the line into fraudulent behavior, the industry should expect that subsequent waves of investigation and attention may involve behaviors that are closer to the line, as opposed to the egregious actions that are the current focus of the government's attention. Moreover, as publicity around such actions continues, whistleblowers will see this as a ripe area and continue to pursue FCA actions.

We may also expect to see more state attorneys general prioritizing actions in this area as a large proportion of substance use treatment is funded through the Medicaid program. As of January 1, 2020, Medicare provides expanded reimbursement for services provided by certified opioid treatment programs. In addition, the CMS Innovation Center has developed two new payment and service delivery models designed to combat the nation's opioid crisis: the Maternal Opioid Misuse (MOM) model and the Value in Opioid Use Disorder Treatment (Value in

Treatment). Beginning in January 2020 for select participants, the MOM model "addresses fragmentation in the care of pregnant and postpartum Medicaid beneficiaries with opioid use disorder (OUD) through state-driven transformation of the delivery system surrounding this vulnerable population."[5] And with a start date in April 2021, the Value in Opioid Use Disorder Treatment Demonstration seeks to "increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce [Medicare program expenditures]."[6]

Federal Initiatives Regarding the Opioid Crisis

As heightened awareness of the consequences of opioid abuse continue, the Trump administration, over its four-year term, pursued a number of federal initiatives aimed at opioid-related fraud. While a detailed discussion of these initiatives is beyond the scope of this text, these initiatives have included:

- **President's Commission on Combating Drug Addiction and the Opioid Crisis**: On March 29, 2017, President Donald Trump signed an Executive Order establishing the Commission on Combating Drug Addiction and the Opioid Crisis.[7] Prior to disbanding in late 2017, the commission released its final report, which included recommendations for a comprehensive solution to the addiction crisis.[8] In 2019, the Executive Office of the President of the United States released an update to the report to detail the progress that had been made in implementing the commission's recommendations.[9]

- **The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act**: On October 24, 2018, President Trump signed into law the bipartisan SUPPORT for Patients and Communities Act, which aims to combat opioid abuse with increased attention to treatment.[10] The wide-reaching compromise legislation combined elements from a number of opioid bills, addressing issues from access to treatment and prevention programs to expanded law enforcement efforts to curtail drug trafficking. Notably, the SUPPORT for Patients and Communities Act contains a new anti-kickback statute, the Eliminating Kickbacks in Recovery Act of 2018 (EKRA), which prohibits remuneration for referrals to recovery homes, treatment facilities, and laboratories (including, as written, laboratories unrelated to substance use treatment). Notably, EKRA applies to remuneration for or to induce referrals to both public and private payors.

- **DOJ initiatives**: DOJ has also specifically increased its response to the prevalent rate of opioid-related crimes with a number of new initiatives. In 2017, it formed the Opioid Fraud and Abuse Detection Unit that targets healthcare fraud using data analytics to investigate and prosecute doctors, pharmacies, and medical providers.[11] Further, in 2018, the DOJ formed the Prescription Interdiction & Litigation Task Force to "aggressively deploy and coordinate all available criminal and civil law enforcement tools to reverse the tide of opioid overdoses in the United States, with a particular focus on opioid manufacturers and distributors."[12] In addition to other specific initiatives, the DOJ has:

    - Assigned experienced assistant US attorneys to opioid "hot spots" to focus energy on opioid-related healthcare fraud;
    - Created new enforcement teams to combat heroin and illicit fentanyl trafficking into the US;
    - Initiated targeted "surges" of special agents, diversion investigators, and intelligence research specialists to "focus on pharmacies and prescribers who are dispensing unusual or disproportionate amounts of drugs;" and

- Created a new enforcement team to target the online sale of drugs.[13]

In addition, as of early 2021, no new actions were taken, but the Biden administration is sure to put in place its own initiatives aimed at combatting the ongoing opioid crisis. During President Joe Biden's campaign, he repeatedly emphasized that he planned to "demand accountability from pharmaceutical companies and others responsible for the opioid crisis, including manufacturers, distributors, and 'pill mill operators.'"[14] The campaign also noted that "[p]harmaceutical executives should be held personally responsible, including criminally liable where appropriate."[15] More recently, there have been reports that the Office of National Drug Control Policy plans to focus on harm reduction, as well as other initiatives aimed at expanding treatment and prevention efforts, to combat the opioid crisis.[16]

FCA Enforcement and Trends

In 2020, DOJ recovered more than $1.8 billion from settlements and judgments (the majority of which were brought by whistleblowers) related to healthcare fraud and false claims.[17] (Note: The $1.8 billion figure is actually even larger, as it does not reflect the additional millions of dollars recovered on behalf of state Medicaid programs.)[18] The targets included drug and medical device makers, managed care providers, hospitals, pharmacies, hospice organizations, laboratories, and physicians. While the amount recovered in 2020 is significantly less than the $2.6 billion recovered from matters involving the healthcare industry in 2019, the overall amount recovered from FCA cases in general was also less in 2020 ($2.2 billion) versus 2019 ($3 billion).[19] Further, the 2020 amount does not include settlements that did not become final before the end of the fiscal year, most notably, the government's resolutions with Indivior and Purdue Pharma.

As a brief overview, in 2020 Indivior (Indivior Solutions, and parent companies Indivior Inc. and Indivior plc) agreed to pay $600 million to resolve both criminal and civil investigations related to the company's marketing of the drug Suboxone, used to treat opioid addiction.[20] In particular, the civil settlement resolved six qui tam lawsuits brought against Indivior, which included claims that the company's Suboxone marketing caused false claims to be submitted to federal healthcare programs. Similarly, in late 2020, DOJ reached a global resolution with Purdue Pharma to resolve criminal and civil investigations related to the company's alleged conduct in promoting and unlawfully inducing prescriptions of opioids.[21][22] The civil settlement to resolve the company's alleged FCA liability, pending bankruptcy court approval, is in the amount of $2.8 billion. In addition, individual owners of Purdue Pharma, members of the Sackler family, will pay $225 million to resolve their own alleged FCA liability.

Among its other recoveries in 2020, DOJ noted that one of the largest opioid-related recoveries was from Practice Fusion Inc., a health information technology developer.[23][24] Practice Fusion agreed to pay $145 million to resolve criminal and civil investigations relating to the solicitation and receipt of kickbacks from an opioid manufacturer. According to the DOJ's news release, "[a]s part of the criminal resolution, Practice Fusion admit[ted] that it solicited and received kickbacks from a major opioid company in exchange for utilizing its EHR [(electronic health records)] software to influence physician prescribing of opioid pain medications."[25]

Looking back to 2019, the DOJ reported that its largest recoveries came from opioid manufacturers—Insys Therapeutics ($195 million to settle civil allegations that it paid kickbacks to induce physicians and other professionals to prescribe Subsys for their patients) and Reckitt Benckiser Group PLC, Indivior's former parent company ($1.4 billion to resolve civil and criminal allegations related to marketing of Suboxone, an opioid addiction treatment drug).[26][27][28] Notably, the recovery from Reckitt is one of the largest recoveries in a case

concerning an opioid drug in US history.[29]

The government's efforts to combat opioid abuse and prevent further loss of life continue to include both criminal prosecutions and civil litigation. In the past, such efforts have focused on manufacturers. We have seen, however, that these efforts have expanded over the past several years. In particular, while there has been an increased focus on opioid-related healthcare fraud in general, there also appears to be an increased focus on investigations and prosecutions of *individual* physicians and others. In contrast to two opioid-related FCA settlements with individuals from 2014 to 2017, the DOJ recovered $4.6 million from five individuals in 2018 alone.[30] Moreover, the recent Practice Infusion settlement demonstrates that "complex EHR-related fraud schemes remain a focus of the Department's work."[31]

Similarly, there is an expanded focus on pharmacies and pharmacists. The DOJ's Prescription Interdiction & Litigation Task Force has been active, bringing a "first of its kind" action against pharmacies and pharmacists in Tennessee for violations of both the Controlled Substances Act and the FCA.[32][33] (Note: The task force also investigates distributors and pharmacies for violations of the Controlled Substances Act.)[34] DOJ alleged that the pharmacies "routinely dispensed controlled substances while ignoring numerous 'red flags' or warning signs of diversion and abuse, such as unusually high dosages of oxycodone and other opioids, prescriptions for opioids and other controlled substances in dangerous combinations, and patients travelling extremely long distances to get and fill prescriptions," and, in addition, that the pharmacies "falsely billed Medicare for illegally dispensed prescriptions."[35] In the context of that litigation, the DOJ used a temporary restraining order to suspend the pharmacy's ability to dispense controlled substances.[36] It is now clear that, in addition to targeting the prescribers, that the DOJ may also target pharmacists and pharmacies that fill illegitimate prescriptions. This expanded focus was echoed in statements made by a deputy assistant attorney general in December 2020: "The Consumer Protection Branch is also going after unlawful actions by others in the opioid supply chain, including pharmacies. Pharmacies are the last lines of defense [against] prescription opioid diversion. But too many pharmacies, for too long, abdicated that responsibility."[37]

Finally, to date, there have been at least two documented prosecutions under EKRA, the new drug anti-kickback statute. First, a woman from Jackson, Kentucky, pled guilty to soliciting kickbacks from a toxicology laboratory in exchange for urine drug testing referrals.[38] She faces up to 20 years in prison and a maximum fine of $250,000.[39] The most recent prosecution involved a multistate patient-brokering scheme, which led to five defendants being named and charged for their respective roles in the scheme. One particular defendant, Dr. Akikur Mohammad, was charged with conspiracy to violate EKRA while in his role as owner/operator of a rehab facility paying referral fees in exchange for patients.[40] In September 2020, Mohammad pled guilty to one count of conspiracy to violate EKRA and faces up to five years in prison and a fine of $250,000 or twice the gross gain or loss from the offense. (Note: In addition to applying to all payers,the definition of "laboratory" is broad, potentially implicating referrals for clinical laboratory tests even if the tests do not relate to substance use testing or treatment. The two enforcement actions under EKRA unfortunately do not provide any further guidance on the impact of the statute. Further, to date, there have been no clarifying regulations promulgated, nor has any agency provided guidance regarding how the federal anti-kickback safe harbors will be reconciled with the exceptions provided in EKRA. Thus, it is important to keep EKRA in mind when structuring arrangements in the substance use disorder context and to reevaluate existing relationships with clinical treatment facilities, recovery homes, and laboratories.)