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2017 Health Care Enforcement Review: Final Thoughts

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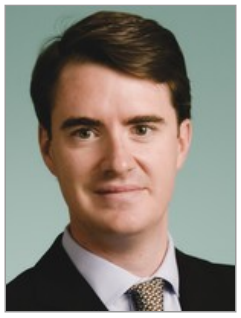
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In both civil and criminal enforcement proceedings, 2017 was perhaps most notable for the cases brought against individual health care providers and small physician practice owners. Among the factors that may have resulted in the uptick in cases against individuals are the Yates memo issued in late 2015, improved and increased reliance on sophisticated data analytics, and the aggressive focus on opioid addiction and its causes.

This article, the final in our "2017 Health Care Enforcement Review" series, examines both criminal and civil health care enforcement trends from last year. Part 1 addressed several trends in FCA cases from 2017, part 2 discussed some of last year's most important FCA-related court decisions, and part 3 explored 2017 developments related to the materiality requirement in FCA cases.

Enforcement Efforts Against Individuals

Criminal Prosecution of Individuals Under the Yates Memo

Along with several blockbuster civil settlements involving health care companies came criminal prosecutions of individuals deemed responsible for the violations. As discussed in a late 2016 post, the Yates memo set the threshold for a company to receive any cooperation credit at providing all relevant facts about all individuals involved in misconduct from the top to the bottom of the company hierarchy. Regardless of whether the cooperation comes at the beginning or the end of the investigation, the government is most likely going to require the company's cooperation as a condition of settlement.

Increasingly, criminal and civil resolutions ensure ongoing cooperation from companies in the government's investigation of individuals. The Tenet case provides an example. The hospital chain paid approximately $513 million in late 2016 to resolve criminal and civil kickback claims. Several Tenet subsidiaries pled guilty to a criminal information, and the parent company and remaining subsidiaries entered into a nonprosecution agreement with strict monitoring and an ongoing requirement to cooperate in the government's investigation of responsible individuals. In 2017, two former Tenet executives were then charged with various kickback-related crimes.

As we noted last year, the government will continue to look to make positive examples of companies that do as the Yates memo requires and opt for early self-disclosure of wrongful conduct and provide all of the evidence about those responsible. We have yet to identify a case that clearly illustrates the benefits afforded to a compliant company, likely because companies benefiting from the Yates memo's provisions strive to keep the specifics of the wrongdoing confidential. Notwithstanding, the government may move toward providing more concrete guidance as to the benefits of disclosure and certainty to companies that must make time-sensitive decisions.

In October, Deputy Attorney General Rod Rosenstein stated that the U.S. Department of Justice was reviewing the Yates memo and considering modifications to it. In a more recent speech, Rosenstein announced a new DOJ policy for Foreign Corrupt Practices Act enforcement. The new policy creates a presumption that the

DOJ will decline to prosecute companies that voluntarily and promptly self-disclose FCPA violations. It further provides that where the conduct requires a criminal resolution, voluntary self-disclosure will earn a 50 percent sentencing guidelines reduction and no requirement of a corporate monitor. Even where a company does not voluntarily self-disclose violations, a "limited credit" of a 25 percent guidelines reduction is available in certain circumstances. Whether those more tangible benefits will be expanded beyond the FCPA context remains to be seen, but the DOJ clearly recognizes the need for more certainty about the benefits of disclosure of wrongdoing in all contexts.

In its annual National Health Care Fraud "Takedown," a coalition of enforcement agencies headed by the Medicare Fraud Strike Force charged 412 defendants, including 115 physicians, nurses and other individual health care providers. At the forefront of the charges brought were those related to the distribution of opioids. U.S. Attorney General Jeff Sessions has repeatedly indicated that combating opioid addiction is a key goal of his administration. True to his word, U.S. attorney's offices around the country are prosecuting physicians and other providers in opioid cases using drug trafficking statutes typically reserved for street drug dealers.

Civil Settlements Involving Individuals

The government also ramped up its civil enforcement efforts against individuals in 2017. The DOJ recently issued its year-end report on recoveries under the False Claims Act in which it discussed several cases involving physicians, executives and employees who either: (1) agreed to be jointly and severally liable with companies settling FCA cases; or (2) separately resolved FCA cases with the DOJ. In fact, the DOJ reported obtaining more than $60 million (representing 2.5 percent of all total FCA recoveries in health care cases in 2017) in resolutions falling into the second category.

A few example cases drive home the DOJ's commitment to holding individuals accountable for the wrongdoing of corporations in the civil context:

- Three founders of eClinicalWorks (ECW), a national vendor of electronic health records (EHR) technology, agreed to joint and several liability for the company's $155 million FCA settlement. ECW agreed to pay this amount to resolve allegations that it falsely obtained certification of the company's EHR software by concealing from its certifying entity that the software did not comply with certification requirements. Three other employees entered into separate settlement agreements with the government to resolve liability for their alleged personal involvement in the conduct at issue (a developer agreed to pay $50,000 and two project managers each agreed to pay $15,000).

- A pain management physician, Dr. Robert Windsor, agreed to a $20 million consent judgment to resolve FCA allegations related to billing federal health care programs for medically unnecessary services and services not performed. Windsor owned pain management clinics in Georgia and Kentucky and was accused of conducting two schemes: (1) causing the submission of false claims to federal health care programs for online intraoperative monitoring of surgeries that neither he nor any other physician monitored despite representations to the contrary; and (2) submitting, or causing the submission of, false claims to federal health care and Medicaid programs for medical tests and procedures. To satisfy the $20 million consent judgment, Windsor agreed to sell all but one of his residential and commercial properties, as well as two boats and four jet skis (among other assets) and pay the net proceeds to the government. In addition, Windsor was sentenced to 28 months in federal prison and three years of supervised release in connection with the conduct alleged with respect to the first scheme.

- Finally, as discussed in a previous post, the government has focused its enforcement efforts in recent years on the business practices of laboratories. That trend continued in 2017 with a number of settlements involving physicians and physician practices who allegedly received kickbacks from laboratories that settled cases. For example, physicians across the country entered into civil settlements with the Office of Inspector General for the U.S. Department of Health and Human Services (OIG) related to their alleged acceptance of illegal remuneration from Millennium Health, which settled FCA allegations back in 2015. In that case, Millennium agreed to pay $256 million to settle allegations of FCA violations based on (1) billing Medicare, Medicaid and other federal health care programs for medically unnecessary urine testing; and (2) providing physicians with free point-of-care urine drug test cups, but only if the physician agreed to return the urine specimens to Millennium for hundreds of dollars' worth of additional testing. The physicians who settled allegedly accepted the point-of-care cups from Millennium.

Aggressive Pursuit of Misconduct Involving Opioids

The recent indictments of several executives and eventually the founder and majority owner of Insys Therapeutics, the maker of a fentanyl spray, is illustrative of the elevated risk of having any connection to opioids. The Insys executives were charged with various kickback-related crimes including Racketeer Influenced and Corrupt Organizations Act conspiracy for paying allegedly sham "speaker fees" to high-volume prescribers of its drug. In contrast, we are aware of several investigations of similar conduct where the government declined to intervene in qui tam cases or civil resolutions and did not charge or otherwise sanction any individuals. Although the government might insist that the scheme employed by Insys was particularly egregious, we speculate that the key difference might be that this case involves opioids.

In addition, a recent civil settlement involving opioids ultimately led to the criminal prosecution of individuals. Galena Biopharma (Galena) agreed to pay more than $7.55 million to resolve allegations under the FCA that it paid kickbacks (including free meals, speaking fees and registry payments) to induce physicians to prescribe its fentanyl-based drug Abstral. The government also alleged that Galena paid approximately $92,000 to a physician-owned pharmacy under a performance-based rebate agreement to induce the owners to prescribe Abstral.

Consistent with the post-Yates memo trend discussed above, Galena cooperated in the prosecution of two physicians to whom the company provided remuneration. Following an extensive investigation, the physicians, who jointly owned and operated two pain management clinics and a pharmacy, were charged with multiple federal felony offenses, including conspiracies to commit wire fraud, mail fraud, health care fraud and to violate the federal Anti-Kickback Statute (AKS). The government also alleged that the physicians knowingly and willfully prescribed Schedule II and III controlled substances, including fentanyl, outside the usual course of professional practice and not for a legitimate medical purpose, but instead to unlawfully enrich themselves. In May, the physicians were sentenced to 240 months and 252 months in prison, respectively, and ordered to pay nearly $14 million in restitution to insurers, including the Medicare and TRICARE programs.

Other Civil Enforcement Trends

2017 was an interesting year from a civil enforcement perspective. Even though the government collected slightly less this year in total judgments and settlements in health care-related FCA matters (approximately $2.48 billion in 2017, as compared to $2.6 billion in 2016), the government shows no signs of slowing down its enforcement activities.

Settlements Announced Involving Patient Assistance Programs

The U.S. Attorney's Office for the District of Massachusetts issued a number of subpoenas in 2017 (and in past years) seeking information about pharmaceutical manufacturers' contributions to patient assistance programs (each a PAP, collectively, PAPs) offering copayment assistance to financially needy patients. In addition, the OIG continued to reexamine compliance with its past guidance and opinions related to PAPs. In late November, the OIG took the unprecedented step of rescinding a previously issued advisory opinion, No. 06-04. In that advisory opinion, the OIG concluded that the requesting PAP could accept donations from pharmaceutical manufacturers and use those funds to provide assistance to federal health care program beneficiaries without running afoul of the Civil Monetary Penalties Law or the AKS based on the existence of certain compliance safeguards.

However, according to the notice of rescission, the OIG has since decided that the requesting PAP (now known to be the Caring Voice Coalition) was not in compliance with those safeguards because it was allegedly providing patient-specific data to pharmaceutical manufacturer donors that would enable them to correlate the amount and frequency of their donations with the number of subsidized prescriptions or orders for their products, and also allowing those donors to influence the identification or delineation of the PAP's disease categories. Presumably to avoid negative press after the Caring Voice Coalition announced it would no longer give financial assistance to patients, the OIG announced in a letter to the Pharmaceutical Research and Manufacturers of America that drug manufacturers can lawfully provide free drugs to Medicare and Medicaid beneficiaries who previously received assistance from the charity, as long as certain safeguards are followed.

The government's interest in the relationships between PAPs and their donors also led to two announced settlements in 2017. Both settlements involved pharmaceutical manufacturers that resolved FCA cases based on allegations that the manufacturers violated the AKS by using a PAP as a conduit for providing copayment assistance to Medicare beneficiaries. It should come as no surprise that one of those

settlements involved a company, United Therapeutics, that made donations to the Caring Voice Coalition. United Therapeutics as well as the other company paid to settle the cases, and each entered into a corporate integrity agreement (CIA). It is notable that neither the settlements nor the CIAs prohibited the manufacturers from donating to PAPs in the future. But the CIAs specifically addressed the implementation of controls and monitoring activities designed to ensure that the PAPs to which the manufacturers donate operate independently. The OIG previously described many of those compliance safeguards in great detail in previously published advisory opinions and guidance documents. These CIAs (you can access the United Therapeutics settlement here) provide useful insight into the government's continuing expectations for relationships between PAPs and manufacturers.

Given the number of subpoenas issued to PAPs and their manufacturer donors over the years, we are sure to see additional activity in this area in 2018.

Hospital-Physician Relationships Continue to Face Scrutiny

Enforcement agencies continued to show strong interest in hospital-physician relationships in 2017. For example, in June the DOJ announced that the entities that own and operate Pacific Alliance Medical Center, an acute care hospital located in Los Angeles, California, agreed to pay $42 million to settle a FCA case involving allegations that the hospital's financial relationships with referring physicians violated the AKS and the Stark Law because the entities paid above-market rates to rent office space in physician offices, and engaged in marketing arrangements that provided undue benefit to the physicians' practices.

While most of the settlements of this nature involved the hospitals, the government did pursue physicians as well. In December, two physician groups agreed to pay over $33 million to resolve allegations that they accepted illegal remuneration in exchange for referring patients to hospitals owned by the now-defunct Health Management Associates (HMA). Executives from one of the practices were also parties to the settlement. Further, the parent company of one of the groups entered into a corporate integrity agreement with the OIG.

Post-Acute Care Services Providers Still on the Hot Seat but 2018 May Bring Some Relief

Over the past year the government announced a number of settlements involving medically unnecessary post-acute care services, continuing a trend from previous years. For example, in October the DOJ announced that Chemed Corp, which owns the largest for-profit hospice chain in the United States, and various subsidiaries agreed to pay $75 million to resolve allegations brought under the FCA premised on the submission of Medicare claims for:

- services provided to hospice patients who were not terminally ill (and thus did not qualify for the hospice benefit), and
- continuous home care services that were not necessary, not actually provided or not performed in accordance with Medicare requirements.

This resolution represented the largest amount ever recovered under the FCA from a hospice care provider. The DOJ announced settlements for similar conduct alleged against other providers of post-acute care services in June and July.

Whether this trend will continue remains to be seen given that some courts have expressed skepticism toward FCA cases based on submission of claims for medically unnecessary services. In last year's advisory concerning 2017 case law developments we discussed the Northern District of Alabama's decision in United States ex rel. Paradies v. AseraCare Inc., where the court held that claims are not "false" under the FCA when the alleged falsity is based on a retrospective difference of clinical opinion about the medical necessity of the services at issue. This case — which is before the Eleventh Circuit — is discussed in greater detail in our article addressing major case law developments.

Another notable case we cover in that same post is United States ex rel. Polukoff v. St. Mark's et al, where another district court found that a relator cannot successfully allege violations of the FCA based on a purported lack of medical necessity unless there is an objective standard articulated by Medicare. We will continue to monitor in 2018 whether this decision and others like it lead to a change in strategy among government agencies (and relators) with regard to FCA cases premised on medical necessity theories of liability.

Given that the revenue from health care fraud actions once again constituted the largest component of government enforcement recoveries in 2017, we can expect continued vigorous prosecution of health care cases civilly and criminally.

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