THE FALSE CLAIMS ACT AND HEALTH CARE: 2020 RECOVERIES AND 2021 OUTLOOK

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U.S. Health Care Fraud and Abuse Alert

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False Claims Act[1] (FCA) civil fraud recoveries in Fiscal Year (FY) 2020 dropped over US$850 million when compared to those in FY 2019. While the more than US$2.2 billion in recoveries in FY 2020 continued a general downward trend in FCA civil fraud recoveries since 2016,[2] the past year's recovery total was likely affected negatively by the global COVID-19 pandemic, which caused government enforcement delays ranging from curtailed in-person meetings/interviews to extended timelines for responses to civil investigative demands and settlements. The FY 2020 recoveries also do not represent significant actual or pending recoveries totaling over US$3.3 billion, which were not realized prior to the close of FY 2020.[3] Given these large, pending recoveries and the nation's potential emergence from the pandemic during the course of 2021, it is highly likely that FY 2020 will be an outlier, while FY 2021 may prove to be an exceptionally high year in terms of FCA recoveries.

As in years past, the lion's share of the government's FY 2020 civil fraud-related recoveries came in health care, which accounted for approximately 83 percent of recoveries.[4] The largest recoveries in FY 2020 came from the pharmaceutical industry.[5] The government also demonstrated a continued commitment in FY 2020 to targeting alleged fraud involving electronic medical records vendors,[6] genetic testing laboratories and companies,[7] schemes to bill federal health care programs for medically unnecessary services,[8] and compensation arrangements between hospitals and employed physicians.[9] The government was particularly focused on medical device manufacturers and durable medical equipment manufacturers in both its FCA and related kickback investigations in FY 2020.[10] As in FY 2019, the government demonstrated in FY 2020 a continued willingness to pursue FCA actions against individuals operating in the health care industry, including physicians, as a means of achieving wider deterrence and establishing accountability for alleged corporate misconduct.[11]

In the past year, health care experienced what certainly felt like fundamental shifts across the industry due to the COVID-19 pandemic, as demonstrated by, among other things, the precipitous expansion of telehealth services,[12] the broad application of blanket waivers to providers navigating the pandemic, and the extensive impact of government aid programs on health care. In considering these shifts and other trends from FY 2020, three areas appear particularly positioned for increased relator and government enforcement activities and/or FCA caselaw development in FY 2021: (1) enforcement efforts targeting recipients of Provider Relief Fund (PRF) funding under the Coronavirus Aid, Relief, and Economic Security (CARES) Act; (2) the role of sub-regulatory guidance in FCA actions; and (3) scrutiny of private equity firms and their investments in health care entities. This article analyzes FCA activity in FY 2020 by the numbers, and considers how those numbers might shift in FY 2021 as a result of the latter emerging areas and governmental priorities in health care fraud enforcement.

To read the full alert, click here.

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FOOTNOTES

[1] 31 U.S.C. § 3729 et seq.

[2] U.S. Dep't of Just., Fraud Statistics Overview (Jan. 14, 2021).

[3] Press Release, U.S. Dep't of Just., Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021).

[4] *Id.*

[5] This included two settlements with Novartis Pharmaceuticals Corporation totaling over US$642 million. See Press Release, U.S. Dep't of Just., Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians (July 1, 2020); see also Press Release, U.S. Dep't of Just., Gilead Agrees To Pay $97 Million To Resolve Alleged False Claims Act Liability For Paying Kickbacks (Sept. 23, 2020), (announcing settlement with Gilead Sciences, Inc.); Press Release, U.S. Dep't of Just., Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Oct. 25, 2019); Press Release, U.S. Dep't of Just., Third Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Nov. 20, 2019); Press Release, U.S. Dep't of Just., Justice Department Recovers Over $2.2 Billion from False Claims Act Cases in Fiscal Year 2020 (Jan. 14, 2021). Based on a 4 February 2021 nationwide settlement with McKinsey & Company for US$600 million for its alleged role advising pharmaceutical companies on how to sell more prescription opioid painkillers, consultants to the pharmaceutical industry may also be at increased risk for FCA liability in the future. See Geoff Mulvihill, McKinsey agrees to pay nearly $600M over opioid crisis, AP NEWS (Feb. 4, 2021). McKinsey neither admitted or denied liability. See, e.g., Final Judgment, California v. McKinsey & Co., Inc., United States, No. RG21087649 (Cal. Super Ct. Feb. 4, 2021).

[6] Press Release, U.S. Dep't of Just., Electronic Health Records Vendor to Pay Largest Criminal Fine in Vermont History and a Total of $145 Million to Resolve Criminal and Civil Investigations (Jan. 27, 2020).

[7] Press Release, U.S. Dep't of Just., Genetic Testing Company and Three Principals Agree to Pay $42.6 Million to Resolve Kickback and Medical Necessity Claims (Oct. 9, 2019).

[8] Press Release, U.S. Dep't of Just., Reference Laboratory, Pain Clinic, and Two Individuals Agree to Pay $41 Million to Resolve Allegations of Unnecessary Urine Drug Testing (Apr. 15, 2020); Press Release, U.S. Dep't of Just., Universal Health Services, Inc. to Pay $117 Million to Settle False Claims Act Allegations (July 10, 2020).

[9] Press Release, U.S. Dep't of Just., West Virginia Hospital Agrees To Pay $50 Million To Settle Allegations Concerning Improper Compensation To Referring Physicians (Sept. 9, 2020); Press Release, U.S. Dep't of Just., Oklahoma City Hospital, Management Company, And Physician Group To Pay $72.3 Million To Settle Federal And State False Claims Act Allegations Arising From Improper Payments To Referring Physicians (July 8, 2020).

[10] Press Release, U.S. Dep't of Just., Resmed Corp. to Pay the United States $37.5 Million for Allegedly Causing False Claims Related to the Sale of Equipment for Sleep Apnea and Other Sleep-Related Disorders (Jan. 15, 2020); Press Release, U.S. Dep't of Just.,DOJ Files Suit against Spine Device Manufacturer and Executives Alleging Kickbacks to Surgeons through Sham Consulting Payments (Mar. 5, 2020); Press Release, U.S. Dep't of Just., Acting Manhattan U.S. Attorney Announces $40.5 Million Settlement With Durable Medical Equipment Provider Apria Healthcare For Fraudulent Billing Practices (Dec. 21, 2020).

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[11] Press Release, U.S. Dep't of Just., Lancaster Surgeon to Pay $4.25 Million to Resolve False Billing and Kickback Claims (Oct. 3, 2019); Press Release,U.S. Dep't of Just., Surgeon Agrees to Pay $1.75 Million to Resolve Allegations that He Accepted Kickbacks from SpineFrontier (Apr. 24, 2020); Press Release, U.S. Dep't of Just., DOJ Files Suit against Spine Device Manufacturer and Executives Alleging Kickbacks to Surgeons through Sham Consulting Payments (Mar. 5, 2020).

[12] For example, according to some studies, March 2020 saw a 154 percent increase in telehealth visits as compared with the same period in 2019. See Lisa M. Koonin, DrPH et al.,Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 30, 2020).

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