22 February 2021

Practice Groups:

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Federal, State, and Local False Claims Act

Policy and Regulatory Area

The False Claims Act and Health Care: 2020 Recoveries and 2021 Outlook

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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

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[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).

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.

FY 2020 Civil Fraud Recoveries

In FY 2020, the government obtained more than US$2.2 billion[13] in total civil fraud recoveries, in large part because of the operation and application of the FCA.[14] These recoveries amounted to a decrease from the US$3 billion collected in FY 2019.[15] As has been the case since FY 2014, however, the government's recoveries have generally trended downward since that year's record high recoveries of US$6.1 billion.[16] Since at least 2014, whistleblower or qui tam lawsuits remained the primary driver of these recoveries, particularly within health care.[17]

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[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).

[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).

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

[14] *See* 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).

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

[16] *Id.*

[17] *Id.*

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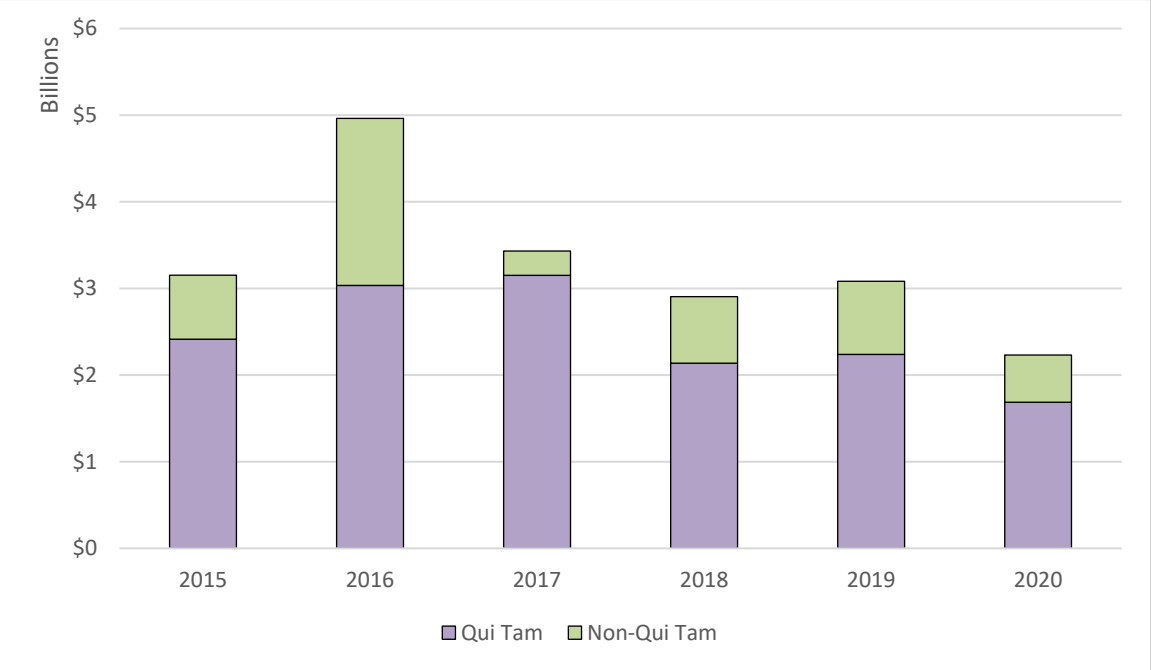

Figure 1: Total Civil Fraud Recoveries[18]

Recoveries in the health care industry decreased dramatically in FY 2019.[19] Specifically, the government recovered approximately US$1.8 billion in civil fraud-related actions involving the health care industry in FY 2020, compared to US$2.6 billion recovered in FY 2019.[20] FY 2020 recoveries in health care represented approximately 83 percent of all recoveries.[21] FY 2020 was the first time in over 10 years that health care fraud recoveries did not surpass US$2 billion.[22]

[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*

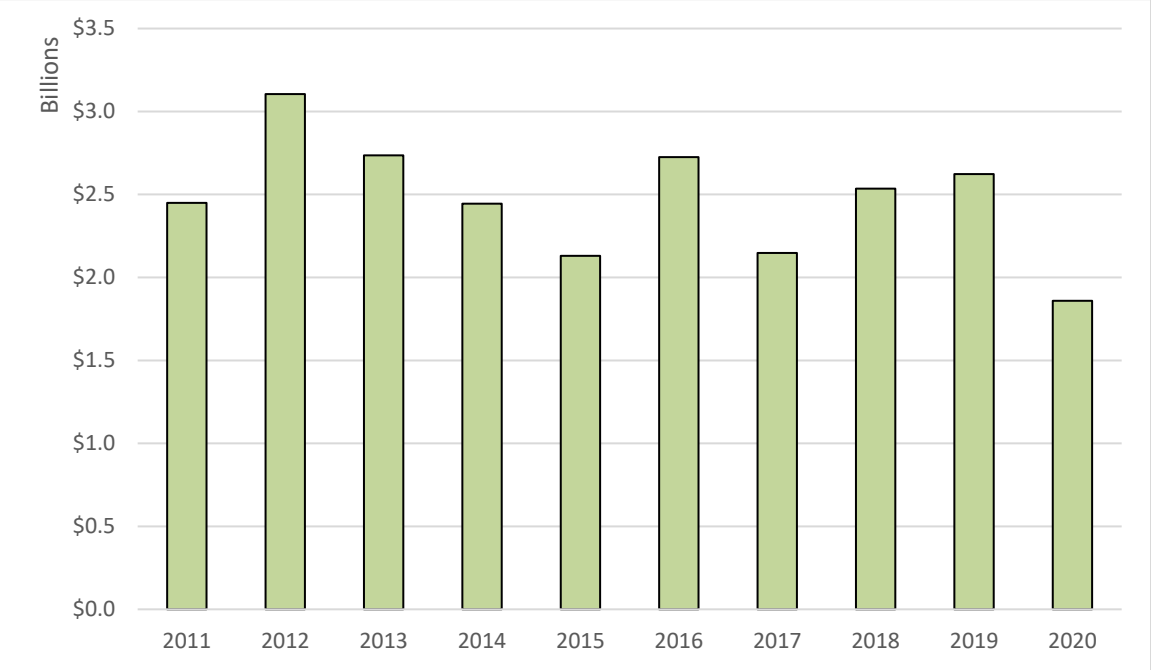

Figure 2: Civil Fraud Recoveries Related to the Health Care Industry[23]

Considering only qui tam actions in which the government intervened, FY 2020 recoveries from interventions totaled US$1.49 billion.[24] In stark contrast, recoveries from non-intervened cases amounted to US$193 million.[25] Of the US$1.49 billion recovered in intervened cases, US$1.28 billion—or approximately 86 percent—involved the health care industry.[26] As illustrated in the graph at Figure 3, from FY 2015 to FY 2020, total recoveries from actions in which the government intervened have generally declined.[27] Recoveries in health care-related actions where the government intervened slightly decreased from approximately US$1.65 billion in FY 2019 to approximately US$1.28 billion in FY 2020.[28] Despite these recent declines in recoveries, efforts to combat fraud in health care remain robust, and government intervention remains the driving force behind the vast majority of civil fraud recoveries inside and outside of health care.

[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*

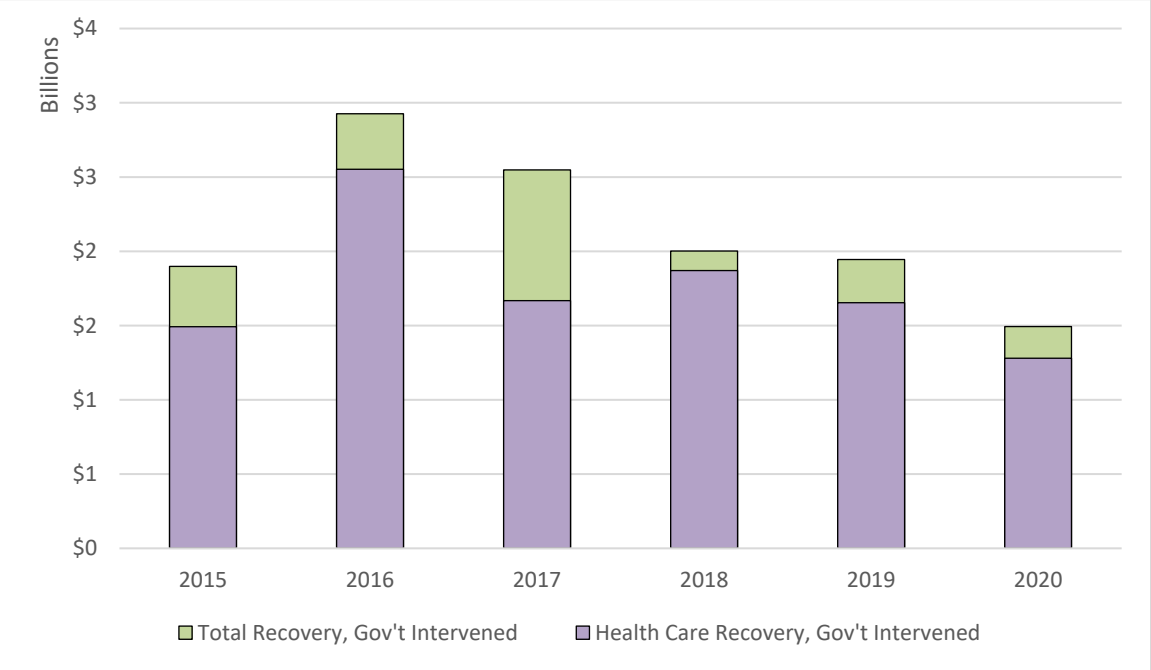

Figure 3: Civil Fraud Recoveries in Government-Intervened Matters[29]

The use of the FCA primarily in health care is also evident in the number of FCA actions filed last year.[30] In FY 2020, 922 new FCA actions were filed, 672 of which were qui tam or whistleblower actions (which amounts to an average of approximately 13 new qui tam cases per week).[31] While the number of new qui tam whistleblower actions has generally remained the same, FY 2020 saw a marked 69 percent increase in non-qui tam actions filed by the government.[32]

Of the 922 new FCA actions, 573—or 62 percent—were related to the health care industry, which represents a small decline from 70 percent in FY 2019.[33] Non-qui tam actions in the health care industry also drastically increased over 100 percent.[34]

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] While it is currently unclear what the specific driver is of the significant increase in non-qui tam FCA actions in FY 2020, the increase is potentially due to government-initiated FCA actions against non-health care recipients of Paycheck Protection Program (PPP) payments under the CARES Act.

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

[34] *Id.*

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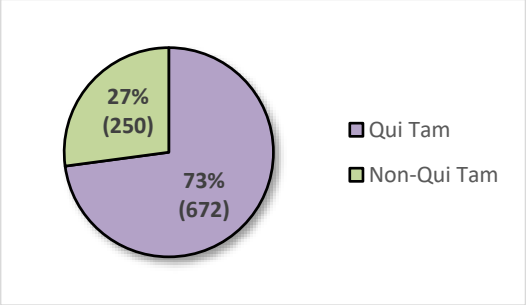

Figure 4: FCA Actions Filed in FY 2020[35]

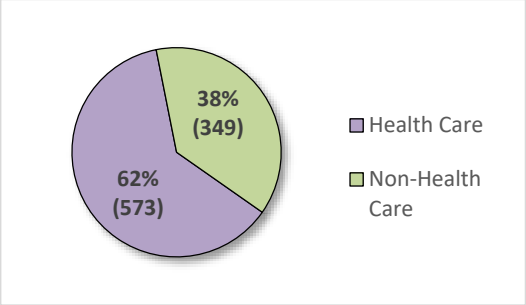

Figure 5: Health Care-Related FCA Actions Filed in FY 2020[36]

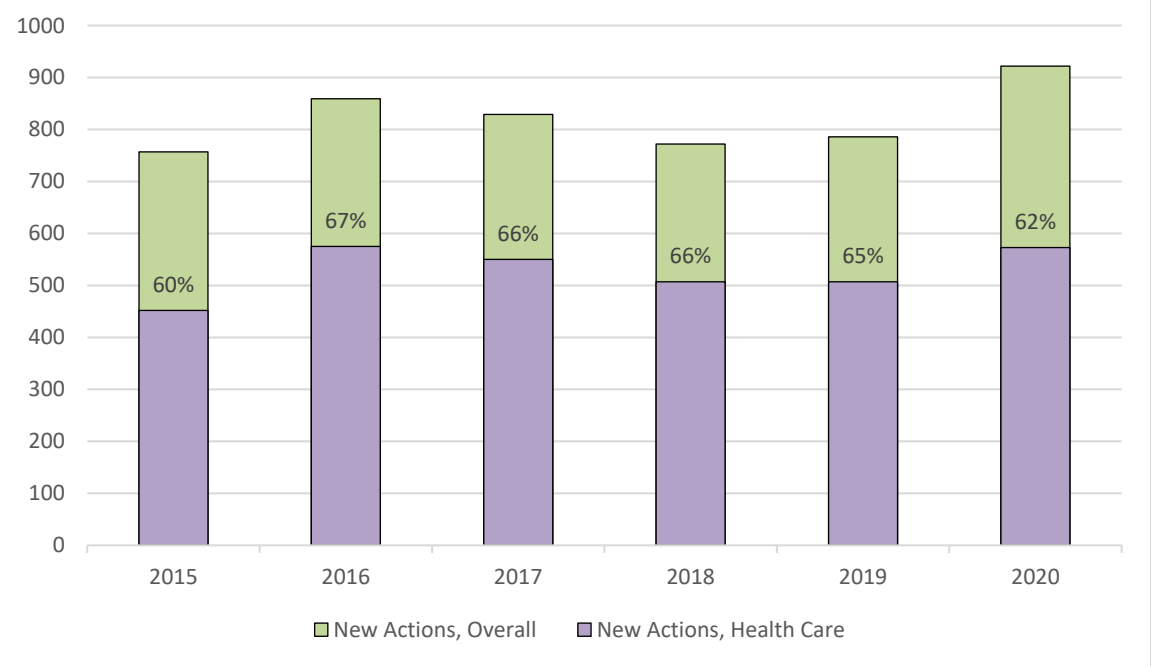

Figure 6: Percentage of New Health Care-Related FCA Actions[37]

The number of new FCA actions increased slightly in FY 2020, although the number of new FCA health care-related actions per year has not changed significantly since 2015.[38] The consistency in the number of actions filed each year is remarkable in light of the increased number of non-qui tam actions and the significant decrease in civil fraud recoveries overall. These numbers may suggest that the average settlement amounts or assessed

[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*

damages/penalties are decreasing and/or that FCA claims are generally less successful overall. Alternatively, the increased number in government-initiated enforcement actions may not result in increased civil fraud recoveries until later fiscal years. The same trend appears to be the case for the health care industry in FY 2020.[39]

Although FY 2020 continued a decline in FCA recoveries, FY 2021 will likely reverse that trend with the potential stabilization of the COVID-19 pandemic nationally. Qui tam actions remain the primary method for initiating FCA enforcement in health care, and relief funds available to providers in 2020 under the CARES Act will likely lead to additional opportunities in FY 2021 for relators to allege improper receipt, usage, and/or retention of government funds. Moreover, the government continues to expand the reach of its FCA investigations in health care to new and more diverse areas, including private equity-related enforcement. As such, not only are FCA recoveries in health care anticipated to exceed US$2 billion in FY 2021 as in years past, but FY 2021 is also positioned to be the most active year for health care fraud enforcement in recent memory.

2021 Outlook

FCA-related actions in health care in FY 2021 are likely to continue the substantial trend of government recoveries that has helped define the last decade of government enforcement. In particular, the following three areas appear particularly positioned for increased relator and government enforcement activities or FCA caselaw development in FY 2021:

1. CARES Act PRF-related FCA enforcement;
2. Continued interpretation of *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), and the enforceability of sub-regulatory guidance under the FCA; and
3. FCA enforcement against private equity firms that invest in health care companies.

These areas are discussed in detail below, along with their potential effect on FCA recoveries and the overall enforcement environment in 2021 and beyond.

CARES Act PRF-Related FCA Enforcement

The COVID-19 pandemic and its associated relief efforts under the CARES Act[40] have created a landscape fraught with civil and criminal enforcement risks for the health care industry. The CARES Act includes an extensive US$2 trillion federal aid package, which is composed of a combination of funding for public health programs, tax benefits for businesses and individuals, appropriations for government programs supporting pandemic relief efforts, and other items to help stabilize the economy. The unprecedented speed with which PRF and PPP funds were distributed under the CARES Act in 2020 and attendant shifting regulatory guidance under those programs generate a substantial potential for liability, primarily through the FCA.

Potential FCA Liability Stemming From PRF Funding

Throughout the latter half of 2020, the U.S. Department of Justice (DOJ) has engaged in aggressive criminal enforcement actions across the country against PPP loan recipients for allegedly falsely certifying compliance with PPP loan requirements, including misrepresenting

[39] *Id.*

[40] Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020).

the existence of the business that applied for PPP funds, inflating the number of the business employees in order to increase the size of stimulus aid received, and misusing funding. Moreover, DOJ has also used the FCA as an enforcement tool against PPP loan recipients for alleged fraudulent conduct.[41] That said, DOJ's enforcement efforts surrounding PPP funds in 2020 was largely focused on alleged conduct that could be characterized as blatantly fraudulent and more easily prosecuted. In contrast to the payment of PPP funds, the PRF likely presents a more nuanced enforcement scenario potentially affecting providers in the health care industry, particularly from a FCA perspective.[42]

Under the CARES Act, PRF funds are intended for those operating in the health care industry to provide for health care-related expenses or lost revenue attributable to the pandemic and increased access to COVID-19 testing and treatment for uninsured Americans. Potential FCA liability surrounding receipt, retention, and/or use of PRF funds largely stems from the attestations required to receive the funds. Namely, in order to receive PRF funds, providers were required to sign attestations confirming receipt of the funds and certifying compliance with certain general distribution terms and conditions (Terms and Conditions), which vary depending on which distribution was received and retained.[43] These Terms and Conditions include a list of compliance obligations, including a restriction on use of funds, a prohibition on reimbursing expenses or losses that had been or could have been reimbursed by other sources, a prohibition on balanced billing, and certain reporting and auditing requirements.[44]

Additionally, the Terms and Conditions include a disclaimer stating that the listed provisions are not exhaustive and that recipients are also required to comply "with any other relevant applicable statutes and regulations." The government also issued PRF Frequently Asked Questions (FAQs) to supplement the Terms and Conditions. Critically, HHS revised the Terms and Conditions on multiple occasions throughout 2020—including while the distributions were being made—and has continued to amend, modify, and revise the FAQs since they were first issued in April 2020. Many provisions of the Terms and Conditions and FAQs are vague, ambiguous, and internally contradictory, and several FAQs were modified or updated after related deadlines had already passed.

This backdrop has left many providers scrambling to assess the regulatory landscape and their respective liability exposure under the FCA.[45] The FCA provides, in part, that the federal

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[41] *See* U.S. Dep't of Just., Press Release, Eastern District of California Obtains Nation's First Civil Settlement for Fraud on Cares Act Paycheck Protection Program (Jan. 12, 2021), available here.

[42] Recipients that spend US$750,000 or more in federal funds, including PRF payments, are subject to the Department of Health and Human Services' (HHS) Office of Inspector General single audit requirements. *See* U.S. Dep't of Health & Hum. Servs., *Reporting Requirements and Auditing* (last updated Jan. 15, 2021). Recipients of PRF payments may be subject to additional auditing to ensure the accuracy of the data submitted to HHS for payment. *Id.*

[43] The government distributed PRF funding to providers through multiple rounds of general and targeted allocations and reimbursement, amounting to over US$100 billion distributed to health care providers and suppliers to date, including US$50 billion in "General Distribution" funding and over US$52 billion in "Targeted Distribution" funding directed to specific types of providers, including skilled nursing facilities; rural health care providers; Medicaid and Children's Health Insurance Program providers; safety net hospitals; tribal hospitals, clinics, and urban health centers; dental providers; and hospitals located in COVID-19 "high-impact" areas.

[44] For a detailed discussion and interpretation of PPP and PRF requirements, *see* John H. Lawrence *et al.*, *Uncertain Relief: Navigating CARES Act Provider Relief Fund Guidance and False Claims Act Risks*, QUI TAM Q. (Nov. 2020).

[45] The first public criminal indictment related to PRF funding was announced on 11 February 2021 and included allegations that the defendant intentionally misappropriated PRF funds for personal expenses. *See* U.S. Dep't of Just., Press Release, Woman First in the Nation Charged with Misappropriating Monies Designed for COVID Medical Provider Relief (Feb. 11, 2021). Specifically, the defendant allegedly received and used PRF funds paid to two health care entities that she owned and operated, despite the fact that both entities closed in 2020 and were not operational during the pandemic. *Id.*

government—or a private party on behalf of the government—may bring a lawsuit against any person who allegedly knowingly presented, or caused to be presented, a false or fraudulent claim for payment, or who made a false statement or used a false record to get a claim paid. Potential FCA liability also attaches for knowingly avoiding, decreasing, or concealing an obligation to pay money to the federal government, or knowingly retaining an overpayment.[46] Accordingly, potential FCA liability for recipients of PRF funds stems from the (1) the execution of attestations certifying compliance with the Terms and Conditions; (2) lack of compliance with PRF-related guidance, primarily in the form of changing and/or unclear FAQs; and (3) provider retention of PRF funds that the government or a relator may claim were improperly acquired.

In bringing an FCA claim in connection to PRF funds, the government or a relator must meet certain burdens to prove falsity, knowledge, and materiality. First, in order to establish FCA liability against a recipient of PRF funds, the government or a relator will need to establish either factual falsity or legal falsity. Factual falsity can be established when there is an incorrect description of the services or goods provided, or when said services or goods were never actually provided.[47] In contrast, legal falsity can be established where "the claimant knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for government payment."[48] While a provider could intentionally misrepresent the factual basis for acquiring PRF funds, such as altering its revenues or expenses in order to wrongfully inflate the calculation of its payment from the fund, it seems likely that most FCA cases surrounding PRF funds—especially those brought by relators—will be based on a theory of legal falsity. Such allegations may include that a provider falsely certified compliance with the Terms and Conditions or the FAQs interpreting the Terms and Conditions.

As discussed above, the ambiguity of both the Terms and Conditions and the FAQs and HHS's frequent modifications of the same may allow the government or relators to argue that a provider falsely certified compliance with the Terms and Conditions by using the funds in an improper manner or otherwise failed to satisfy the FAQ guidance. That said, the ability to use PRF-related guidance (such as Terms and Conditions/FAQs) as the basis for an FCA claim is questionable given the holding in *Allina* and its progeny in the FCA context, as discussed in more detail herein.

Second, the government or a relator must establish that a provider acted with knowledge surrounding allegedly fraudulent conduct related to PRF funds. Specifically, to satisfy this scienter requirement, the government or a relator must show that the provider had actual knowledge that the claim was false or acted with "deliberate indifference" to or "reckless disregard" for the truth or falsity of the claim. Mere negligence is not actionable under the FCA. Where the government or a relator relies on a theory that the provider's claim is false because it was submitted in violation of a statute, regulation, or guidance—or falsely certified compliance with a statute or regulation—ambiguous language complicates the ability to prove the scienter element. Therefore, a provider's reasonable interpretations of the PRF guidance will likely serve as a key defense to FCA liability.

Third, the FCA also requires that the false statement be material, which the statute defines as "having a natural tendency to influence, or be capable of influencing, the payment or receipt

[46] *See* 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B), (a)(1)(G).

[47] *See* Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 931–32 (E.D. Pa. 2019).

[48] *Id.*

of money or property."[49] The U.S. Supreme Court's 2016 decision in *Universal Health Services, Inc. v. United States ex rel. Escobar*[50] provides potentially robust defenses in false certification cases under the FCA's materiality prong. Namely, *Escobar* established two key principles in analyzing whether a defendant's alleged false certification of compliance with regulatory or other guidance is material. First, *Escobar* held that the mere fact that compliance with a particular regulatory requirement is designated as a condition of payment does not in itself establish that a violation of that provision is material.[51] Second, *Escobar* held that an agency's knowledge and behavior is relevant to materiality.[52] Accordingly, if the agency regularly pays claims despite having knowledge that a defendant is in violation of some technical rules or requirements, it "is strong evidence that the requirements are not material."[53]

These specific principles in *Escobar* may serve defendants in the PRF context in light of the changing and, at times, inconsistent PRF guidance, as well as the patterns of PRF-related payments. For example, HHS's conflicting guidance on permissible calculations of "lost revenue due to the coronavirus" originally allowed providers to "use any reasonable method" of estimating lost revenue, but it later required a more specific calculation limiting lost revenue to the amount of a provider's 2019 net gain from health care-related sources.[54] Given the fact that payments were made under both standards of lost revenue calculations, this potentially supports a lack of materiality as to that specific requirement for payment under *Escobar*.

Accordingly, while perceived violations of PRF guidance may form the basis of future FCA claims, the above discussion highlights the uncertainty as to the effectiveness of potential FCA claims in this area, including (1) the extent to which ambiguous or changing guidance and/or regulations may create enforcement problems where recipients interpreted the regulations in good faith, (2) the inability to satisfy the materiality element where HHS knows about provider non-compliance with certain guidance, but declines to request reimbursement or initiate an investigation, and (3) whether the government and relators will be able to establish falsity through relying on the informal and frequently updated FAQ guidance documents.

Government's FCA Gatekeeping Functions

The government will play a critical role in the focus and direction of FCA enforcement surrounding PRF funds throughout 2021, and it remains to be seen what that direction will entail. DOJ has represented on a handful of occasions in 2020 that it is not interested in pursuing FCA claims against providers who acted in good faith surrounding the receipt, retention, and/or usage of PRF funds. For example, on 24 August 2020, K&L Gates co-sponsored the "COVID-19 Health Care Fraud Town Hall," where the former head of DOJ's Civil Division maintained that DOJ recognizes that the PRF is an important effort to help the private sector cope with the pandemic; providers have been overwhelmed in trying to determine how best to utilize funds in a compliant manner; and, while DOJ intends to combat fraud surrounding the PRF, it is not interested in pursuing FCA cases involving honest mistakes or simple misunderstandings. These comments are similar to those made by the

[49] 31 U.S.C. § 3729(a)(1)(B), (a)(1)(G), (b)(4).

[50] 136 S. Ct. 1989 (2016).

[51] *Id.* at 2003–04.

[52] *Id*.

[53] *Id.* at 2002–04.

[54] U.S. Dep't Health & Hum. Servs., General and Targeted Distribution Post-Payment Notice of Reporting Requirements (Sept. 19, 2020).

same DOJ official on 26 June 2020 when he maintained, regarding CARES Act funding, "you can rest assured that the Civil Division will not pursue companies that made immaterial or inadvertent technical mistakes in processing paperwork, or that simply and honestly misunderstood the rules, terms and conditions, or certification requirements."[55]

However, it remains an open question what these statements will actually mean in practice and how DOJ will apply similar perspectives to qui tam actions brought against providers that received PRF funds. It is currently unclear, for example, whether the government will (1) exercise its authority under the FCA to dismiss the qui tam actions involving PRF funds where providers acted in good faith to adhere to the sometimes shifting and unclear PRF-related guidance; (2) decline to intervene in these matters, allowing relators and their counsels to advance these cases against providers; or (3) ultimately elect to intervene in some of these matters. Depending on how DOJ decides to approach its gatekeeping functions, PRF-related claims could be a large potential driver of FCA activity and recoveries in FY 2021.

Interpretation of *Azar v. Allina Health Services* and Its Application to the FCA

Significant developments in the interpretation of the 2019 Supreme Court case, *Azar v. Allina Health Services* (*Allina*)—as it is applied across federal district and appellate courts—have the potential in FY 2021 to significantly alter the landscape of FCA actions predicated on guidance that was not subject to notice-and-comment rulemaking. In *Allina*, the Supreme Court considered whether HHS was required to undertake notice-and-comment rulemaking under the Medicare Act before it changed an important reimbursement formula for hospitals that treat many low income patients.[56] The Supreme Court's decision turned on whether the alteration of the payment formula at issue "establishe[d] or changed a substantive legal standard governing … the payment for services."[57]

In its opinion, the Supreme Court differentiated between "substantive rules" under the Administrative Procedures Act and a "substantive legal standard" under the Medicare Act, further elaborating that "substantive rules are those that have the force and effect of law, while interpretive rules . . . merely advise the public of the agency's construction of the statutes and rules which it administers."[58] The Supreme Court went on to hold—in a 7–1 decision—that the Centers for Medicare and Medicaid Services' (CMS) "failure to give notice and a chance to comment was fatal under § 1395hh(a)(2)" because, "when the government establishes or changes an avowedly 'gap'-filling policy, it can't evade its notice-and-comment obligations under § 1395hh(a)(2) . . . [,]" assuming that an underlying statute does not speak directly to an issue.[59]

Allina's holding is significant in that it establishes a requirement for notice-and-comment rulemaking for any gap-filling policy that interprets a broadly worded statute or regulation in order for said policy to be valid and enforceable. As such, *Allina*'s holding has potential far-reaching implications within the context of FCA actions. Defendants can argue, for example, that, under *Allina*, the government cannot establish an FCA claim when the sole basis for

[55] Ethan P. Davis, "Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform" (June 26, 2020).

[56] Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019).

[57] *Id*. at 1810.

[58] *Id.* at 1810–14.

[59] *Id.* at 1817.

liability is a substantive legal standard that has not been subject to notice-and-comment rulemaking.

Recent caselaw interpreting and applying *Allina* in the FCA context underscores its potential effect on FCA claims. In *Polansky v. Executive Health Resources, Inc.*, 422 F. Supp. 3d 916, 933 (E.D. Pa. 2019), for example, the U.S. District Court for the Eastern District of Pennsylvania maintained that a relator's FCA claim was subject to dismissal where it was based on an alleged violation of sub-regulatory guidance. In doing so, *Polansky* emphasized that any policy that determines a party's entitlement to, or the amount of, federal reimbursement is a substantive legal standard that requires notice-and-comment rulemaking pursuant to the holding in *Allina*.[60]

In *Polansky*, the "core of [r]elator's theory of liability [was] that Defendant exploited the difference in reimbursement rates for inpatient and outpatient services, causing hundreds of thousands of claims for medical services to be billed as inpatient when they should have been billed as outpatient."[61] At specific issue in the case was a 24-hour CMS reimbursement policy, which was solely contained in the 1989 edition of the Medicare Hospital Manual.[62] The government moved to dismiss the case under 31 U.S.C. § 3730(c), seven years after the case's initial filing, and based this action, in significant part, on the government's "genuine concerns regarding the likelihood that [r]elator [would] successfully establish FCA liability."[63] The court went on to discuss why dismissing the matter on summary judgment grounds was also appropriate based on *Allina*. Specifically, the court found that, if the 24-hour reimbursement policy was a substantive legal standard within the scope of § 1395hh(a)(2), "then [r]elator's claims fail[ed] as a matter of law, because it [was] undisputed that the 24-hour policy did not go through notice and comment as required by Section 1395hh(a)(2) for substantive legal standards."[64]

In holding that the policy was a substantive legal standard, the court applied the definition of "substantive legal standard" used by the U.S. Court of Appeals for the District of Columbia Circuit, which stated that the term, "'at a minimum include[d] a standard that creates, defines, and regulates the rights, duties, and powers of parties.'"[65] The court further elaborated that caselaw applying the District of Columbia Circuit's definition for "substantive legal standard" illuminates a distinction between, on the one hand, rules that determine reimbursement and, on the other hand, statements that set forth enforcement policies. If a policy affects the right to, or amount of, reimbursement, it is more likely to be deemed a "substantive legal standard," whereas if it does not affect the authority of CMS, but simply provides instructions for enforcement, it is more likely not to be characterized as a "substantive legal standard."[66]

Accordingly, *Polansky* concluded that the 24-hour policy "must be included within the District of Columbia Circuit's definition for substantive legal standard…[because it] delineates the circumstances in which a hospital is entitled to higher inpatient reimbursement."[67] As *Polansky*

[60] 422 F. Supp. 3d. at 930.
[61] *Id.* at 919.
[62] *Id*. at 932–33.
[63] *Id.* at 932.
[64] *Id.* at 934.
[65] *Id.* (quoting Allina Health Servs. v. Price, 863 F.3d 937, 943 (D.C. Cir. 2017) (emphasis added)).
[66] *Id*. at 935.
[67] *Id.*

explains, "the 24-hour policy, though only expressed in CMS manuals, 'affects a hospital's right to payment' because it sets the standard by which a hospital's entitlement to the higher reimbursement rate for inpatient claims is assessed."[68] As such, the court deemed the 24-hour policy as a substantive legal standard and maintained "that the law required advance public notice and an opportunity to comment prior to implementation of the 24-hour policy. Because there was no such public notice or a chance to comment, the policy [could not] withstand scrutiny under *Allina*'s interpretation of the Medicare Act."[69]

The potential importance of *Polansky* to defendants in FCA actions predicated solely on guidance is clear: Pursuant to *Allina*, the government or a relator may not be able to establish an FCA claim when the sole basis for liability is a substantive legal standard that has not been subject to notice-and-comment rulemaking. In other words, FCA defendants may be able to argue forcefully that alleged non-compliance with a substantive legal standard that has not gone through the notice-and-comment process cannot form a basis for establishing falsity. A key question remains how the caselaw will continue to develop across district and circuit courts applying *Allina*'s holding to the FCA. The specific contours of *Allina*'s application in FCA cases are currently being developed, with a handful of courts taking divergent approaches from *Polansky.*[70] As such, interpretation of *Allina* will continue and has the potential to heavily impact FCA-related matters in FY 2021 and beyond.

Government Focus on Private Equity Firms in Health Care

On 26 June 2020, the former head of DOJ's Civil Division delivered remarks at the U.S. Chamber of Commerce's Institute for Legal Reform regarding FCA enforcement over the next few years.[71] In those remarks, the former DOJ official expressly stated that DOJ enforcement efforts may include more focused attention on private equity firms that invest in companies receiving government funds, including CARES Act funds.[72] He further stated that private equity firms investing in highly-regulated spaces, including health care or life sciences, should be aware of the laws and regulations designed to prevent fraud in those industries and warned that any firm that takes an active role in illegal conduct by an acquired company can expose itself to FCA liability.[73]

Notably, the former head of DOJ's Civil Division cited *United States* ex rel. *Medrano v. Diabetic Care Rx*, No. 0:15-cv-62617-BB (S.D. Fla.)—where the government chose, in February 2018,

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[68] *Id.* (quoting Azar v. Allina Health Servs., 139 S. Ct. 1804, 1811 (2019)).

[69] *Id.*

[70] Since *Polansky* was decided, other federal courts have addressed the issue of *Allina*'s application to FCA actions. *See United States v. Anesthesia Servs. Assocs., PLLC*, No. 3:16-CV-0549, 2019 WL 7372510, at *15 (M.D. Tenn. Dec. 31, 2019) (distinguishing *Allina* where defendants argued that the government's implied false certification claims failed because the local coverage determinations (LCDs) issued by various Medicare Administrative Contractors were nonbinding interpretive guidance and stating that "*Allina* did not concern LCDs and certainly did not establish that *all* LCDs set forth substantive legal standards, nor did it address the question of whether a false certification of compliance with an LCD may form the basis of a claim under the FCA…" (emphasis in original)); *United States ex rel. Gray v. Mitias Orthopaedics, PLLC*, No. 315CV000127MPMJMV, 2021 WL 79615, (N.D. Miss. Jan. 11, 2021) (declining to extend *Allina* to the FCA context); *United States ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, No. SA-17-CV-00317-XR, 2020 WL 7342662, at *18 (W.D. Tex. Dec. 14, 2020) (declining to extend *Allina* and limiting its holding as having "established a rule that the government cannot retroactively change the method by which it calculates how much to reimburse for submitted claims without going through the notice and comment procedure set out by the Administrative Procedure Act").

[71] Ethan P. Davis, Principal Deputy Assistant Attorney General Ethan P. Davis delivers remarks on the False Claims Act at the U.S. Chamber of Commerce's Institute for Legal Reform (June 26, 2020).

[72] *Id.*

[73] *Id.*

to intervene in a qui tam complaint against private equity firm Riordan, Lewis, and Haden (RLH)—as evidence of the government's commitment to holding private equity firms accountable if they knowingly engage in fraud.[74] In *Medrano*, DOJ intervened against Diabetic Care Rx, LLC d/b/a Patient Care America (PCA) and its majority owner, RLH, alleging that PCA, under the management of RLH, paid kickbacks to outside marketing companies, resulting in prescriptions regardless of patient need that were reimbursed by a government payor.[75]

In *Medrano*, the government argued that "RLH d[id] not get a special pass because it happen[ed] to be a private equity firm" and contended that there was "nothing 'unprecedented' . . . about seeking to hold an entity," even a private equity firm, "liable for causing the submission of false claims to federal health care programs."[76] In particular, the government focused on RLH's active management of PCA by placing two of its members on PCA's board, RLH's experience in the health care sector, and RLH's incentive to quickly turn around PCA's finances.[77] On 18 September 2019, DOJ announced that it reached an agreement with the defendants in *Medrano* to settle DOJ's allegations.[78] Without admitting or denying liability, PCA and RLH agreed to pay over US$21 million to settle the matter.[79]

In another example of government enforcement against private equity firms operating in health care, in January 2018, the state of Massachusetts elected to intervene in a qui tam complaint filed in *United States* ex rel. *Martino-Fleming v. South Bay Mental Health Center, Inc.*, No. 0:15-cv-62617-BB (S.D. Fla.), against its private equity firm owners.[80] This intervention was based on allegations that the private equity firms and another company they created to acquire South Bay Health Centers (South Bay) became directly involved in the management of South Bay and rejected recommendations to bring South Bay in compliance with Massachusetts Medicaid requirements.[81] The United States declined to intervene.[82]

The government has also previously intervened in qui tam actions against management companies in the health care space, and these cases are instructive when considering the potential contours of FCA enforcement surrounding private equity firms. For example, in *United States* ex rel. *Longo v. Wheeling Hospital, Inc*., No. 2:17-cv-01654 (W.D. Penn.), the government intervened in a relator's qui tam complaint against Wheeling Hospital, Inc. (Wheeling), R&V Associates, LTD. (R&V), and R&V's managing director who was appointed CEO of Wheeling, Ronald Violi.[83] In its complaint in intervention, the government focused on R&V's control over Wheeling via Wheeling's CEO, Violi; R&V's claims on its website of specific

[74] The United States of America's Complaint in Intervention at 9-10, United States *ex rel*. Medrano v. Diabetic Care Rx, LLC, No. 0:15-cv-62617-BB (S.D. Fla. Feb. 16, 2018).

[75] *See id.*

[76] The United States' Consolidated Response to Defendants' Motions to Dismiss Complaint in Intervention at 29, United States *ex rel*. Medrano v. Diabetic Care Rx, LLC, No. 0:15-cv-62617-BB (S.D. Fla. May 1, 2018).

[77] *Id.*

[78] Press Release, U.S. Dep't of Just., Compounding Pharmacy, Two of Its Executives, and Private Equity Firm Agree to Pay $21.36 Million to Resolve False Claims Act Allegations (Sept. 18, 2019).

[79] *Id.*

[80] *See* United States *ex rel.* Martino-Fleming v. S. Bay Mental Health Ctr., Inc., No. 15-cv-13065 (Mass. Nov. 1, 2017).

[81] *See* United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr., Inc., No. 15-13065-PBS, 2018 WL 4539684 at *7 (D. Mass. Sept. 21, 2018).

[82] *See* Government's Notice of Election to Decline Intervention by United States of America, United States *ex rel.* Martino-Fleming v. S. Bay Mental Health Ctr., Inc., No. 15-cv-13065 (Mass. Nov. 1, 2017).

[83] *See* United States' Complaint in Intervention, United States *ex rel.* Longo v. Wheeling Hospital, Inc., No. 2:17-cv-01654 (W.D. Penn. Mar. 25, 2019).

expertise in the health care industry and compliance; R&V's awareness of potential compliance issues at the managed company; and R&V's failure to implement protocols to ensure compliance at Wheeling.[84] Wheeling, R&V, and Violi eventually settled the case with the government without admitting or denying liability, with Wheeling agreeing to pay the government US$50 million.[85]

In another case where the government declined to intervene, *United States* ex rel. *Ruckh v. La Vie Health Care Centers, Inc.*, No. 8:11-cv-01303 (M.D. Fla.), a relator successfully tried a qui tam action against the operating and management companies for skilled nursing facilities, alleging that the management companies systematically "upcoded" claims submitted to Medicare and provided more therapy to patients only on days falling during government assessment periods, resulting in inflated billings.[86] After the relator secured a US$347.9 million judgment at trial, the U.S. District Court judge granted the defendants' renewed motion for judgment notwithstanding the verdict (JNOV), finding that the relator failed to offer evidence of materiality, a required element in an FCA action.[87] On appeal, the U.S. Court of Appeals for the 11th Circuit determined that the relator did establish the materiality element with respect to the Medicare claims and that she presented sufficient evidence "to permit a jury to reasonably conclude that [the defendants] caused the submission of false claims," including pressure from the management companies to upcode and "ramp up" levels of service for the purpose of increasing reimbursements.[88] The appellate court also focused on the management company's practice of reprimanding employees for failing to meet budgets based on artificially increased levels of service.[89] The appellate court reversed the district court's grant of JNOV and remanded to the district court with instructions to reinstate the jury's verdict in favor of the relator, the United States, and the State of Florida against defendants in the amount of approximately US$255.4 million, including treble damages.[90]

Medrano and *Martino-Fleming*—along with potentially analogous management company cases—highlight the importance that government enforcers have recently placed on active management in the portfolio company and the inherent money-making motivations of private equity firms when evaluating potential FCA liability. Key risks for private equity firms investing in the health care industry, as demonstrated in the above cases, include the firm's level of involvement in directing and controlling a portfolio company's business practices;[91] the firm's level of experience in and knowledge of the health care industry and its laws and regulations; and the potential conflict between a firm's investment goals and the portfolio company's legal compliance.

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[84] *Id.*

[85] 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).

[86] Complaint and Demand for Jury Trial, United States *ex rel.* Ruckh v. La Vie Health Care Ctrs., Inc., No. 8:11-cv-01303 (M.D. Fla. June 10, 2011).

[87] United States v. Salus Rehab., LLC, 304 F. Supp. 3d 1258 (M.D. Fla. 2018), *aff'd in part, rev'd in part and remanded sub nom.* Ruckh v. Salus Rehab., LLC, 963 F.3d 1089 (11th Cir. 2020).

[88] *Ruckh*, 963 F.3d 1089.

[89] *Id.*

[90] *Id.* The 11th Circuit affirmed the district court's grant of JNOV regarding Medicaid claims, which explains the discrepancy in award figures.

[91] As the private equity business model frequently has firms maintain a significant amount of control over management and the boards of directors of portfolio companies, this particular factor may increase risk across all private equity firms engaged in the health care industry.

Additionally, the government appears open to expanding its theories of liability to include less active private equity investors. For example, toward the beginning of FY 2021, DOJ intervened in a qui tam complaint and announced a US$1.5 million settlement involving private equity firm The Gores Group (TGG) in connection with allegedly improper off-label marketing by its former portfolio company, Therakos, Inc. (Therakos).[92] However, unlike in *Medrano* or *Martino-Fleming*, the relators solely alleged in their complaint that TGG hired a new CEO and allowed the purported misconduct at Therakos to continue during its ownership.[93] Consequently, this settlement potentially foreshadows the government's willingness to pursue private equity firms for the conduct of their portfolio companies, even where the private equity firm has taken a more passive management approach to the company.

These cases, along with DOJ's public comments in June 2020 on private equity-related enforcement, portend increased FCA exposure for private equity firms operating in health care in FY 2021 and beyond. Additionally, relators may be particularly drawn to filing qui tam complaints against private equity companies operating in the health care industry because of the firm's perceived "deep pockets."[94]

K&L Gates will continue to closely monitor these trends as they develop in FY 2021.

Conclusion

The year 2020 was an unprecedented one in many respects, including due to the unique and demanding environment that the COVID-19 pandemic created nationwide for the government and health care providers alike. Although the pandemic can be said to have been one of the primary causes of the decrease in civil fraud recoveries in health care in FY 2020, the billions of dollars in government aid paid via the CARES Act will likely serve as a primary target of FCA actions and recoveries in FY 2021 and beyond. Indeed, FCA recoveries and the number of qui tams per year will likely experience a surge throughout FY 2021, as PRF funds and PPP loans take center stage in FCA enforcement actions.

However, as highlighted above, it would be a mistake to confine predictions surrounding the anticipated wave of FCA enforcement in FY 2021 solely to the CARES Act. FCA enforcement in health care has remained remarkably consistent for well over a decade in terms of the number of actions per year, the amount of recoveries per year, and the breadth of enforcement across the health care industry. The government and relators also continue to find new frontiers for FCA enforcement as health care continues to evolve, and FY 2021 will be no different.

Accordingly, it is essential for those operating in health care—particularly those that bill federal and state health care programs —to now, more than ever, ensure their financial arrangements and billing activities are compliant with applicable federal and state health care fraud and

[92] Press Release, U.S. Dep't of Just., Former Owners of Therakos, Inc. Pay $11.5 Million to Resolve False Claims Act Allegations of Promotion of Drug-Device System for Unapproved Uses to Pediatric Patients (Nov. 19, 2020). The Gores Group neither admitted nor denied liability in connection with the settlement.

[93] *See* Third Amended Complaint for Damages and Other Relief Under the *Qui Tam* Provisions of the False Claims Act and Similar State Provisions, United States *ex rel*. Johnson v. Therakos, Inc., No. 12-cv-1454 (E.D. Pa. Dec. 14, 2016).

[94] *See, e.g.*, First Amended *Qui Tam* Complaint for Violations of Federal and State False Claims Acts and Demand for Jury Trial, United States *ex rel.* Cho v. Surgery Partners, Inc., No. 8:17-cv-00983 (M.D. Fla. Jan. 15, 2019) (relator amending their complaint to include additional private equity investors as defendants); *see also* Heather Perlberg, *How Private Equity Is Ruining American Health Care*, BLOOMBERG BUSINESSWEEK (May 5, 2020) (Private equity firms have invested in excess of US$10 billion in medical practices over the last five years.).

abuse laws. Accordingly, those operating in health care should work with health care regulatory counsel to design, implement, and enforce properly functioning compliance programs and other efforts to best avoid FCA exposure, costly litigation, and penalties.

K&L Gates' health care fraud group routinely assists private equity firms, health systems, hospitals, and other providers and suppliers with legal advice regarding FCA, Anti-Kickback Statute, and Stark Law compliance, including internal compliance reviews, transactional due diligence, external and internal investigations, and general strategic considerations.

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