WILMERHALE

COVID-19: Healthcare Fraud in a Public Health Emergency

June 26, 2020

This is the third in a series of client alerts addressing the likely role of the False Claims Act in the wake of the massive federal government response to the COVID-19 pandemic.[1]

The healthcare industry is no stranger to False Claims Act (FCA) enforcement. In 2018, the Department of Justice (DOJ) recovered $2.5 billion in settlements and judgments for violations of the FCA by companies and individuals working in the healthcare industry, including large hospitals, drug and medical device manufacturers, pharmacies, hospice organizations, and doctors.[2] And in 2019, healthcare recoveries amounted to more than 85% ($2.6 billion out of $3 billion) of total amounts paid under the FCA.[3]

The COVID-19 pandemic is a public health emergency.[4] In response, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Pub. L 116-136 (2020), to reinforce the country's healthcare industry. The CARES Act has sought to do this in two ways: by promoting healthcare innovation among medical device and pharmaceutical manufacturers to combat COVID-19, including by developing a vaccine, and by providing federal monies to healthcare providers who have been affected by the pandemic.[5]

---

[1] Other alerts in this series include "COVID-19 What History Tells Us About the Importance of the False Claims Act in a Time of Pandemic" (Matthew Benedetto and Elizabeth Purcell Phillips—May 11, 2020) and "COVID-19: FCA Risks for Industries Fighting the Pandemic" (Matthew Benedetto, Elizabeth Purcell Phillips and Joseph Michael Levy—May 29, 2020).
[2] Department of Justice, *Justice Department Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018* (Dec. 21, 2018), https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018.
[3] Department of Justice, *Justice Department Recovers over $3 Billion from False Claims Act Cases in Fiscal Year 2019* (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019.
[4] Alex M. Azar II, "Determination that a Public Health Emergency Exists" (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.
[5] CARES Act Title VIII, Department of Health and Human Services; Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116–139, 134 Stat. 620 (2020).

Attorney Advertising

Healthcare providers who participate in CARES Act programs must pay close attention to the attendant risks under the FCA, 31 U.S.C. § 3729 *et seq*. The FCA requires companies and individuals to make truthful and accurate representations about their eligibility to receive federal funds, and about the goods and services they provide through federally funded programs. It imposes treble damages and civil penalties of $11,665 to $23,331 per false claim (when adjusted for inflation),[6] and it offers rewards for insiders who file claims on behalf of the government (known as *qui tam* plaintiffs).

This alert examines the potential liability risks under the FCA that are specific to the healthcare industry's response to the COVID-19 pandemic. Healthcare providers have typically found themselves to be targets of FCA enforcement because of their participation in Medicare or Medicaid, which condition reimbursement on the making of truthful certifications about, for example, the healthcare service provided, the amount of time involved and the proper billing code under applicable regulations.[7] Under the fee-for-service billing structure of these programs, a doctor, nurse or physician's assistant, for instance, provides healthcare services to a patient and is then required to certify that the treatment was "medically necessary" in order to receive reimbursement. After providers are reimbursed, Medicare or Medicaid may conduct a post hoc audit to determine whether the claims were billed properly. Any claims for "unnecessary" treatment would be false claims.

Funds distributed to healthcare providers under the CARES Act are likely to be the focus of close scrutiny by federal and state oversight authorities and the plaintiffs' bar. Indeed, the chairpersons of two House committees have already expressed concerns about the CARES Act's Provider Relief Fund and the "lack of transparency with Congress and the American people about how funds are being spent or loans are being made."[8] This early congressional attention provides a clear signal that recipients of these federal funds will be scrutinized, potentially by oversight authorities created by the CARES Act itself, DOJ or private civil plaintiffs through an FCA lawsuit.

The CARES Act Responds to a Health Crisis

The CARES Act sought to support America's healthcare system and workforce in the fight against COVID-19 as well as provide economic stabilization and assistance to the struggling US

---

[6] 15 CFR § 6.3(a)(3) (Jan. 15, 2020).
[7] Medicare is an insurance program through which medical bills are paid from trust funds into which covered individuals have paid. It serves primarily people over age 65 and younger disabled people and dialysis patients. Medicaid is a federal–state assistance program that serves low-income people of every age at no cost. *See* Department of Health and Human Services, *What is the difference between Medicare and Medicaid?*, available at https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html (last accessed June 22, 2020).
[8] Letter from the Honorable Frank Pallone Jr., Chairman, Committee on Energy and Commerce, and the Honorable Richard E. Neal, Chairman, Committee on Ways and Means, to the Honorable Alex M. Azar II, Secretary, Department of Health and Human Services, and the Honorable Seema Verma, Administrator, Centers for Medicare & Medicaid Services (May 7, 2020).

economy. Title III contains numerous provisions to mitigate drug and medical supply shortages, expands coverage and regulates pricing for diagnostic testing for COVID-19, mandates coverage of any future COVID-19 vaccines, and significantly relaxes telehealth regulations. The CARES Act also appropriated $100 billion—later supplemented by an additional $75 billion—to a "CARES Act Provider Relief Fund" for "eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus."[9] We discuss below the potential FCA risks in connection with these programs.

Medicare Advantage Plans

One area of potential FCA risk that has been created by the CARES Act relates to Medicare Advantage Plans (MA Plans). Medicare Advantage (MA), formally known as Medicare Part C, allows private insurance companies, acting as Medicare Advantage Organizations (MAOs), to offer insurance plans and administer Medicare benefits. MAOs contract with healthcare providers to provide Medicare services to the plans' enrollees. Instead of receiving reimbursement on a traditional fee-for-service basis, MAOs provide benefits under a capitated payment system, whereby government reimbursement is based on each individual beneficiary's risk adjustment data.

The CARES Act imposes additional requirements on MA Plans that, if not followed, may result in FCA claims based on a theory of implied false certification. The capitated payment structure of MA Plans also subjects them to distinct FCA risks, particularly in connection with new, reimbursable telehealth services made possible by the CARES Act. Increased scrutiny and rapidly changing regulations in the wake of COVID-19 make it more important than ever that healthcare providers made adequate risk adjustment verifications to mitigate systemic risks of FCA liability when seeking payment under MA Plans.

1. Implied False Certifications

Title III of the CARES Act imposes new requirements on MA Plans that could result in FCA liability if they are violated. Regulators and *qui tam* plaintiffs commonly bring FCA actions against Medicare providers on a theory of implied false certification. This theory posits that submitting a claim for reimbursement to Medicare implicitly certifies compliance with various healthcare regulations that are important to Medicare, so that if a provider is out of compliance with those regulations when such a claim is submitted, that claim is "false." In the healthcare context, such actions have been successfully brought on the basis that healthcare providers failed to comply with Medicare regulations at the time they submitted claims for payment.[10]

[9] CARES Act Title VIII, Department of Health and Human Services; Paycheck Protection Program and Health Care Enhancement Act, Pub. L. No. 116-139, 134 Stat. 620 (2020).
[10] In the MA context, the claim would be made at the time the MA Plan seeks a risk adjustment for a higher capitated fee.

The CARES Act imposes two additional requirements on MA Plans that pose new FCA risks. First, Section 3713 of the Cares Act requires MA Plans to cover any future COVID-19 vaccine without cost-sharing. If and when such a vaccine becomes available, MA Plans must ensure that they provide it to patients without cost-sharing or risk FCA liability based on a theory of implied false certification.

Second, Section 3714 requires MA prescription drug plans to allow enrollees during the pandemic to obtain a 90-day supply of covered drugs without restrictions, which was previously optional. Evidence that MA Plans failed to do so at the request of enrollees may also form the basis for an implied false certification claim.

2. New Medicare Advantage Risks Under the Telehealth Provision of the CARES Act

Healthcare participants in the MA program also face unique FCA risks stemming from its "capitated" payment structure. Standard Medicare plans operate on a fee-for-service basis, typically resulting in FCA actions that allege "upcoding": inflated fees or fees for procedures that were never performed or were more expensive versions of procedures than were necessary. Under MA Plans, this type of upcoding is not possible because healthcare services under MA Plans are not paid on a fee-for-service basis. Instead, providers who participate in the MA program receive payments per plan enrollee on a capitated monthly fee basis. This fee may be increased through a process called "risk adjustment," which is based on the health risks of certain patients. For example, an MA enrollee diagnosed with a medical condition that results in high treatment costs may be assigned a higher risk adjustment score, allowing that enrollee's provider to claim a higher capitated payment for that enrollee. It is through this diagnosis and risk adjustment process that FCA risks arise.

Healthcare provider participants in MA Plans may obtain higher capitated payments if enrollees are diagnosed with certain health conditions. What qualifies as a "diagnosis" is specific and subject to numerous requirements. For example, according to the Centers for Medicare & Medicaid Services (CMS), "medical history alone may not be used as a source of diagnoses for risk adjustment purposes. For a chronic condition to be accepted for risk adjustment, the patient must have a ***face-to-face visit each year***."[11] Submitting a risk adjustment claim based on a diagnosis made without a face-to-face visit could be considered a false claim under the FCA. FCA claims continue to be brought on the theory that diagnoses made for the risk adjustment process violate this face-to-face requirement.

Recognizing the difficulty of in-person diagnoses during the COVID-19 pandemic, Congress included in the CARES Act telehealth provisions that relax the face-to-face requirement in certain circumstances. These provisions are effective during the COVID-19 public health emergency as declared and renewed by the Secretary of Health and Human Services (HHS).[12] For

[11] *See* Medicare Managed Care Manual, Ch. 7, §§ 40, 120.1.1.
[12] The telehealth provisions of the CARES Act define the "emergency period" as the emergency period defined in section 1135(g)(1)(B) of the Social Security Act (the Act). Section 1135(g)(1)(B) of the Act

example, Section 3705 creates a temporary waiver of the face-to-face requirement for visits between home dialysis patients and their physicians. Section 3706 also allows the use of telehealth for recertification of hospice-care eligibility, which normally requires a face-to-face meeting. Section 3707 similarly encourages telehealth for home health services that are provided during the emergency period.

Complementing these CARES Act provisions, CMS also announced a rule expressly allowing certain telehealth visits to meet the face-to-face requirement for risk adjustment purposes. This gives MA providers the ability to obtain risk-adjusted capitated fees during the COVID-19 pandemic, since face-to-face diagnostic visits are now often not feasible or even allowed. According to CMS, "diagnoses resulting from telehealth services can meet the risk adjustment face-to-face requirement when the services are provided using an interactive audio and video telecommunications system that permits real-time interactive communication."[13] MA providers must therefore ensure that any diagnoses used to support risk adjustment claims meet this interactive and real-time requirement (and should be amply documented) in order to avoid potential liability under the FCA.

3. Systemic FCA Risks for MA Plans

Insurance companies that offer MA Plans should continue to monitor and verify their business practices to ensure there are no systemwide FCA risks resulting from inadequate monitoring of healthcare providers. If healthcare providers fail to comply with telehealth requirements in making diagnoses, for example, and MA Plans receive higher capitated payments, MA Plans may themselves be liable under a reverse false claims theory for overpayments of which they are aware yet do not repay to Medicare. MA Plans may also be liable under the FCA for one-sided "retrospective reviews" of diagnosis codes. If an MA Plan conducts a review to find additional diagnosis codes to submit to CMS that were mistakenly not submitted, but turns a "blind eye" to results that would require *downgrading* a diagnosis code (meaning the capitated payment received was too high), that can form, and has formed, the basis for a reverse false claim allegation. Given the increased scrutiny of the healthcare industry in light of COVID-19 and the CARES Act's programs, it is important that both healthcare providers in MA Plans and the insurance companies that offer these plans ensure that they are properly following additional requirements imposed by the CARES Act.

---

defines the emergency period as the period during which there exists a public health emergency under section 319 of the Public Health Service Act. The Secretary of HHS's public health emergency declaration for COVID-19 was effective on January 27, 2020, so the emergency period as defined in section 1135(g)(1)(B) began then and continues through any renewal of the Secretary of HHS's public health emergency declaration. The Secretary of HHS last renewed the public health emergency on April 26, 2020, and it will continue for 90 days unless again renewed. Press Release, Secretary of Health and Human Services, Renewal of Determination That a Public Health Emergency Exists (Apr. 21, 2020).

[13] Department of Health and Human Services, Applicability of Diagnoses from Telehealth Services for Risk Adjustment (Apr. 10, 2020), https://www.cms.gov/files/document/applicability-diagnoses-telehealth-services-risk-adjustment-4102020.pdf.

Nursing Homes

Nursing homes, already common targets of FCA enforcement actions, are also likely to face heavier scrutiny due to COVID-19. The pandemic has struck nursing homes with particular severity, with one-third of all COVID-19 deaths in the United States reportedly occurring among nursing home residents or workers.[14] Even before the pandemic, regulators were preparing to increase scrutiny of nursing homes. On March 3, 2020, for example, the DOJ announced the launch of its "National Nursing Home Initiative" to "coordinate and enhance civil and criminal efforts to pursue nursing homes that provide grossly substandard care to their residents."[15]

In the wake of the pandemic, regulators have been even more explicit in their intentions to investigate nursing homes, especially related to COVID-19 infections and deaths. For example, the HHS Office of Inspector General announced in March that it would conduct "Nursing Home Life Safety and Emergency Preparedness Reviews" due to the vulnerability of nursing homes to disasters and disease outbreaks, specifically citing COVID-19.[16] The DOJ also stated that it "is committed to pursuing all manner of fraud in federal health care programs, including violations disclosed by whistleblowers under the False Claims Act, especially during this critical time as our nation responds to the outbreak of COVID-19."[17] On April 30, CMS announced that it was creating an independent commission "that will conduct a comprehensive assessment of the nursing home response to the 2019 Novel Coronavirus (COVID-19) pandemic."[18]

Congress is also scrutinizing nursing homes, and the House committee overseeing the federal response to COVID-19 has launched a broad investigation into the country's largest nursing homes.[19] In addition to these expanded federal investigations, state attorneys general have also increased their focus on these facilities. State investigations of nursing homes are already

---

[14] *See* Karen Yourish et al., N.Y. TIMES, *One-Third of All U.S. Coronavirus Deaths Are Nursing Home Residents or Workers* (May 11, 2020), https://www.nytimes.com/interactive/2020/05/09/us/coronavirus-cases-nursing-homes-us.html.
[15] Department of Justice Press Release, Department of Justice Launches a National Nursing Home Initiative (Mar. 3, 2020).
[16] *See* US Department of Health and Human Services Office of Inspector General, *Medicaid Nursing Home Life Safety and Emergency Preparedness Reviews*, https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000453.asp (last accessed June 11, 2020).
[17] *See* Lydia Wheeler, BLOOMBERG LAW, Coronavirus False Claims Task Force Urged at Justice Department (Mar. 17, 2020), https://news.bloomberglaw.com/health-law-and-business/coronavirus-false-claims-task-force-urged-at-justice-department.
[18] *See* Centers for Medicare & Medicaid Services, *CMS Announces Independent Commission to Address Safety and Quality in Nursing Homes* (Apr. 30, 2020), https://www.cms.gov/newsroom/press-releases/cms-announces-independent-commission-address-safety-and-quality-nursing-homes.
[19] Kyle Cheney & Rachel Roubein, POLITICO, *House Coronavirus Task Force Launches Probe into Nursing Homes* (June 16, 2020), https://www.politico.com/news/2020/06/16/house-coronavirus-task-force-nursing-homes-probe-322616.

underway in Massachusetts, New Mexico, New York, New Jersey and Pennsylvania through the states' federally funded Medicaid Fraud Control Units.[20]

FCA risk is heightened for nursing homes that receive funding from the CARES Act's Provider Relief Fund. On May 22, HHS announced the distribution of $4.9 billion to skilled nursing facilities affected by COVID-19, with a fixed distribution of $50,000 per facility and an additional $2,500 per bed.[21] Recipients must attest that they will use funds only for "permissible purposes" as described in HHS's Terms and Conditions and agree to comply with any future government audit and reporting requirements.[22] Those Terms and Conditions give the Secretary of HHS broad discretion to increase reporting requirements. On June 9, HHS announced a further $15 billion distribution to eligible providers that participate in Medicaid and the Children's Health Insurance Program (CHIP) that have not yet received Provider Relief Funds, including assisted-living facilities and other home- and community-based services providers.[23]

Given widely publicized reports of deficient care in nursing home facilities, there is significant FCA risk involved in the receipt and use of these Provider Relief Funds by such facilities. In addition to potential audits of facilities that receive Provider Relief Funds by federal regulators, employees of such facilities may allege that funds are being mismanaged in private whistleblower actions that they file under the FCA against their employers. To mitigate the risk of FCA liability, nursing homes should therefore ensure that detailed plans, including compliance and document retention protocols, are in place to properly allocate, spend and document Provider Relief Funds in accordance with HHS's Terms and Conditions.

Telehealth Beyond Medicare Advantage

The CARES Act, and subsequently issued regulations, have also temporarily eased telehealth regulations outside the MA context, thus greatly expanding the ability of providers to offer and utilize telehealth services during the COVID-19 public health emergency. In addition to the FCA risks faced by MA Plans and providers as discussed above, these new regulations involve broader

---

[20] *See* NBC BOSTON: STAFF REPORTS, *Mass. AG Investigating Coronavirus Response at Littleton Nursing Home* (May 27, 2020), https://www.nbcboston.com/news/coronavirus/ag-investigating-covid-response-in-littleton-nursing-home/2131838/; KRQE, *NM Attorney General investigates nursing home with high number of coronavirus cases* (Apr. 16, 2020), https://www.krqe.com/health/coronavirus-new-mexico/nm-attorney-general-investigates-nursing-home-with-high-number-of-coronavirus-cases/; Press Release, New York State Office of the Attorney General, Attorney General James Statement on Protecting Nursing Home Residents (Apr. 23, 2020); Joseph De Avila & Jon Kamp, WALL ST. J., New Jersey Nursing Home Under Investigation After Coronavirus Deaths (Apr. 16, 2020), https://www.wsj.com/articles/deadly-coronavirus-outbreak-ravages-new-jersey-nursing-home-11587052720; Press Release, Pennsylvania Office of Attorney General, AG Shapiro: We Are Investigating Pennsylvania Nursing Homes for Criminal Neglect (May 12, 2020).

[21] Press Release, Department of Health and Human Services, HHS Announces Nearly $4.9 Billion Distribution to Nursing Facilities Impacted by COVID-19 (May 22, 2020).

[22] *Id*.

[23] Press Release, Department of Health and Human Services, HHS Announces Enhanced Provider Portal, Relief Fund Payments for Safety Net Hospitals, Medicaid & CHIP Providers (June 9, 2020).

FCA risks outside of the MA context. While some of these risks predate COVID-19,[24] new risks necessarily follow from these revised regulations.

For example, although relaxed regulations may seem to reduce enforcement risk, the opposite may actually be the case. Because the relaxed regulations increase the number of patients who are eligible for telehealth services, the opportunities for fraud and abuse may increase. Less stringent cybersecurity requirements for telehealth communications also amplify the risk that hackers will be able to obtain private medical information, which could in turn form the basis for fraudulent reimbursement requests or other forms of identity fraud. Telehealth providers will no doubt be scrutinized closely by government regulators and should seek legal counsel on FCA and other risks before taking advantage of relaxed telehealth regulations.

Funds to Fight the Pandemic: Healthcare Innovation and Healthcare Services

As discussed in a prior alert,[25] Title III of the CARES Act expands the ability of the Secretary of HHS to enter into agreements with the private sector to foster "flexible, strategic partnership[s] between the government and industry" in support of coronavirus-related biomedical innovation.[26] This sort of partnership raises FCA risk with regard to the ultimate efficacy of the proposed innovation, particularly under the "worthless services" theory of FCA liability recognized by some courts. That theory would allow a regulator or *qui tam* plaintiff to allege not only that a coronavirus-related drug, device or vaccine did not work, but that, as a matter of law, it had no medical value at all, which is akin under the FCA to no performance whatsoever, and which significantly increases the magnitude of potential damages.

The CARES Act's Provider Relief Fund also carries with it a number of FCA risks: for example, it requires healthcare providers receiving payments to sign an electronic attestation confirming their receipt of funds and their agreement to certain Terms and Conditions.[27] The Terms and Conditions, in turn, require healthcare providers to make a number of certifications, including

[24] For example, in April 2019, well before the pandemic, DOJ charged multiple defendants, including executives of five telemedicine companies, for their alleged participation in a healthcare fraud scheme "to exploit telemedicine technology" resulting in losses of $1.2 billion.
[25] "COVID-19: FCA Risks for Industries Fighting the Pandemic" (Matthew Benedetto, Elizabeth Purcell Phillips and Joseph Michael Levy—May 29, 2020).
[26] CARES Act § 4003(g)(2); WilmerHale Client Alert, *False Claims Act Exposure Risks for Industries Fighting COVID-19*, Matthew Benedetto, Elizabeth Phillips and Joseph Levy (May 29, 2020).
[27] Department of Health and Human Services, *CARES Act Provider Relief Fund*, https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html (last accessed June 10, 2020).

that the provider provides diagnoses, testing or care for individuals with "possible or actual cases of COVID-19."[28]

Provider Relief Fund FAQs published by HHS supply further detail on the Terms and Conditions to which recipients must agree, including that the provider provided diagnoses, testing or care for individuals with possible or actual cases of COVID-19 after January 31, 2020, and that none of the funds appropriated shall be used to pay the salary of an individual in excess of $197,300.[29] However, the press has reported that, despite this cap on executive salaries, large hospital chains receiving Provider Relief Funds have executives who continue to earn millions of dollars.[30]

HHS has made clear that "HHS will have significant anti-fraud monitoring of the funds distributed, and the Office of Inspector General will provide oversight as required in the CARES Act to ensure that Federal dollars are used appropriately."[31] With heavy scrutiny by both the government and media of the use of these funds,[32] it is imperative that providers ensure their attestations are truthful and that the uses of funds are supported and well documented.

Critically, however, neither the CARES Act nor the Terms and Conditions themselves define what it means to be a "possible case of COVID-19." The Provider Relief Fund FAQs published by HHS state that "HHS broadly views ***every patient*** as a possible case of COVID-19" (emphasis added), although the FAQs themselves do not carry the force of law.[33] This ambiguity may therefore give rise to FCA risk, especially if a *qui tam* plaintiff were to allege that recipients of Provider Relief Funds were using those funds on services that were patently not related to the pandemic.

What counts as "expenses" or "lost revenues" that are attributable to coronavirus is also ambiguous. HHS has stated that "[t]he term 'healthcare related expenses attributable to coronavirus' is a broad term that may cover a range of items and services purchased to prevent, prepare for, and respond to coronavirus," listing various inclusive examples.[34] And HHS has

---

[28] Department of Health and Human Services, *Acceptance of Terms and Conditions*, https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-20-b.pdf (last accessed June 10, 2020); CARES Act Title VIII, Department of Health and Human Services.
[29] Department of Health and Human Services, *CARES Act Provider Relief Fund Frequently Asked Questions*, https://www.hhs.gov/sites/default/files/provider-relief-fund-general-distribution-faqs.pdf (last accessed June 11, 2020).
[30] Jesse Drucker, Jessica Silver-Greenberg and Sarah Kliff, *Wealthiest Hospitals Got Billions in Bailout for Struggling Health Providers*, THE NEW YORK TIMES (May 25, 2020), available at https://www.nytimes.com/2020/05/25/business/coronavirus-hospitals-bailout.html?action=click&module=Top%20Stories&pgtype=Homepage.
[31] *Id.*
[32] *See, e.g.*, Adam Cancryn, POLITICO, *The Trump Administration Has Yet to Pay Out Billions in Emergency Health Aid* (June 2, 2020), https://www.politico.com/news/2020/06/02/emergency-health-aid-coronavirus-297701?cid=apn.
[33] *See* Department of Health and Human Services, *supra* note 22.
[34] *Id*.

defined “lost revenues” in a circular way, stating “[t]he term ‘lost revenues that are attributable to coronavirus’ means any revenue that you as a healthcare provider lost due to coronavirus.”[35]

FCA risk resides in the ambiguity of these key statutory terms. That said, an FCA plaintiff must still prove the required elements of falsity and knowledge in order to succeed on an FCA claim. Courts are split, however, on whether the alleged false statement must represent an “objective falsehood”—in other words, whether a plaintiff would have to prove in the COVID-19 context that the healthcare provider objectively did not provide diagnoses, testing or care for individuals with “possible cases of COVID-19” or that expenses or lost revenues were objectively not “attributable to coronavirus.”

Both the Third Circuit and the Ninth Circuit have recently held, in “medical necessity” cases involving federal healthcare programs, that proof of an “objective falsehood” is not required in order to succeed on an FCA claim. In *United States v. Care Alternatives*, 952 F.3d 89, 100–01 (3d Cir. 2020), the Third Circuit “reject[ed] the objective falsehood standard,” concluding instead that a “claim may be ‘false’ under a theory of legal falsity, where it fails to comply with statutory and regulatory requirements.” The court explicitly rejected the “bright-line rule that a doctor’s clinical judgment cannot be ‘false.’” *Id.* at 98. The Ninth Circuit similarly held that the FCA does not include a requirement of proving “objective falsity” in the Medicare reimbursement context. *Winter ex rel. United States v. Gardens Regional Hosp. and Med. Ctr., Inc.*, 953 F.3d 1108, 1113 (9th Cir. 2020).

However, both the Third Circuit and the Ninth Circuit seem to agree that any alleged false statement must be capable of being verified as false. *See Winter*, 953 F.3d at 1119 (a medical opinion can be false if “not honestly held, or if it implies the existence of facts—namely, that inpatient hospitalization is needed to diagnose or treat a medical condition, in accordance with accepted standards of medical practice—that do not exist.”); *Care Alternatives*, 952 F.3d at 97 (“FCA falsity simply asks whether the claim submitted to the government as reimbursable was in fact reimbursable, based on the conditions for payment set by the government.”).

These cases teach us that, at least in certain circuits, a healthcare provider may not simply rely on his or her stated clinical judgment that he or she has treated a “possible case” of COVID-19. Healthcare providers who have received Provider Relief Funds and are treating “possible cases” of COVID-19 should thus be prepared clinically to support any diagnoses in order to avoid potential liability under the FCA.

Conclusion

COVID-19 is a public health crisis, and the CARES Act has allocated substantial federal resources to shoring up the country’s healthcare system. Healthcare companies and providers who participate

[35] *Id.*

in CARES Act programs or seek its funding should be mindful of the FCA risks that attach to such funding and thus ensure that any representations they make to the government are truthful.

With a team of veteran litigators, prosecutors and former DOJ and Department of Defense lawyers, WilmerHale brings significant knowledge and experience to defending against FCA litigation brought by relators, the DOJ and state attorneys general. Our experienced team of lawyers and policy professionals are available to help clients navigate this challenging environment. In particular, WilmerHale has a Coronavirus Task Force and dedicated site with frequent legal updates on critical issues affecting our clients' companies, including access to alerts, news, guidance and analysis. Please reach out to the authors of this alert or your WilmerHale contacts should you have any questions.

Contributors

Matthew D. Benedetto
PARTNER

matthew.benedetto@wilmerhale.com
+1 213 443 5323

Elizabeth Purcell Phillips
SENIOR ASSOCIATE

liz.phillips@wilmerhale.com
+1 202 663 6726

Thomas Costello
ASSOCIATE

thomas.costello@wilmerhale.com
+1 213 443 5473