IMPLICATIONS OF COVID-19 CRISIS FOR FALSE CLAIMS ACT COMPLIANCE

To Our Clients and Friends:

Industries worldwide are confronting unprecedented challenges and uncertainties sparked by the novel coronavirus (COVID-19) public health crisis, which has shuttered businesses, disrupted travel, supply chains, and the financial markets, and threatened global economic stability. In response to the pandemic, the United States government has responded with a $2.2 trillion economic stimulus package—the largest in history. This massive new program comes on the heels of other local, state, and federal emergency measures, including significant spending on critical supplies and the federal government’s invocation (albeit on a limited basis) of a wartime statute to direct U.S. industry to manufacture needed medical supplies and equipment.

In the midst of this crisis, companies that do business with the government, including entities in the health care industry and a range of government contractors, have prioritized the public and raced to meet government needs. The fast-paced corporate decisions and actions that this effort has required may not be scrutinized in detail today, in the heat of the moment. But if history is any indicator, today’s responses to the COVID-19 crisis will be scrutinized in the years to come, and could lead to future legal action under the False Claims Act (“FCA”), 31 U.S.C. § 3729 et seq. In the aftermath of past crises, the U.S. Department of Justice (“DOJ”) and qui tam relators have vigorously pursued FCA claims targeting entities that benefited from government spending—efforts contributing heftily to the nearly $40 billion that the federal government has recovered under the FCA in the last decade alone.

There is no reason to believe that the COVID-19 crisis will be any different. DOJ already announced it will “prioritize the investigation and prosecution of Coronavirus-related fraud schemes” and established a national hotline for whistleblowers to report suspected fraud. Accordingly, any company receiving government funds would do well to take steps today to protect against the risk of potential future FCA liability. Below, we summarize these developments, identify potential areas of likely COVID-19-related FCA enforcement, and offer tips for managing risks and other mitigation efforts.

I. Background

The FCA has served as the principal tool for combatting fraud in government programs for more than 150 years. FCA enforcement has been particularly robust when emergency government spending ramps up, giving opportunists the chance to exploit the public fisc, even when lives are at stake. The FCA itself is the product of such a national crisis: Congress enacted the statute during the Civil War in 1863 in response to unscrupulous suppliers defrauding the Union Army,[1] providing defective goods such as “spavined beasts and dying donkeys” in place of healthy horses, sand instead of sugar, and “experimental failures of sanguine inventors” instead of working firearms.[2]
Flurries of FCA activity also have followed more recent crises, particularly those that involve significant emergency government spending. This includes, for example, the wars in Iraq and Afghanistan, natural disasters such as Hurricane Katrina, the 2008 financial crisis and Troubled Asset Relief Program (“TARP”), and the ongoing national opioid epidemic. In addition to DOJ’s enforcement activities, private plaintiffs’ attorneys representing qui tam relators have, in the wake of past crises, enthusiastically pursued FCA actions against all types of government contractors and industries receiving government funds.

In connection with the 2008 financial crisis, for example, a DOJ task force charged with rooting out fraud in federally insured mortgage and lending programs was the vanguard of aggressive FCA enforcement. The task force’s efforts, focused primarily on lenders participating in government programs and other institutions receiving government funds, led to record-setting annual FCA recoveries upwards of $6 billion in the years that followed, and their effects still linger more than a decade later. And even just the most recent of these crises proves the point. In the last few years, DOJ has boldly pursued FCA claims against manufacturers, prescribers, health systems, and others involved in the opioid distribution chain, recovering more than $1.5 billion last year alone.

The COVID-19 crisis has prompted federal action that may well dwarf expenditures on prior crises. Just days ago, for example, the Coronavirus Aid, Relief, and Economic Security Act (“CARES Act”) became law. The CARES Act, the largest emergency stimulus package in history, will devote $2.2 trillion worth of government funds to mitigate the effects of COVID-19. As we reported in detail earlier this week, several key provisions in the Act provide relief for businesses, industries, individuals, employers, and states, including as follows:

- Establishment of a Small Business Administration (“SBA”) loan program offering up to $350 billion in loans forgivable under certain conditions, with relaxed eligibility requirements relative to existing law;
- Provisions for direct rebates and other tax relief for individuals and employers;
- Provisions for hundreds of billions of dollars in funding and other resources for the health care industry, education sector, defense contractors, and lending institutions; and
- Establishment of a $500 billion economic stabilization program to provide loans and loan guarantees for eligible businesses, states, and municipalities.

In addition to passage of the CARES Act, the government’s efforts have included the following steps, on which we reported last week:

- Enacting legislation appropriating more than $8 billion dollars in government spending for supplies, vaccines, tests, isolation and quarantine costs, sanitization of public areas and more;
- Declaring a state of emergency authorizing the release of up to $50 billion in spending in government efforts to combat the virus;
Invoking the wartime-era Defense Production Act to direct U.S. industries to manufacture critical medical supplies, including respirator masks and ventilators; and

- Announcing intended partnerships with the private sector to expand COVID-19 testing.

These steps, and others that are sure to follow as the crisis develops, will set the stage for potential COVID-19-related FCA enforcement activity in years to come.

II. DOJ Prioritizes COVID-19 Fraud Cases and Whistleblower Attorneys Gear Up

DOJ has already confirmed that it will focus resources on COVID-19-related fraud. In a March 16 memorandum to all U.S. Attorneys and a March 20 press release, Attorney General William Barr announced that DOJ will prioritize the investigation and prosecution of coronavirus-related fraud schemes.[5] In addition, Attorney General Barr directed U.S. Attorneys to appoint a “Coronavirus Fraud Coordinator” in each district—responsible for coordinating enforcement and conducting public outreach and awareness—and also established a national system for whistleblowers to report suspected fraud.[6] DOJ further affirmed in a March 17 public statement that it is “committed to pursuing” violations of the FCA “especially during this critical time as our nation responds to the outbreak of COVID-19.”[7] Although still in their infancy, DOJ’s efforts harken to similar government actions in past times of crisis.

DOJ’s efforts will be complemented by the CARES Act’s creation of a new oversight committee called the Pandemic Response Accountability Committee (“PRAC”) to promote transparency and oversight of CARES Act appropriated funds.[8] The Act’s emergency appropriations included $80 million for the PRAC, which will be comprised of various agency Inspectors General to “(1) prevent and detect fraud, waste, abuse, and mismanagement; and (2) mitigate major risks that cut across program and agency boundaries.”[9]

In addition to potentially drawing scrutiny from DOJ and agency Inspectors General, companies contracting with or receiving government funds are likely to see a slew of future qui tam whistleblower complaints in connection with the COVID-19 crisis and economic downturn. The plaintiffs’ bar has already signaled its willingness to begin this effort, including a widely publicized request by a whistleblower attorney and national whistleblower advocacy group for DOJ to form a task force “to monitor and investigate” COVID-19-related FCA cases,[10] and numerous firms issuing calls for would-be relators to come forward and pursue qui tam actions relating to COVID-19.[11]

III. Potential FCA Pitfalls in Responding to the COVID-19 Crisis

Entities in the following industries are most exposed to the risk of future COVID-19-related FCA enforcement actions.

A. Life Sciences and Health Care Industries

Given the nature of the COVID-19 crisis, companies in the life sciences and health care industries—including drug and device manufacturers and suppliers, diagnostic companies, health care providers, and
insurers—are perhaps the most likely to have their decisions and conduct scrutinized through the lens of the FCA in the future.

In its recent announcement prioritizing COVID-19-related enforcement actions, DOJ specifically targeted fraud in treatment by providers, such as “obtaining patient information for COVID-19 testing and then using that information to fraudulently bill for other tests and procedures.”[12] This echoed DOJ officials’ comments from February, which focused on the practice of Medicare Advantage insurers indiscriminately billing the government for “every possible patient diagnosis,” including “unsupported diagnosis codes” ineligible for reimbursement. Entities billing federal programs (as well as state programs) for treatment of those affected by COVID-19 should exercise particular care in selecting diagnostic codes when seeking reimbursement.

Other activities that fall within the types of buckets that resulted in FCA actions in the past (whether successful or not)—and could serve as the basis of COVID-19 related FCA actions—could potentially include:

- “upcoding” for testing or treatments of different types or amounts than those actually provided;[13]
- billing for treatment or testing that is not medically necessary, especially treatment whose safety or efficacy is unsupported and may even cause harm;
- billing for treatment, testing, or medical supplies that do not comply with regulatory requirements;
- billing for treatment that is grossly and materially substandard; and
- making false or misleading statements in connection with marketing drugs or devices.

The bar for pursuing frontline health care providers under the FCA is likely to be higher when it comes to the COVID-19 crisis, given the critical need to provide treatments to patients during this crisis. Notably, the CARES Act provides immunity to many treatment providers for claims under federal or state laws relating to emergency health care services provided with respect to COVID-19.[14] Further, the CARES Act recognizes liability immunity for certain respiratory protective devices that HHS has deemed a priority for use during this public health emergency. Nevertheless, frontline providers may still face situations where the government or qui tam whistleblowers allege after the fact that the emergency care provided was not undertaken in good faith and instead was to profit off of the crisis.

B. Other Industries Receiving COVID-19 Relief Funding

FCA liability is a potential risk even for entities that do not directly conduct business with the government, but nevertheless accept government funding in some manner, including in the form of loans, grants, or other programs.
1. **Loan Programs.** The CARES Act injects nearly a trillion dollars’ worth of loan and loan guarantee programs into the economy. This aid is partially specific to certain industries, such as the passenger airline and air cargo sectors, but the bulk is more widely available to a range of domestic-based businesses. Further, the Act makes SBA loans available to any business that qualifies as a “small business” under eligibility requirements more inclusive than existing law. Any participant in these programs, or similar government relief programs, will be subject to certain required conditions of participation and/or payment, which can be complex and may create a potential minefield from an FCA perspective.

With respect to the $500 billion CARES Act loan program, some portions of funding are restricted to passenger air carriers ($25 billion), cargo air carriers ($4 billion), and any “businesses critical to maintaining national security” ($17 billion). As to the eligibility requirements for the remainder of the fund, while the CARES Act does specify some requirements—such as that a business be domiciled and have significant operations and a majority of its employees in the United States—the complete terms and conditions for eligibility remain to be determined, as the legislation directs the Secretary of the Treasury to promulgate the full requirements no later than 10 days after enactment, i.e., the first week of April.

Although the CARES Act does provide clearer standards of eligibility for the SBA loan program (i.e., any company with no more than 500 employees may be eligible), the Act also contains numerous exceptions that expand its reach. For example, the CARES Act’s limited waiver of existing SBA affiliation rules—affecting whether or how the head count for certain affiliates are included in calculating the number of employees when determining eligibility for the program—will allow certain businesses in the accommodation and food services industries to still qualify for loans depending on their classification and the number of employees per physical location. But outside the Act’s enumerated exceptions, businesses must still abide by the requirement to aggregate their employee headcounts or revenues with those of their affiliates to determine whether they are eligible for the SBA loan program. Although the CARES Act provides an expanded avenue for relief to some businesses seeking financial assistance, companies (including those with private equity ownership) should familiarize themselves with both the SBA affiliation rules and the CARES Act’s limited exceptions before seeking to obtain SBA loans.

2. **Grants.** The CARES Act includes emergency appropriations providing funding to the CDC, NIH, and other agencies for research, health surveillance programs, and other resources to respond to the COVID-19 crisis, as well as prepare for future public health emergencies. In addition, as relief efforts continue, the government may provide future funding for charitable or research grant programs, or similar types of funding—all of which implicate the FCA.

In recent years, a variety of entities, including private companies, universities, and even municipalities, have faced FCA claims alleging violations in connection with obtaining or performing federal grants, ranging from a failure to comply with regulations and grant conditions, to falsifying grant applications or fabricating study data. In one case, a private university paid more than $100 million to settle *qui tam* claims that it violated the FCA by submitting applications and progress reports that contained falsified
research data.[20] In another case, a national energy company paid nearly $30 million to resolve allegations it received inflated payments by misrepresenting its eligibility for federal grant funds.[21]

And while it might be natural to think that the government would be more forgiving when charitable or good causes are involved, such as this, history counsels otherwise. For example, a children’s hospital paid nearly $13 million to resolve FCA claims alleging that the hospital misreported its available bed count when seeking grant funding from HHS for pediatric resident training.[22] And certain courts have upheld, in FCA cases, the award of treble damages on the entire amount of the research grants at issue, including in cases based on alleged false statements made in grant renewal applications.[23] Companies receiving federal funds in the future, whether charitable relief, or in connection with COVID-19 research grants, should be mindful of these pitfalls.

3. Other Government Programs. As we covered in our report, the CARES Act also impacts rules and requirements relating to numerous government programs and revenue streams, including appropriations for national defense, debt restructuring, lending by financial institutions, and federally-backed mortgages.[24] The Act therefore has implications for a wide range of industries, including defense contracting, the education sector, and banks and other lending institutions, among others, that receive government funding or relief and are all potential targets for FCA relators and their attorneys.

IV. Guidance for Minimizing FCA Risks in Government Procurement and Relief Programs

As the government expands spending to address the COVID-19 crisis, any entity receiving government funding or taking advantage of government-backed or guaranteed loans should consider the practices outlined below to mitigate the risk of future FCA legal action:

- **Stay informed:**
  - Ensure that you understand government contracting regulations detailing what you are required to do and when.
    - Know when you are contractually required to notify the government of your right to an equitable adjustment of a contract price, delivery schedule, or both. For example, FAR 52.243-1 requires notification to the Contracting Officer within 30 days.
    - Track and understand the complex requirements imposed by regulations specific to your industry, e.g., Medicare and Medicaid requirements.
  - Monitor announcements by the government and agencies appropriately to ensure that you remain informed of waivers, modifications, and other developments in regulatory requirements, or guidance for industry, which may change as the crisis unfolds.
    - CMS and HHS-OIG, for example, have begun providing blanket waivers and made broadly applicable modifications to provider requirements aimed at
permitting hospitals to operate with fewer restrictions and maximize the treatment of COVID-19 patients.[25]

- Remember that even unintentional or implied misrepresentations of regulatory compliance can lead to FCA enforcement actions, if material to payment and done with “reckless disregard.”

- **Adopt best practices for ensuring compliance with government requirements:**

  - Continue to implement effective risk management and auditing procedures during the COVID-19 crisis to minimize the risk of such liability.

    - Keep in mind that while some risks of FCA liability are readily apparent even in a time of crisis—such as in the case of providing substandard or defective equipment or services to the government—it can be easier to lose sight of other, less obvious pitfalls during an emergency, such as billing the government for goods or services that do not strictly comply with all regulatory requirements. This could include, for example, billing for work performed by unqualified personnel, or for work done by personnel other than those represented to the government as having performed the work.

  - Implement effective procedures and controls around any required certifications regarding what the government is paying for.

    - Account for any requirements imposed by statute, regulation, rules, or contract, whether generally applicable, or that apply to your industry and/or the specific goods or services provided—which, for example, could include ADA requirements, the Buy American Act, or the Trade Agreements Act.

    - Document your compliance with any such requirements and/or the bases of any required certifications.

  - Avoid unilaterally deciding to forego or not complete any government requirements (e.g., skipping mandated procedures, tests, certifications, and so forth) even if intended to fast track production given the urgency involved, unless there is explicit and clear (and written) government authorization to do so, as outlined further below.

    - Remember that efforts that involve cutting corners might appear entirely reasonable to anyone in the midst of a crisis, but may well appear hasty, ill-advised, or even wasteful when viewed in hindsight months or years later.

    - Claims for payment that involve misrepresentations of compliance with government requirements have resulted in significant FCA liability—even when those claims were made during times of past crises. For example, a telecommunications company that designed and built Iraq’s national 911
emergency communications system during the height of the Iraq War settled FCA claims based on allegations the company had certified completion of certain testing and validation that it had not actually performed.[26] Similarly, a company constructing urgently needed housing for first responders following Hurricane Katrina settled FCA claims alleging that it failed to abide by the specific requirements in its contract.[27]

Be aware that FCA liability requires more than a “bare assertion that defendants delivered goods that did not conform to contractual specifications.”[28] And even in cases where the government pays for what it later discovers to be defective, for example, “ineffective vaccines,” courts have dismissed FCA claims for lack of scienter.[29]

Exercise care when participating in any COVID-19 loan, grant, or other relief program to ensure that any government requirements are met, and that any representations made to the government as part of the funding process are accurate.

Be aware of the risks posed to those directors and officers responsible (directly or through private equity ownership) for a company availing itself of government funding, such as through the CARES Act’s SBA loan program, particularly those who certify compliance with government requirements. If the individual is found to have caused the submission of a false claim, they may face arguments that their conduct satisfies the falsity element of FCA liability.

If the director or officer is found to have proceeded in good faith, however, it would be difficult for a plaintiff to satisfy the scienter element. It is thus important to document the rationale and bases underlying the good faith belief (including, for instance, communications with the government, or others in the industry, or counsel, etc.). Advice of counsel, in particular, can constitute very strong evidence on scienter for the officer or director (but, of course, likely would result in waiver of privilege as to the relevant subject matter). To the extent that you believe that an insurance policy could be applicable, consult your insurance counsel about potential coverage issues.

Document any governmental modification or waiver of requirements:

Ensure that any such waivers or modifications are authorized by a government official or agency with sufficient authority to act (i.e., by the Contracting Officer, or by an authorized government agency), and are thoroughly and adequately documented in writing.

Be aware that in past FCA cases, defendants have faced arguments that government officials who modified requirements lacked the “unilateral authority” to amend requirements, and that therefore defendants should still be subject to liability.[30]
Seek confirmation regarding changes in government requirements, even if you already believe them to be clear.

- Keep in mind that the fluid nature of the COVID-19 situation has reportedly created confusion and apparent inconsistencies in guidance from federal agencies.[31]

Compile in real time written evidence or documentation of the modifications or waivers and their purpose to meet government or public needs.

- Understand that memories are likely to be treated as less reliable than documentation, and what may seem obvious today may not be in the future when the crisis has abated. Adequately-documented decisions by authorized officials are likely to provide a strong defense on scienter and materiality elements.

- Evidence of this “government knowledge” will be a key issue with respect to materiality and scienter, as courts have acknowledged that such evidence can “negate both of these elements,”[32] although in some instances, have held that scienter is negated only if the government communicates its knowledge and approval back to the contractor.[33]

- Do not assume that you are in the clear simply because the government is aware of your actions. Rather, it is critical to document a communication from the government expressing approval, under the line of cases requiring the government’s knowledge and approval be communicated back to the contractor to negate scienter.

Consider publicly announcing any government approved waivers or modifications to existing requirements, as well as your reliance on such actions.

- For example, as noted above, CMS and HHS-OIG have waived or modified certain requirements with respect to hospitals to maximize the availability of COVID-19 treatment. Similarly, FDA has modified or waived certain regulatory requirements with respect to respirator masks for use by health care personnel to encourage manufacturers to make additional masks available.[34]

- Making public your reliance on the government’s actions serves not only to highlight a lack of scienter, but may also bolster future arguments that FCA claims are subject to the statute’s “public disclosure” bar. If the key elements of the alleged fraud are published in the news media, this can support dismissal unless the whistleblower is an “original source” that materially adds to the information in the public domain.
• **Ensure that you have effective reporting systems in place to discover potential compliance issues and then take them seriously:**

  o Know that many whistleblowers are current and former employees. With the increased furloughs and layoffs brought on by the COVID-19 crisis, there may be a significant rise in whistleblowing activity. In addition to compliance and reporting systems, you should ensure that you pay close attention to any allegations or issues raised as part of exit interviews.

  o Statistics show the overwhelming majority of whistleblowers first report their allegations internally and are willing to wait for the internal investigation process.[35] If you become aware of any claims of misconduct or fraud in connection with requests for or receipt of government funding involving your company, ensure that your response is handled by appropriate compliance or legal personnel and treat allegations seriously, including by conducting a thorough, well-documented investigation.

  o By taking these steps, you may be able to satisfactorily resolve the concerns raised internally, and avoid escalation to outside agencies or counsel. Studies have shown that a company’s internal whistleblower report volume is associated with fewer and lower amounts of government fines and material lawsuits.[36]

• **Steer clear of anti-competitive conduct:**

  o Be mindful of DOJ’s recently announced focus on enforcement of antitrust laws—violations of which may form the basis of related FCA claims—in connection with COVID-19.

    β As we have reported recently, on March 9, DOJ warned that it will be on “high alert” for collusive practices, including fixing prices or rigging bids for personal health equipment such as face masks, respirators, and diagnostic equipment, especially by companies selling to federal, state, and local agencies.[37]

    β DOJ has in the past brought enforcement actions under the FCA against companies—for instance, generic drug manufacturers—on the grounds that claims for government program reimbursement of drugs allegedly tainted by price-fixing conspiracies were false or fraudulent.[38]

If you have any doubts about the propriety of any action when it comes to government contracts, funding, or government loans, stop and seek guidance of counsel. We are all working through this crisis together, and Gibson Dunn's lawyers are available to assist with any questions you may have regarding FCA and government contracting developments related to the COVID-19 outbreak.


[8] Gibson, Dunn & Crutcher LLP, CARES Alert, Section IV.

[9] Id.


Gibson, Dunn & Crutcher LLP, CARES Alert, Section III.

Id., Section I and IV.

Id., Section IV.

Id.

Id., Section I and IV.

Id.


See U.S. ex rel. Feldman v. van Gorp, 697 F.3d 78, 81 (2d Cir. 2012).

See Gibson, Dunn & Crutcher LLP, CARES Alert, Section IV.


[29] Id. at 52.

[30] Id. at 55.


[32] See *U.S. ex rel. Hunt v. Cochise Consultancy, Inc.*, 887 F.3d 1081, 1092 n.10 (11th Cir. 2018); see also *Kelly v. Serco, Inc.*, 846 F.3d 325, 334 (9th Cir. 2017) (finding that relator “failed to establish a genuine issue of material fact regarding materiality” on FCA claim where the government continued to make payment after learning of alleged noncompliance).


Gibson Dunn attorneys regularly counsel clients on issues raised by this pandemic, and we are working with many of our clients on their response to COVID-19. Please also feel free to contact the Gibson Dunn attorney with whom you usually work, any member of the False Claims Act Group, or the authors:

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