

WEBINAR

FCA Playbook: Managing Risks of COVID-19 Relief and Response Programs

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COVID-19 Relief and Response Programs

Opportunities and Risks

- The Federal Government has allocated more than **\$2 trillion in emergency relief** to address the ongoing crisis via **the CARES Act** and other measures.
- Federal relief programs include, among others:
 - *Economic Injury Disaster Loans (EIDL)*
 - *Paycheck Protection Program (PPP)*
 - *SBA Express Bridge Loans / Debt Relief*
 - *COVID-19 Telehealth Program*
 - *Provider Relief Fund*
 - *Higher Education Emergency Relief Fund – Student Aid*
- Opportunities also presented by R&D funding, the EUA, and the Defense Production Act.

With These Opportunities Come Expanded Risks of Potential Liability Under the False Claims Act

Why should we expect increased FCA enforcement?

- Significant influx of government funds → increased pressure on law enforcement to police funds
- FCA → one of the government's most powerful civil enforcement tools for rooting out fraud in connection with government funds
- Government announcements of commitments to protect federal funds from fraud and abuse
- History is a strong indicator
- Nearly **\$38 billion** recovered through FCA enforcement over the past decade
- Breadth of CARES Act means FCA risks impact many industries, including health care, financial services, travel, higher education, food services, manufacturers, telecommunications, technology and various essential service providers

What Should We Expect from Law Enforcement?

- **Task Forces**: Joint efforts among federal, state, and local law enforcement agencies to crack down on fraud and misuse of relief funds.
 - All 93 U.S. Attorneys were instructed to establish task forces to prioritize the investigation and prosecution of COVID-19 fraud.
 - Examples include:
 - The Washington Metropolitan Area COVID-19 Anti-Fraud Task Force
 - The Virginia Coronavirus Fraud Task Force
 - The New Jersey Covid-19 Fraud Task Force
 - Other DOJ Task Forces and Efforts include:
 - COVID-19 Hoarding and Price Gouging Task Force
 - Market Integrity and Major Frauds Unit is overseeing PPP-related investigations and coordinating with various U.S. Attorney's Offices.
 - Similar to past responses to crises: e.g., Enron Task Force (2001), Joint Task Force Katrina (2005), and Financial Fraud Enforcement Task Force (2009).

What Should We Expect from Law Enforcement – cont'd

Agency Oversight – Report on Fraud, Waste and Abuse in Connection with Federal Programs

- ***Inspectors General (“IG”)*** – Have robust investigatory authority. Will play key role in overseeing pandemic response and expenditure of federal funds.
- ***Office of the Special Inspector General for Pandemic Recovery (“SIGPR”)*** – Responsible for performing audits and investigations of loans, loan guarantees, and other investments under any program established under the CARES Act and can refer matters to the DOJ for civil or criminal enforcement.
- ***Pandemic Response Accountability Committee (“PRAC”)*** – Comprised of various agency Inspectors General; has auditing and reporting responsibilities; can refer matters to the DOJ for civil or criminal investigation.
- ***United States Government Accountability Office (“GAO”)*** – the CARES Act provides a mandate for GAO reports to Congress on all expenditures of funds under the CARES Act.

Similar to what was put into place in response to earlier crises:

- e.g., the Office of the Special Inspector General for the Target Asset Relief Program following the 2008 financial crisis.

What Should We Expect from Law Enforcement – cont'd

Congressional Oversight

- ***House Select Committee on the Coronavirus Crisis (H. Res. 935)***
 - Charged with investigating and reporting on the issues generally relating to the pandemic including:
 - reports of waste, fraud, abuse, price gouging, profiteering, or other abusive practices;
 - the protection of whistleblowers who provide information about waste, fraud, abuse or other improper activities related to the coronavirus crisis
- ***Bicameral Congressional Oversight Commission (created by the CARES Act)***
 - Charged with overseeing the implementation of the CARES Act
 - Composed of five members chosen by the majority and minority leaders of both houses of Congress.
 - Responsible for submitting regular reports to Congress on the CARES Act, its impact on U.S. citizens and the U.S. Economy, and effectiveness of loans and investments under the CARES Act.

What To Expect From Law Enforcement – cont'd

Whistleblower Initiated Investigations and Claims

- Many Whistleblower Hotlines have been implemented and promoted by the Government
- Whistleblowers are incentivized by the prospect of sharing in recoveries and the award of attorneys fees and expenses
- Last year alone, 636 (82%) of the 782 new FCA actions were filed under the FCA's whistleblower, or *qui tam*, provisions

What Should We Expect From Law Enforcement – cont'd

To Date, We Have Seen Aggressive Investigations and Filing of Criminal Charges Where Significant Evidence of Intent to Defraud:

- **Schemes to Defraud the PPP and the EIDL:**
 - Investigations involving search warrants, trash pulls, witness interviews, undercover recorded conversations.
 - Government has already filed criminal charges in multiple cases involving alleged schemes to defraud the PPP (loans ranging from \$500,000 to \$20 million).
- **Schemes Involving Price Gouging:**
 - Criminal charges brought against individuals for alleged violations of the DPA, wire fraud and conspiracy based on price-gouging in relation to the sale of N95 masks.

Civil Enforcement:

- Historically – government relies heavily on civil enforcement tools, like the FCA, to police federal funds, given lower standard of proof, no need to prove intent to defraud, potential for treble damages and exclusion from government programs.

Bottom Line:

- Individuals and companies receiving federal funds or otherwise transacting business with or funded by the government will be subject to intense scrutiny.
- Critical to understand and mitigate risks of potential FCA liability.

FCA Primer

Overview of the FCA

- The False Claims Act imposes liability on any person or entity that:
 - Knowingly submits or causes another to submit a false claim to the government for payment;
 - Knowingly makes or uses a false record or statement to get a false claim paid by the government;
 - Knowingly makes or uses a false record or statement material to an obligation to pay money to the government; or
 - Knowingly conceals, avoids, or decreases an obligation to pay money to the government.

Key Elements of an FCA Claim

- The falsity was **material** to the government's payment decision
 - Materiality standard is demanding (*Escobar*)
 - Continued government payment is evidence of non-materiality
- The defendant acted **knowingly**
 - Actual knowledge
 - Deliberate ignorance
 - Reckless disregard

Common Theories of FCA Liability

- Express false statements (certification)
- Implied false certification
 - Submission of claim implicitly certifies compliance with all relevant statutes, regulations, and contract provisions
- Fraudulent inducement
 - Government contract obtained through false statements – all claims under contract considered false claims
- Reverse false claims
 - Failure to return money improperly obtained from the government

FCA – Aggressive Enforcement Tool

- FCA Liability is “Essentially Punitive”
 - Treble damages and mandatory penalties
 - Penalties recently doubled, from \$5,500-11,000/per claim to \$11,665-\$23,331/per claim
- Significant Costs
 - Statutory attorney’s fees and costs
 - May result in exclusion from participating in federal programs
 - Lengthy investigations and litigation
 - Follow-on costs (e.g. Corporate Integrity Agreement, monitor, etc.)

FCA – *Qui Tam* Provision

- A private person or company (“relator” or “whistleblower”) can file an FCA suit (“*qui tam* complaint”)
 - Often current or former employees or competitors
 - Need not have personally suffered harm
 - Must be an original source of information
- May receive 15-30% of the government’s recovery
- Automatically remains under seal for 60 days
 - DOJ can seek extensions.
 - DOJ can:
 - Intervene and take over control from the relator;
 - Decline to intervene (maintain right to intervene later or veto settlement/dismissal);
 - Settle with the defendant; or
 - Move to dismiss the case.

Lifecycle of an FCA Matter

- Government Investigation (60 days to several years)
 - Subpoenas or Civil Investigative Demands (CIDs) for
 - Documents
 - Depositions
 - Written interrogatories
 - Employee Interviews
 - Internal Investigation
- Settlement Discussions
- Complaint Filed (or *Qui Tam* Complaint Unsealed)
- DOJ Intervenes, Declines to Intervene, or Moves to Dismiss
- Litigation

Collateral Issues and Consequences

- Parallel state FCA investigations
- Parallel criminal investigations
- Whistleblower retaliation claims
- Privacy and data security issues
- Follow-on federal securities litigation (including shareholder demands for books and records, shareholder derivative actions and class actions)
- Congressional investigations that can amplify negative publicity and undercut privileges
- Range of collateral business consequences
 - Negative publicity
 - Stock price decline
 - Suspension or termination of a contract award; exclusion from government programs
 - Audits and increased reporting obligations (e.g., Corporate Integrity Agreement)

Examples of Specific Program Risks

Paycheck Protection Program, the CARES Act and Agency Level Actions on Funding

- Paycheck Protection Program (nearly \$650B in forgivable loans for employers)
 - Applies to any qualified small business irrespective of the industry in which they participate.
- Billions of dollars are also directed at the healthcare and life sciences industries
 - CARES Act Centers for Disease Control (CDC) and Prevention (\$4.3 billion): Public Health Data Surveillance and Infrastructure Modernization (\$500 million); Centers for Medicare and Medicaid Services (\$200 million): Survey and Certification of Healthcare Facilities (\$100 million)
 - Follow on agency level decisions re directed funded, e.g., at biopharma industry, and waivers that lift regulatory restrictions on provider services, e.g., telehealth and in-home patient care.

What Could Go Wrong?

- FCA risk flows from the eligibility criteria and requirements for use of funds by recipients and related reporting obligations.
- Trap doors include:
 1. lack of comprehensive guidance
 2. improper certification of eligibility
 3. improper attestation of use of the funds
 4. failure to return funds once ineligibility is established
 5. failure to adjust business practices once waivers of service restrictions expire after the public health emergency ends
 6. difficulty of segregating funds for the specified use, i.e., appearance of “fungibility”

PPP and Related Loan Risk Areas

- **Necessity for the loan:**

- Loan application requires certification that “[c]urrent economic uncertainty makes this loan request necessary to support the ongoing operations of the Applicant.”
- No clear cut guidance but SBA has stated that it is “unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith[.]”
 - SBA’s supplemental interim final rule also cautioned borrowers backed by private equity firms to reassess their certifications.

- **Amount of loan requested:**

- Amount of PPP loan permitted is based on a formula averaging monthly payroll costs, up to \$100,000 cash compensation for each employee on an annualized basis, for a designated period, multiplied by 2.5.

Eligibility and Restrictions on Use of Funds

- Use of funds related to PPP loans:
 - Borrowers who want to obtain loan forgiveness must use PPP loans for a specific purposes, including: payroll, employee benefits, mortgage interest, rent, utilities
 - Loan forgiveness is only possible where loan is primarily used (75% or more) to cover payroll costs and employee count and compensation is maintained for 8 weeks following the receipt of the loan
 - Loans of \$2 million or more will be audited
- Use of funds for services related to COVID-19 diagnosed patients:
 - For example, proof that services, reimbursed by Medicare, were for COVID-19 patients
 - Proof that patients were suffering from COVID-19 when so many are not either (1) not tested before services are provided or (2) not tested prior to death and, therefore, never diagnosed
 - Substantial retrospective audit risk exists here

HHS Waivers of Regulatory Restrictions

- Waivers authorized by CMS
 - These agency level decisions have relaxed regulatory restrictions in multiple areas affecting providers
 - Temporary relaxation of restrictions during public health emergency
 - Care and billing practices that would otherwise carry obvious FCA and overpayment billing risk are now permitted
- ESRD services
- Telehealth
- Health systems providing patient care in the home
- Hospice care intake and coding

Effective Risk Management Takeaways

- Balance the benefit of relaxing operational safeguards against the risk that these measures cannot be effectively rolled back in short order
- Carefully assess where your highest operational risk is before engaging in relaxation of established compliance procedures
- Make sure to train employees on the new operational processes as you would pre-COVID-19
- Document the changes with new policies and procedures and “kick the tires” to make sure it is sustainable
- In the healthcare arena, document the prescribing and diagnostic decision-making even if a waiver has been granted
- In the non-healthcare industries, document communications with government contracting officers regarding concurrence on performance expectations
- Evaluate the effectiveness of COVID-19 and suspected COVID-19 patient tracking to facilitate internal auditing

Provider Relief Fund

Provider Relief Fund – Overview

\$175 billion in total funding available

- CARES Act established \$100 billion Public Health and Social Services Emergency Fund (“Provider Relief Fund”)
- Purpose to provide financial relief to healthcare providers affected by the COVID-19 pandemic
- Paycheck Protection Program and Health Care Enhancement Act added \$75 billion to the Provider Relief Fund

Provider Relief Fund – Overview

- Critical support for hospitals, physician-owned practices, and other providers facing dual impact of (a) responding to the COVID-19 crisis; and (b) losing revenue due to the suspension of elective procedures
- \$100 billion dedicated to healthcare providers
 - \$50 billion = General distribution to Medicare facilities and providers impacted by COVID-19
 - \$30 billion initial tranche
 - \$20 billion second tranche
 - \$50 billion = Targeted allocation to providers in areas particularly impacted by COVID-19, rural providers, and those that serve low-income and uninsured populations
 - \$10 billion to rural health clinics and hospitals
 - \$225 million to Rural Health Clinics (“RHCs”) for COVID-19 testing from Health Resources and Services Administration (“HRSA”)
 - \$400 million to Indian Health Service (“IHS”); \$500 million to tribal hospitals, clinics, urban health centers
 - \$15 billion to eligible Medicaid and CHIPS providers

Terms & Conditions

- While funds were largely distributed automatically, recipients required to sign attestation confirming receipt and agreeing to terms and conditions within 45 days of payment – extended to 90 days
 - Acceptance of funds subject to extensive terms and conditions accompanied by potential liability under the FCA
 - Ambiguous language in some T&Cs and (as noted earlier) extensive government enforcement action create a perfect storm of risk
- FCA risk may arise from “false certification” of compliance with T&Cs
 - *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016) (“implied false certification theory can be a basis for liability” under the FCA)

Terms & Conditions

- Restrictions on Use of Funds
 - Prohibition on losses reimbursed by other sources
- Restriction on Seeking Out-of-Pocket Payments from Patients
 - No “balance billing” patients for “all care for a presumptive or actual case of COVID-19”
- Reporting Requirements
- Recordkeeping Requirements



The Recipient certifies that the Payment will only be used to prevent, prepare for, and respond to coronavirus, and that the Payment shall reimburse the Recipient only for health care related expenses or lost revenues that are attributable to coronavirus.

Terms & Conditions - \$50B General Distribution

- Billed Medicare in 2019
- Provides health care services for COVID-19 patients;
- Eligible for Medicare and Federal Health Care programs; has active Medicare billing privileges (“Medicare and Federal Health Programs Eligibility Certification”)
- Payment will only be used to respond to COVID-19 cases and that reimbursement is only for health care expenses attributable to COVID-19 (“COVID-19 Treatment Certification”)
- Will not use Payment to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse
- Shall submit reports to HHS as needed to ensure compliance (“Compliance Reporting Requirement”) and submit general revenue data for calendar year 2018
- All information it provides as part of its application is true, accurate, and complete to the best of its knowledge; deliberate omissions, misrepresentations, or falsification may be punishable by law, including revocation of Medicare billing privileges, exclusion from federal health care programs, and/or imposition of fines, civil damages, and/or imprisonment (“True, Accurate, and Complete Certification”)
- HHS reporting requirement within 10 days after the end of each calendar quarter for any entity receiving more than \$150K (“\$150K+ Reporting Requirement”)
- Maintain appropriate records and cost documentation; agrees to fully cooperate in all audits the Secretary, Inspector General, or Pandemic Response Accountability Committee conducts to ensure compliance with these Terms and Conditions (“Appropriate Records and Documentation Condition”)
- Will not seek to collect patient out-of-pocket expenses for out-of-network treatment (“Out-of-Network Provider Condition”)

Enforcement Risk

- HHS-OIG Audits
 - Final audit of relief funds due to Senate and House Committee on Appropriations
 - HHS obligated to provide report on obligation of funds every 60 days
 - At minimum, disallowed funds may have to be returned following audit
- FCA Liability
 - Exposure arising out of knowingly presenting, or causing to present, a false claim for payment to the government
 - Also protects against knowingly avoiding or concealing an obligation to return money back to the government (“reverse false claim”)
 - Failure to abide by terms and conditions of relief fund payments could result in FCA liability for providers that use the funds

Key Takeaways

- Provider Relief Fund recipients should consider the following best practices:
 - Carefully track use of funds received to ensure compliance with use of funds limitations in T&Cs
 - Maintain contemporaneous records of how funds are used pursuant to T&Cs
 - Monitor guidance from HHS regarding use of funds and clarification of ambiguous T&Cs
 - Ensure that retention of funds is consistent with intended purpose of Provider Relief Fund to avoid “reverse false claims” risk (i.e., providers are obligated to return funds to which it was not entitled)
 - Seek advice of counsel to evaluate whether potential uses of program funds are consistent with the T&Cs

Government Contracting

FCA Exposure for Government Contractors

- Goods/services paid for/funded by the government resulting from COVID-19 initiatives
 - Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020
 - CARES Act, Section 3610
 - Defense Production Act
- FCA liability risks based on false statements, false certifications, fraudulent inducement, reverse false claims, conspiring, waiver issues, price gouging, kickbacks
 - Nexus to large amounts of funding channeled to states and localities dealing with the crisis

Coronavirus Preparedness and Response Supplemental Appropriations Act – March 6, 2020

- ~\$8 Billion in emergency funding to government agencies
- Biomedical Advanced Research and Development Authority (BARDA)
 - Approximately \$3+ Billion in R&D funding
 - Vaccines, therapeutics, diagnostics, rapidly deployable capabilities
 - Partnerships with ~29 companies (small, large) to date
 - Number of these partnerships include subcontracts
 - Emergency Use Authorizations

Research & Development Watchouts

- Government induced to provide funding based on false statements, promises or conduct
 - Probability of technical and regulatory success (PTRS)
- Misrepresenting results
- Falsifying data
- Directing funding to non-COVID related research or activities
- Not fully vetting subcontractors capabilities
- Misrepresenting sourcing (materials and ingredients) capabilities
- Non-compliance Buy America Act/Trade Agreement Act provisions
- EUA - Government induced to provide authorization

Section 3610 of CARES Act

- Agencies permitted to use any "funds made available to the agency" by Congress to reimburse contractors for workers' lost time from March 27 to September 30, if the contractor provides leave to its employees or subcontractors "to maintain a ready state, including to protect the life and safety of Government and contractor personnel"
- Agencies may modify contracts unilaterally or bilaterally to reimburse allowable paid leave costs, without securing additional consideration
- Provide reimbursement on any commercial or non-commercial contract with any contract type without invoking the need for terms and conditions associated with a reimbursable item
- Reimburse at contractor billing rates, which might include certain overhead costs in addition to labor, but shall not include profit or fees

Section 3610 Watchouts

- Misclassifying employees or subcontractor employees who could work remotely
- Labor rate mischarging
- Double-dipping and not acknowledging credits used from other programs (*e.g.*, PPP)
- Misrepresenting on agency certification requirements
- Not being clear on each agency's guidance and interpretation

Defense Production Act

- The Defense Production Act of 1950 (DPA), 50 USC § 4501, et seq., was enacted during the Korean War and gave the president authority to direct production in the private sector to support the war effort
- Allows the government to assign a priority rating to a contract and to direct companies operating in the private sector to meet government delivery requirements before addressing the requirements of a company's commercial customers – “Rated Orders”
- On March 18, President Trump issued an executive order authorizing use of the DPA to acquire “health and medical resources needed to respond to the spread of COVID-19”
- \$1 Billion reserved under CARES Act

DPA Watchouts

- Charging unjustifiably higher prices than similar unrated orders (i.e. charging higher prices to offset costs associated with unrated orders or to profit from the governments urgency)
 - PPE suppliers should ensure that costs are well documented
- Applying less favorable terms and conditions, such as warranty, discounting, or adjacent support
- Using lesser quality components without a corresponding price reduction
- Not acquiring needed production items in a timely manner to satisfy the delivery requirements and flow down rating to subcontractors
- Not meeting BAA or TAA sourcing requirements
- No PREP Act immunity

Best Practices

General Guidance For All Compliance Programs

- Two overarching goals of a compliance program:
 - **To detect and prevent fraud and misconduct;** and
 - **To ensure that fraud or misconduct gets reported and properly investigated and remediated.**
- Updated guidance issued by DOJ Criminal Division on June 1, 2020 (“Evaluation of Corporate Compliance Program”):
 - 1) Is the corporation’s compliance program well designed?
 - 2) Does the corporation’s compliance program work in practice?
 - 3) Is the program being applied earnestly and in good faith?
- In considering these questions, must ensure:
 - Full support and commitment from management and allocation of adequate resources
 - More than a “paper program”
 - Designed, implemented, and reviewed in an effective manner
 - Tailored to the needs and risks of the specific business
 - Periodic reassessment of business and risk profile and appropriate tailoring of program accordingly
 - Effective reporting system in place, including procedures for investigating and addressing reports of wrongdoing

Now is the Time to Reassess and Enhance Compliance Programs in View of COVID-19

- May 7, 2019 DOJ Guidance in FCA Cases:
 - DOJ's memo, titled "Guidelines for Taking Disclosure, Cooperation, and Remediation into Account in FCA Cases" provides that a company may be eligible for leniency if FCA investigation/claims ensue.
- Do Not Cut Corners:
 - Despite the ongoing pandemic, must be strict compliance with all legal, regulatory, and contractual obligations.
 - Remind employees of importance of maintaining ethical and compliant workplace; reiterate reporting obligations.
 - Offer training for employees on new obligations as a recipient of federal relief funds.
- Consult with Counsel:
 - Especially important for companies unaccustomed to doing business with the government to ensure understanding of governing statutes, regulations, contractual provisions, and program requirements.
- Stay Informed and Monitor Developments:
 - As federal and agency rules pertaining to the CARES Act continue to change, it is crucial to monitor relevant regulatory announcements and implement appropriate procedures to maintain compliance.
- Maintain Appropriate Documentation
 - When investigations and inquiries start to arise, critical to have documentary evidence of compliance.
- Develop a Crisis Response Plan:
 - Have a plan in place to respond to a government investigation or inquiry swiftly and effectively.

Practical Steps for Minimizing FCA Risks Arising from Relief Programs Providing Loans or Other Funding:

- Ensure thorough understanding of specific eligibility requirements, required certifications, other conditions, and obligations.
- Update compliance protocols to address specific risks related to applicable loan or funding program.
 - Develop and implement procedures for ascertaining and documenting eligibility and related certifications.
 - Develop and implement procedures to ensure that funds are used as required.
 - Develop and implement procedures for compliance with all ongoing reporting obligations.
 - Maintain clear and contemporaneous records.

Practical Steps for Minimizing FCA Risks Arising From Providing Goods/Services to or Funded by the Government:

- Understand and ask questions about express and applicable implied certifications.
- Ensure a full understanding of all applicable regulatory requirements:
 - Federal Acquisition Regulations (FAR) governs the purchase of goods and services by executive branch agencies and addresses, among other things: 48 CFR §52.211-15 (Defense priority and allocation requirements); 48 CFR §52.249-14 (Excusable delays); 48 CFR §52.249-8 (Fixed price supply and service)
 - The Defense Priorities and Allocations System (DPAS) governs sales under the DPA (codified at 15 CFR Part 700)
- Update protocols addressing risks:
 - Account for use of government contract funds.
 - Ensure all representations regarding the products are accurate and supportable.
 - Ensure accurate pricing, with documented support.
 - Promptly investigate any issues raised regarding product defects; make all required disclosures of findings.
 - Respond promptly and accurately to billing inquiries.
 - Evaluate and audit business partners and subcontractors.

Consider Whether to Self-Report if Wrongdoing is Discovered

- If you discover a potential FCA violation, consider the risks and benefits of self-reporting.
 - The FCA (31 U.S.C. § 3729(a)(2)) provides for double, rather than triple damages, where a company makes a disclosure within 30 days after the date the defendant obtained the information.
 - Disclosure must be made prior to the company's knowledge of an FCA investigation in order to receive the benefit of this provision.
- Self-reporting may entitle the individual or corporation to cooperation credit.
 - May 7, 2019 DOJ's Guidelines for Taking Disclosure, Cooperation, and Remediation into Account in FCA Cases (Justice Manual 4-4.112) provides that a company is eligible for cooperation credit if it makes a voluntary self-disclosure of information previously unknown to the government that could lead to FCA liability or administrative remedies.
- Prior to making any decision on self-reporting, consult with counsel.

Conclusion