The Coming Tsunami: Anticipated Regulatory and Enforcement Trends in the Wake of COVID-19 and the Unique Role of State Attorneys General

10 Min Read By: Miranda Hooker, Ashley L. Taylor, Jr., Ryan J. Strasser, Katherine E. Stark June 9, 2020

IN BRIEF

- Governmental investigations and enforcement actions have followed a familiar pattern when arising out of a public crisis.
- The forthcoming investigation and enforcement actions by the federal, state, and local governments relating to the governmental disbursement of trillions of dollars to the private sector in response to the COVID-19 crisis will create a tsunami, the likes of which the private sector has never seen.
- What measures can companies take to reduce the risk of, and defend against, regulatory inquiries?

Throughout the 20th and 21st centuries, every national crisis in the United States has left a long wake of investigations in its trail at all levels of government. Those governmental investigations and enforcement actions have followed a familiar pattern when arising out of a public crisis.

First, investigative and regulatory bodies at both the federal and state levels target the obvious scammers. In the context of the COVID-19 crisis, this includes obvious frauds such as selling snake oil as a panacea to COVID-19; selling fake tests to consumers and to states; and promising to deliver medical supplies to hospitals, receiving payment from the government, and then disappearing before ever delivering the goods. This "first wave" of enforcement actions generally takes priority among regulators because the conduct at issue directly impacts public safety. Indeed, the Office of the Inspector General (OIG) announced a "strategic plan" outlining the following four goals relating to the enforcement and protection of the Department of Health & Human Services' (HHS) COVID-19 response and recovery efforts: (1) protect people, (2) protect funds, (3) protect infrastructure, and (4) promote effectiveness of HHS programs—now and into the future.[1] Unsurprisingly, COVID-19's first wave has already begun.[2]

Once the first wave is well underway, the government shifts focus to its next target: the more reputable companies and businesses operating in a potentially "grey" area. Typically, the targets of these cases believe they complied with the law but have a genuine disagreement with the government about how a law, regulation, or contractual condition should apply or be interpreted. Although these cases are more resource-intensive, they correspondingly present an opportunity

for the government to recover larger amounts of money and generate bigger headlines. These cases constitute the "second wave" of enforcement; notably, most investigative and regulatory bodies follow this two-wave paradigm, whether it be the U.S. Department of Justice (DOJ), the state attorneys general, the Federal Trade Commission, the Consumer Financial Protection Bureau, or the most recent player, local governments.

In the context of the COVID-19 crisis, the second wave is coming, and when it hits, it will be a tsunami.

1. What the COVID-19 Tsunami Will Look Like

The second wave of the COVID-19 crisis is likely to be more extreme and long-lasting than ever before. The factors leading up to the second wave are unprecedented in our history—the federal government has disbursed trillions of dollars to the private sector with minimal federal oversight—and those factors create an environment that is ripe for downstream allegations of fraud. The federal government will have a groundswell of public support to exact retribution against those companies and individuals who took advantage of the public trust during the crisis. In parallel, state and local governments are starving for revenue as a result of severe budget shortfalls caused by COVID-19. As such, the need for funding will usher in an unparalleled era of state and local enforcement action, where states, led by state attorneys general, and localities will rely on lawsuits and investigations as a means of recapturing lost revenue for both consumers and the governmental entities more so than ever before.

A. The Federal Government's Disbursement of Funds

Whenever the federal government disburses funds to private actors, especially at alarming rates, an environment exists for fraud to flourish because those funds are typically disbursed with numerous conditions tied to them. Such conditions can take the form of details in the statute, regulations promulgated by agencies, or even less formal regulatory guidance. Yet, the risk that many companies accepting those funds run is the failure to comply, even inadvertently, with the "fine print," thus exposing them to claims of having wronged the government.

In such times, the federal government will turn to a familiar and favorite tool in its box: the Federal False Claims Act (FCA), 31 U.S.C. § 3729–3733. The FCA is no stranger to the healthcare, medical device, or pharmaceutical industries in that the DOJ has used it extensively for decades to successfully combat fraudulent claims for reimbursement submitted to Medicare, Medicaid, TRICARE, and other governmental payors, and to recover tens of billions of dollars in the process. The FCA is a particularly potent tool because it enables the federal government to recover not only treble damages, but also statutory penalties of $5,500 to $11,000 *per violation*. The crippling exposure that the FCA often generates, sometimes in the billions, is enough to strongarm most companies into lucrative settlements, even where those companies have highly meritorious defenses.

This tool is likely to be front and center in the investigations and enforcement space over the next five to ten years. In the first three months of the COVID-19 crisis, the federal government disbursed trillions of dollars to stimulate the economy to save small businesses and to facilitate the transfer of personal protective equipment (PPE), ventilators, testing, swabs, prescription drugs, and other medical supplies to states and localities. In an effort to contribute during the national crisis, numerous companies have answered the call to provide the necessary medical supplies that states and the nation required to save lives, accepting federal government dollars as payment for those services.

To the extent those companies did not fully comply with *all* of the terms and conditions of taking those funds, however, they face the very real risk of allegations of fraud or other impropriety by employee whistleblowers or the federal government. That risk is heightened by the speed at which these contracts were executed and funds received, where there often was insufficient time for a thorough review of the associated obligations by outside counsel or even in-house legal departments in some cases.

For these reasons, a spike in FCA investigations and lawsuits is likely coming. Indeed, the OIG has already stated its intentions to audit fund recipients in connection with its goal of protecting HHS funds.[3] Although no industry is immune, the healthcare, pharmaceutical, biotech, and medical supply industries are especially at risk; similarly, companies that participate in the manufacturing, distribution, and brokerage of medical equipment are likely to be hard hit. In the same vein, hospitals, long-term care facilities, testing labs, and nursing homes must be on high alert.

B. The State Response and the Role of State Attorneys General

States, meanwhile, are in dire straits as a result of budget shortfalls caused by COVID-19. The impact will likely continue to plague states for at least the next three to five years. The stay-at-home orders across the country have decreased sales tax revenue, delayed deadlines for filing state income tax returns and paying state income taxes due, and vastly reduced the use of public transportation and toll roads. At the same time, the federal government has largely required the states to assume the responsibility for procuring PPE, tests, ventilators, and other medical supplies at their own expense. Neither the CARES Act nor other federal legislation disbursing federal funds provided significant relief to the states in this regard.

Making matters worse, many states claim to be victims of fraud and contractual breaches at the hands of the private sector. The governor of Massachusetts, for example, claimedthat "millions of pieces of [medical] gear evaporate[d] in front of us" after confirmed orders with private vendors. Likewise, Maryland canceled a $12.5 million contract for PPE with a firm that allegedly failed to deliver masks and ventilators as promised. That matter has already been referred to Maryland's attorney general for review.

States, though, have more ability than ever to combat these two problems simultaneously. Most states have noticed the potency of the federal FCA and enacted state analogs to that statute over the past three decades; however, only recently have states started enforcing them aggressively.

That trend is likely to intensify because the state false claims acts empower states to recover treble damages and statutory penalties of approximately $5,500 to $12,000 dollars per violation against actors who defraud the state—a windfall in this era where states are desperate for dollars. Even some large localities, like Miami-Dade and Philadelphia, have tagged along and implemented analogous ordinances, and like their federal counterpart, the exposure generated by these state and local false claims acts often force companies to the settlement table, even where they have worthwhile legal defenses. Such settlements, even at the state or local level, are rarely cheap. Consequently, states and localities will have incentive to file claims under these statutes to pursue revenue windfalls that can help offset their budgetary gaps.

In addition, state attorneys general have ratcheted up enforcement actions in recent years. In addition to prosecuting cases under the state false claims acts, state attorneys general also have power to bring actions against companies that are reported for violations that harm consumers under state consumer protection acts. In light of the public harm that COVID-19 has inflicted, consumer protection act cases are likely to skyrocket in coming months. For these reasons, companies must look not only at the activity of DOJ and federal regulatory bodies, but also at enforcement trends and activity commencing at the state and local level.

Together, the forthcoming investigation and enforcement actions by the federal, state, and local governments will create a tsunami, the likes of which the private sector has never seen.

2. How Companies Can Prepare

There are several steps companies can take to reduce the risk of, and defend against, regulatory inquiries:

- Prioritize compliance programs and involve both the compliance department and in-house legal department in all aspects of decision-making during the COVID-19 crisis, including the decision to accept federal funds. Document in detail decisions that were made and the reasons for doing so.
- Carefully consider all aspects of accepting federal funds, including the statutory, regulatory, and contractual terms implicated by that acceptance. Closely scrutinize any submission to a government actor that could be construed as a misrepresentation or material omission.
- Ensure complete transparency when interacting with federal, state, and local government actors when a government contract or public funds are involved.
- Carefully think through the ethical or moral implications of decisions involving governmental funds or contracts. Dilemmas raising ethical or moral considerations are the type to generate media coverage and public interest when a company makes a controversial decision and are also the type that can catch the attention of regulators.
- Seek the outside advice of someone with expertise in this area of the law when confronting novel or thorny issues that implicate the federal, state, or local government.
- Monitor settlements and enforcement actions because they will provide visibility into ongoing regulatory trends.

[1] *See* OIG Strategic Plan: Oversight of COVID-19 Response and Recovery (May 2020), at 2.

[2] *See, e.g.,* United States v. Purity Health & Wellness Ctrs., Inc., No. 3:20-cv-00985-L (N.D. Tex. filed Apr. 22, 2020) (seeking injunctive relief of alleged scheme to defraud where defendants purportedly sold "ozone therapy" as a preventative and cure to COVID-19); DOJ Press Releases, *Georgia Man Arrested for Orchestrating Scheme to Defraud Health Care Benefit Programs Related to COVID-19 and Genetic Cancer Testing* (Mar. 30, 2020) (defendant allegedly conspired to be paid kickbacks on a per-test basis for COVID-19 tests bundled with more expensive respiratory tests incapable of diagnosing and treating COVID-19); *Georgia Woman Arrested for Role in Scheme to Defraud Health Care Benefit Programs Related to Cancer Genetic Testing and COVID-19 Testing* (May 15, 2020) (defendant allegedly sought to pay and receive illegal kickbacks in exchange for referring Medicare beneficiaries for COVID-19 tests); *New Jersey Man Arrested For $45 Million Scheme to Defraud and Price Gouge New York City During COVID-19 Pandemic* (May 26, 2020) (alleging used-car salesman lied about his authority to sell large quantities of PPE to New York City at grossly inflated prices).

[3] *See* OIG Strategic Plan: Oversight of COVID-19 Response and Recovery (May 2020), at 3.

ABOUT THE AUTHORS

Miranda Hooker

Miranda Hooker is a partner at Pepper Hamilton LLP in Boston. A former…

+ Follow

Ashley L. Taylor, Jr.

Ashley L. Taylor, Jr. is a partner at Troutman Sanders…

+ Follow

Ryan J. Strasser

Ryan J. Strasser is an associate at Troutman Sanders in…

+ Follow

Katherine E. Stark

Katherine E. Stark is an associate at Pepper Hamilton in Boston.…

+ Follow