Dealing With Prior DOJ Health Investigations During COVID-19

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PROFESSIONAL

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What do these recent news items from the U.S. Department of Justice have in common?

- Indivior Solutions pleaded guilty to felony charge and Indivior entities agreed to pay $600 million to resolve criminal and civil investigations as part of DOJ's largest opioid resolution.
- Universal Health Services Inc. and related entities agreed to pay $122 million to settle False Claims Act allegations relating to medically unnecessary inpatient behavioral health services and illegal kickbacks.
- Oklahoma City Hospital, Management Company and Physician Group agreed to pay $72.3 million to settle federal and state False Claims Act allegations arising from improper payments to referring physicians.
- Novartis Pharmaceuticals Corp. paid over $642 million to settle allegations of improper payments to patients and physicians.

Two things. First, these are all major health care-related enforcement actions reported this summer. Second, they have nothing to do with COVID-19.

For the last several months, commentators have breathlessly followed federal enforcement efforts related to the coronavirus pandemic. Servers are overloaded with Zoom webinars scrutinizing DOJ prosecutions concerning personal protective equipment hoarding and fraudulent Paycheck Protection Act loan applications.

Yet even while the DOJ attacks this recent strain of fraud, the agency has recently announced important resolutions in preexisting health care fraud investigations involving familiar theories such as kickbacks, overbilling and Stark Law violations. The cases cited above represent just four of hundreds of open DOJ health care investigations nationwide.

The resolutions are an unwelcome reminder to providers who are besieged by COVID-19 challenges that preexisting cases have not gone away — even if an investigation has been quiet of late. These investigations cannot be ignored, and, in fact, providers may have opportunities in the current environment to resolve preexisting investigations and enforcement actions on favorable terms, allowing them to focus their resources on treating patients and shoring up compliance activities.

COVID-19 Enforcement Efforts

To be sure, combating coronavirus-related fraud is a top priority at the DOJ. Shortly after the virus took root in the U.S., the DOJ began investigating brazen pandemic-related fraud schemes. Indeed, the first DOJ enforcement action related to the virus targeted the operators of a website, coronavirusmedicalkit.com, that purported to offer access to a World Health Organization vaccine kit in exchange for a shipping charge of $4.95 — secured by a customer's credit card.

A federal judge in Austin, Texas, granted the DOJ's temporary restraining order blocking public access to the website. [1] This prosecution was emblematic of preliminary federal enforcement efforts, embodied in a new DOJ task force charged with investigating market manipulation, hoarding and price gouging associated with COVID-19.

Later in the spring, Congress passed the Coronavirus Aid, Relief, and Economic Security, or CARES, Act, which included the Paycheck Protection Program. The PPP provided small businesses with forgivable loans to cover up to eight weeks of payroll expenses. Administered by the Small Business Administration, through Aug. 8, the PPP more than 5.2 million loans worth more than $525 billion, with an average loan of $101,000. [2]

This was a massive government program, administered at lightning speed. To no one's surprise, shortly after the PPP's launch, the DOJ began investigating individuals who obtained PPP loans under false pretenses, and to date the government has charged dozens of individuals with wire fraud for defrauding the SBA. [3]

The CARES Act also created the Provider Relief Fund, or PRF, a $175 billion program designed to assist hospitals and health care workers on the front lines of the pandemic. [4] Beginning in April, the U.S. Department of Health and Human Services began distributing payments from the PRF to hospitals, skilled nursing facilities and other health care facilities.

All applicants for PRF payments must complete an attestation that they meet the terms and conditions of the fund. The primary condition is that providers agree that PRF payments "will only be used to prevent, prepare for, and respond to coronavirus" and will only offset "health care related expenses or lost revenues that are attributable to coronavirus." [5]

Providers agree to maintain appropriate records and cost documentation for at least three years. The terms and conditions have not been a model of clarity, shifting frequently over the summer and health care lawyers have speculated that the PRF will spawn a wave of investigations. Unlike the PPP, where patently fraudulent loan applications may be readily identifiable, PRF enforcement activity has not yet materialized and will likely take longer to develop, as the HHS Office of Inspector General scrutinizes if providers are using PRF payments consistent with program requirements.

The Impact of COVID-19 on Health Care Investigations

When the pandemic hit, many health care investigations came to a screeching halt. The nuts and bolts of a typical investigation — search warrants, interviews, hearings and trials — simply could not be conducted while the virus is raging, particularly with courts closed, grand juries not sitting, and millions of Americans working from home.

As spring turned to summer, prosecutors, agents and defense lawyers became accustomed to video interviews and communicating remotely, but the investigative pace was decidedly slower.

Apart from logistical challenges, two important facets of the pandemic resulted in the slowdown of preexisting investigations: (1) health care prosecutors and agents were faced with new, pressing demands to investigate COVID-19 fraud, as described above, and (2) many providers simply did not have the bandwidth to respond to investigative requests, dedicating every available resource to treating patients struck with the virus. Many investigations and cases were simply paused.

And yet — these cases have not gone away. They never go away.

For years, the DOJ has aggressively investigated health care fraud. Last year, the DOJ returned more than $3.6 billion to the federal government in health care fraud judgements and settlements, opened more than 2,100 new criminal and civil health care fraud investigations, filed criminal charges in 485 cases, and secured convictions against 528 defendants in health care cases — all while the HHS OIG excluded 2,640 individuals and entities from participating in health care programs. [6]

The DOJ has had a steady diet of cases against pharmaceutical companies, hospitals, skilled nursing facilities, laboratories, physicians and other health care providers for many years.

The recently disclosed settlements continue this trend. In the Indivor PLC case, the manufacturer of Suboxone, the opioid addiction treatment medication, pleaded guilty to a felony and agreed to pay $600 million to resolve allegations that it made false statements to the Massachusetts Medicaid program regarding accidental pediatric exposure to Suboxone Film.

Previously, Indivor's former CEO pleaded guilty in connection with these allegations, and Indivor's former parent, Reckitt Benckiser Group PLC, paid $1.4 billion to resolve criminal and civil allegations regarding the marketing of Suboxone. [7]

In the Universal Health Services Inc. case, the owner of almost 200 psychiatric and behavior treatment facilities agreed to pay $122 million to resolve a sprawling False Claims Act investigation involving allegations that UHS admitted patients who were not eligible for psychiatric treatment and billed for services not rendered, while at the same time failed to provide adequate staffing and training and services for patients who needed care. [8]

In the Oklahoma matter, an orthopedic specialty hospital, its part-owner and management company paid $72.3 million to resolve FCA, Stark Law and Anti-Kickback Statute allegations; the government alleged that the hospital provided free or below-market office space, employees and supplies to physicians who referred the most patients to the hospital — in addition to paying excessive compensation and granting equity shares in the hospital to these physicians. [9]

And in the Novartis investigation, the pharmaceutical company agreed to pay $642 million to resolve two FCA/AKS investigations where the government alleged that Novartis caused charitable foundations to offset patient copayments for expensive drugs, in addition to paying speaker fees to physicians to induce referrals of numerous drugs. [10]

Each case was resolved this summer. While most commentators were focusing on the federal coronavirus fraud response, the DOJ quietly announced these substantial settlements, each involving the kind of allegations — overbilling, kickbacks, Stark Law violations — that the agency has pursued regularly in health care cases for many years.

Handling Your Preexisting Investigation in the Current Climate

Clearly, then, the DOJ has not abandoned its preexisting investigations. Yet, for many overworked in-house health care lawyers, the last thing they want to deal with right now is another document production to the government in a pre-COVID-19 investigation. How should health care providers manage preexisting investigations and think about compliance in a post-COVID-19 world?

First, prosecutors must recognize — most do — that health care providers are facing unprecedented financial challenges. Providers have deferred elective treatments and many patients are postponing care altogether while the virus rages — while providers incur staggering costs to procure equipment and supplies to treat infected patients.

Through June 30, the American Hospital Association estimated that hospitals and health systems lost more than $202 billion during the first four months of the pandemic. [11] This financial crunch impacts preexisting investigations in several ways.

Providers may be more reluctant to incur costly investigative expenses, compliance personnel find themselves asked to do more with fewer resources, and targets of investigations may simply not be able to satisfy the financial demands that the government expects to resolve a case.

In light of these unprecedented circumstances, providers have a few options.

Hit the pause button.

For providers that are truly overwhelmed, preparing for trial or even participating in a government investigation is impossible or impractical. For those providers, a stay of the investigation or litigation is appropriate. In my experience, prosecutors and judges are sympathetic to pandemic-related stay requests.

Indeed, a stay of proceedings is often necessary, as many courts remain closed or are just beginning to reopen. For docketed cases, a stay request must be memorialized in a motion, identifying specific factors, ideally supported by an affidavit.

For instance, in the Varsity Blues prosecution in Boston, the court recently allowed a joint motion to continue the first trial, initially scheduled for October, to February, citing the difficulties inherent in preparing for, and holding, a trial of this magnitude in the middle of the pandemic.[12]

For investigations, a request to stay activities — interviews, subpoena/CID responses, etc. — can be made informally with the assistant U.S. attorney. However, the government may request a tolling agreement in exchange for their agreement to pause proceedings.

Resolve the case on favorable terms.

While providers cannot ignore pre-pandemic investigations, there is no question that the terrain has changed. The world has been turned upside down. COVID-19 has touched all aspects of our lives — and federal health care enforcement is no exception. Prosecutors and agents are stretched thin, focusing a substantial portion of their time on pandemic-related crime.

A prosecutor may view a legacy investigation about a technical regulatory dispute differently in light of a pressing report from an agent about a phony coronavirus treatment scam. Meanwhile, in long-running investigations, False Claims Act seal deadlines may be drawing closer, and it is unclear when in-person investigative activities can resume.

In short, a prosecutor may be open to resolving a preexisting case on more reasonable terms today than previously. This could be an attractive option for providers who want to resolve an old investigation. It may go against the instincts of providers — and certainly defense counsel — to resolve a case before all facts have been developed and all legal challenges explored.

But the benefits of a favorable resolution — a manageable payment, certainty and freeing up resources to focus on treating patients, all while avoiding costly investigative expenses — likely outweighs the risks, and providers should consider proactively contacting prosecutors to initiate settlement negotiations for pre-pandemic investigations.

Providers in difficult financial straits who are nevertheless motivated to resolve an investigation should consult the DOJ's ability-to-pay guidelines. The DOJ recently issued updated guidance for financially distressed providers who are prepared to resolve an investigation but are unable to pay a criminal fine; similar principles likely apply for civil resolutions as well.[13]

Do nothing.

Another option is to simply wait it out. Health care investigations always take a long time to complete, and time is usually on the provider's side. If no deadlines exist (i.e., the investigation is prelitigation and there is no subpoena-related deadline pending), and the target simply has not heard from the government in a while, it is perfectly acceptable to let sleeping dogs lie.

Particularly where the government has not requested a tolling agreement, the provider may be able to run out the clock while the government is focusing on more pressing, pandemic-related priorities. The risk of this approach is that if (really, when) it dawns on the government that the statute is about to run, there will likely be a flurry of activity, the government may choose to charge the case/bring the lawsuit rather than let it go, and the opportunity for a favorable resolution may be lost.

Don't skimp on compliance.

Finally, whichever path is chosen, now is not the time to skimp on traditional compliance activities. Without question, new coronavirus compliance priorities have materialized: PRF and PPP attestations must be made, government payments must be tracked, and new regulations and waivers must be followed.

But, as the recent settlements demonstrate, the government continues to cash in on traditional health care fraud investigations. Thus, even as providers navigate new fraud and abuse challenges brought by the pandemic, they must

continue to track arrangements, audit high-risk billing activities, and conduct all other traditional compliance functions to keep the government and qui tam relators at bay.

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[1] See https://www.justice.gov/opa/pr/justice-department-files-its-first-enforcement-action-against-covid-19-fraud.

[2] See https://home.treasury.gov/system/files/136/SBA-Paycheck-Protection-Program-Loan-Report-Round2.pdf.

[3] See, e.g., https://www.justice.gov/opa/pr/texas-man-charged-5-million-covid-relief-fraud; https://www.justice.gov/opa/pr/hollywood-film-producer-charged-17-million-covid-relief-fraud; https://www.justice.gov/usao-sdny/pr/acting-manhattan-us-attorney-announces-charges-7-million-scheme-defraud-loan-programs.

[4] See https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html.

[5] See https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-20-b.pdf.

[6] See https://oig.hhs.gov/publications/docs/hcfac/FY2019-hcfac.pdf.

[7] See https://www.justice.gov/opa/pr/indivior-solutions-pleads-guilty-felony-charge-and-indivior-entities-agree-pay-600-million.

[8] See https://www.justice.gov/opa/pr/universal-health-services-inc-and-related-entities-pay-122-million-settle-false-claims-act.

[9] See https://www.justice.gov/opa/pr/oklahoma-city-hospital-management-company-and-physician-group-pay-723-million-settle-federal.

[10] See https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians.

[11] See https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due.

[12] See *U.S. v. Sidoo, et al.*, 19-cr-10080-NMG, ECF No. 1454 (Aug. 6, 2020).

[13] See https://www.justice.gov/opa/speech/file/1207576/download.

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