Enforcement Risks For COVID Labs To Identify And Avoid

By **Ashwin Ram, Nicholas Silverman and Caitlin Conroy** (March 2, 2022)

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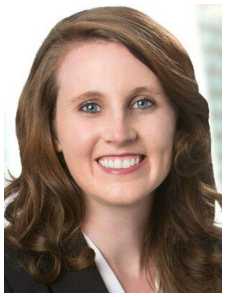

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COVID-19 upended segments of the U.S. economy, while, at the same time, contributing to significant growth for various industries.

Overnight, offices were forced to learn how to collaborate remotely, restaurants were tasked with redefining their product, and health care providers were challenged to develop resources to treat COVID-19 and adjust to an overburdened health care system.

This article sketches the landscape of the COVID-19 diagnostic testing industry, identifies potential enforcement threats and provides high-level guidance to industry professionals.

The COVID-19 Testing Landscape

Rapid Expansion of Diagnostic Testing

Testing is an important part of the effort to reduce the spread of COVID-19. The U.S. Centers for Disease Control and Prevention reports that over 800 million tests have been administered.[1] Over 29,000 diagnostic and medical laboratory businesses in the U.S. support this massive testing effort.

Many long-standing labs have pivoted to fill the unprecedented need for efficient COVID-19 testing. For example, Aegis Sciences Corp. — a three-decade old firm — launched its COVID-19 testing program in April 2020 and has already performed over 11 million COVID-19 tests.

Other laboratories more closely resemble startup companies. For example, at the onset of the pandemic, a startup called Color Health Inc. immediately set up a COVID-19 laboratory. According to Fortune magazine, Color Health now has more than 6,500 testing sites, a glowing reputation and is valued at $4.6 billion.

Not all startups have been as successful at building a good reputation. The Illinois-based Center for COVID Control made recent headlines because of compliance concerns and investigations. The Center for COVID Control is run by a suburban Chicago couple, who ran ax-throwing lounges and photographed weddings before they decided to buy a lab after COVID-19 hit.

Their lab received over $150 million in reimbursements before they were sued by several states, and they are reportedly under both state and federal investigations for an array of issues including alleged reimbursement fraud, objectionable promotional materials and failure to adhere to licensing obligations.

Most startups have not been quite so prolific. However, the rapid expansion of testing and the financial success of diagnostic laboratories, made possible in large part by government funding, and the limited number of investigations announced to date all but guarantee that the COVID-19 diagnostic laboratory industry will soon be under intense scrutiny from

regulators and potentially even prosecutors.

Reimbursement

COVID-19 diagnostic tests are virtually guaranteed reimbursement as long as they are medically necessary.

In the private insurance industry, that guarantee comes from the Families First Coronavirus Response Act Section 6001, as amended by Section 3202(a) of the Coronavirus Aid, Relief and Economic Security Act, which requires that health insurers cover approved forms of COVID-19 testing at no cost to patients, and that the insurers reimburse labs at a negotiated rate, or in the absence of an agreement, the cash price posted on the lab's website.[2]

For those who are uninsured, Medicaid and the Health Resources and Services Administration each offer coverage for COVID-19 diagnostic tests.

One important limitation on guaranteed reimbursement is that the testing must be diagnostic to qualify for guaranteed reimbursement. Reimbursement is therefore not required for the general screening that some workplaces require or for other routine testing.

The Centers for Medicare & Medicaid Services has published guidance regarding what testing it considers to be diagnostic and has emphasized that testing conducted to screen for general workplace health and safety (such as employee "return to work" programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA.[3]

Health insurance plans are not required to cover nondiagnostic tests without cost-sharing.

The guaranteed reimbursement of COVID-19 diagnostic tests has led to concerns from CMS and insurers that a minority of labs will engage in price-gouging, namely, the setting of cash prices that are completely divorced from the costs associated with the testing.

In addition to government agencies asking for comments on what they can do to stop price-gouging,[4] the private industry has attempted to wade into the fold. In October 2021, Premera Blue Cross sued GS Labs LLC alleging that the lab was unlawfully charging $385 for COVID-19 PCR test processing.[5]

Price-gouging often attracts negative publicity and potential enforcement activity. Given the requirements to post COVID-19 testing prices publicly, laboratories would be wise to avoid excessive or unjustifiable prices that could draw the attention of regulators, media and public advocates.

Enforcement Threats

Diagnostic laboratories sit at the intersection of health, privacy and public welfare. It is therefore unsurprising that they are subject to a confusing array of regulatory regimes at both the federal and state levels.

These include the federal Clinical Laboratory Improvement Amendments, or CLIA, licensing regime, which establishes lab standards for accuracy, reliability and timeliness of test results, as well as the applicable state requirements where laboratories do business.

The U.S. Food and Drug Administration, the Centers for Disease Control and Prevention, and CMS each have unique roles in ensuring quality laboratory practices under CLIA.

CMS specifically is responsible for enforcing CLIA and its implementing regulations, and has broad authority to impose sanctions, including suspending or revoking the certificates of noncompliant laboratories, and imposing civil monetary penalties.[6] Any person who intentionally violates CLIA requirements could also be subject to criminal penalties, including fines or imprisonment.[7]

Failing to adhere to federal and state regulations can lead to an array of potential administrative, civil and criminal enforcement risks. Key risks to consider include:

False Claims and False Statements

Fraudulent claims and false statements or misrepresentations in connection with an application for health care payments for laboratory testing are subject to potential civil liability under the False Claims Act[8] and potential criminal liability under the criminal False Claims Act,[9] the prohibition on false statements relating to health care matters,[10] and the false statement amendment.[11]

The FCA is particularly important because it contains a qui tam provision incentivizing employees and others to come forward as whistleblowers with allegations that a laboratory is defrauding the federal government.

Although the FCA applies to many industries that seek reimbursement from the federal government, a record 90% of federal government FCA recoveries came from the health care sector in 2021. To the extent any misrepresentations are made to the government, the False Statements Accountability Act of 1996[12] may also apply.

Fraud

Federal law makes it a crime to commit fraud in connection with the delivery of health care services or payment for health care benefits.[13]

Depending on the circumstances, such fraud could also be prosecuted under the mail and wire fraud statutes,[14] the conspiracy statutes[15] and Title 18 of the U.S. Code, Section 669, which prohibits embezzling, stealing or converting money from a health care benefit program without the rightful owner's authority.

Kickbacks and Referrals

The payment, receipt, offer or request of kickbacks or bribes in exchange for using or recommending any laboratory testing service are subject to potential criminal liability under the Anti-Kickback Statute.[16]

Moreover, a violation of the Anti-Kickback Statute can lead to derivative liability for consequent claims for payment under the theory that the claim assured the payor that no kickback was paid. The Stark Amendments[17] impose additional civil liability on referrals to laboratories in which the referring physician or their family members have a financial relationship.

The Eliminating Kickbacks in Recovery Act of 2018 was passed as part of the Substance

Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act.

EKRA's provisions reach far beyond substance abuse, and add an independent prohibition on the solicitation, receipt, payment or offer of "any remuneration" — even noncash, in-kind benefits — if that remuneration is directly or indirectly used to induce a referral to a laboratory or in exchange for a person using a laboratory.[18]

No nexus to federal funds or substance abuse is required. Instead, EKRA applies to all insurance payors and all laboratories. EKRA increases the coverage of the Anti-Kickback Statute's prohibitions, in part, by limiting the safe harbors in the Anti-Kickback Statute.

For example, while the Anti-Kickback Statute permits sales and marketing employees to be compensated through commissions, EKRA prohibits basing an employee's pay on the volume of referrals they generate.

Obstruction

Obstruction of investigations into the above offenses may result in liability under Title 18 of the U.S. Code, Section 1518, which prohibits obstruction of criminal investigations of health care offenses.

Price-Gouging

Allegations of price-gouging attract significant attention, and both federal and state governments are likely to utilize a variety of statutes to pursue price-gouging — even where the conduct was undertaken without wrongful intent.

These statutes include state-level prohibitions on price-gouging, federal prohibitions on anti-competitive activities and potential administrative oversight from federal agencies.

Indeed, last month, senators urged the Federal Trade Commission to pursue fraud and price-gouging in the COVID-19 testing market. Sen. Richard Blumenthal, D-Conn., suggested that the FTC could pursue administrative remedies and refer criminal acts to the U.S. Department of Justice. The FTC has statutory power to bring administrative cases against companies for unfair or deceptive practices, which can result in substantial fines.

The media has generated a consistent stream of articles about the profitability of COVID-19 testing. The focus on profitability guarantees that civil and criminal enforcement agencies will pay close attention.

In addition to the GS Labs and Center for COVID Control reports described above, the New York Times reports that attorneys general in New Mexico, New York, Massachusetts, Oregon, Florida, Minnesota, California, Illinois, Colorado and Washington have all shut down or sued testing sites in recent weeks.

We expect that many more laboratories will face similar complaints and investigations in the coming months and years. In addition to potential criminal investigations, we will likely see whistleblower lawsuits, investigations by various health care agencies, and investigations by consumer protection organizations both inside and outside the government.

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[1] https://covid.cdc.gov/covid-data-tracker/#cases_totaltests.

[2] CARES Act § 3202(a).

[3] https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf.

[4] See 85 Fed. Reg. 71153 (CMS request for comment).

[5] Compl., Premera Blue Cross v. GS Labs, LLC, No. 21-cv-1399, Dkt. 1 (W.D. Wash. Oct. 14, 2021).

[6] 42 CFR § 493.1800 et seq.

[7] See 42 CFR § 493.1800(a)(3).

[8] 31 U.S.C. § 3729.

[9] 18 U.S.C. § 287.

[10] 18 U.S.C. § 1035.

[11] 42 U.S.C. § 1320a-7b(a).

[12] 18 U.S.C. § 1001.

[13] 18 U.S.C. § 1347.

[14] 18 U.S.C. §§ 1341, 1343.

[15] 18 U.S.C. §§ 371, 1349.

[16] 42 U.S.C. § 1320a-7b(b).

[17] 42 U.S.C. § 1395nn.

[18] 18 U.S.C. § 220.