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COVID-19 Testing Fraud Enforcement Initiatives and Other Legal Developments

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New Fraud Initiatives and Enforcement Landscape: Laboratories should be aware that law enforcement authorities and no longer turning a blind eye to improper practices that may have been under investigation or tolerated during the height of the pandemic as many rules were relaxed to facilitate a quick roll of testing. The U.S. Department of Health and Human Services Office of Inspector General ("OIG"), Federal Bureau of Investigation ("FBI"), Food and Drug Administration ("FDA"), and other federal and state authorities have increased their efforts to prosecute fraudulent COVID-19 pandemic laboratory testing practices during the pandemic. "It's clear fraudsters see the COVID-19 pandemic as a money-making opportunity – creating fraudulent schemes to victimize beneficiaries and steal from federal healthcare programs," said Deputy Inspector General for Investigations Gary L. Cantrell of the OIG.

Federal and state agencies are working in tandem to identify these fraudulent practices in an effort to prosecute perpetrator labs on a federal level, threatening severe penalties for labs accused of defrauding consumers and government agencies. On May 26, 2021, the Department of Justice announced criminal charges against 14 defendants charged in seven federal districts across the U.S. for alleged exploitation of the COVID-19 pandemic and involvement in healthcare fraud.

State legislators and enforcement authorities are also seeking to clamp down on laboratory practices that they deem to be non-compliant or abusive. For example, on December 24, 2021, New York State Senator Zellnor Myrie introduced the COVID-19 Fraud Accountability Act, stating that as demand for PCR and at-home rapid COVID tests has reached an all-time high, "bad actors" have exploited the high demand for testing "to seek ill-gotten profit from New Yorkers." The legislation seeks to increase penalties for white-collar crimes and define "fraud in connection with an abnormal disruption of the market" in the New York General Business Law.

Agencies are warning the public to remain alert for fraudulent testing schemes used to capitalize on the pandemic. These include the sale of unauthorized tests, collecting payment for testing kits not delivered or tested, making false statements about a tests' reliability, and using personal details such as Medicare information and saliva or blood samples to submit fraudulent claims for unrelated, medically unnecessary, and more expensive laboratory tests.

No Surprises Act: Clinical laboratories also face substantial new operational and compliance hurdles with the passing of the federal "No Surprises Act" (NSA"). The NSA became effective on January 1, 2022, with the goal of increasing price transparency for consumers. Laboratory compliance with the NSA requires an in-depth understanding of the new law as well as greater communication among laboratories, providers, facilities, and healthcare insurers before bills for laboratory services are submitted. You can read more about the NSA and its impact on clinical laboratories at: https://www.bpslaw.com/how-medical-testing-laboratories-must-comply-with-the-federal-ban-on-surpirse-billing/.