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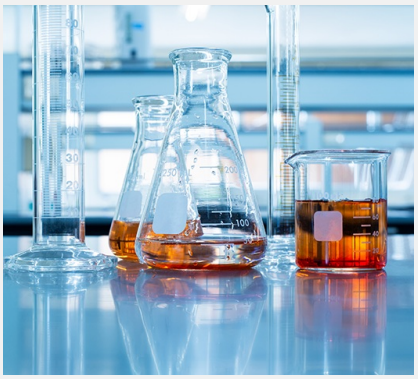
Clinical ColLABorative

Legal Insights in Laboratory Compliance



What To Do When The Government Knocks On Your Lab's Door

The volume of federal enforcement actions involving laboratories has increased dramatically over the last few years. Not a month seems to pass without a press release from the United States Department of Justice (DOJ) trumpeting a conviction of, or multi-million-dollar settlement with, a lab, lab owners, or lab personnel. In late April, for example, the DOJ announced a nationwide coordinated effort aimed at COVID-19 testing fraud, which encompassed target labs in California, New York, Florida, Maryland, and other states, and resulted in criminal charges against 21 defendants across nine federal districts [You can read the DOJ's Press Release at this link]. While the government certainly has invested significant resources in pursuing pandemic-related issues, the scope of enforcement in the lab space is far broader in regard to COVID-19 issues.

The potential consequences of an enforcement action mean that few events are more disruptive to a laboratory than a knock on the door from federal or state government investigators. The "knock" is really an attempt by the government to obtain information and documents, and there are three methods typically used:

- Informal Requests,
- Subpoenas or Civil Investigative Demands (CID), and
- Search Warrants.

Although the first two methods do not create the same public spectacle as the execution of a search warrant, all three should be treated with equal seriousness and care, as each may signal the start of a lengthy legal ordeal. Oftentimes, how the lab responds initially could alter the course of events to follow, for better or worse.

Read full article for a detailed discussion of time-tested practices for responding to each of these three methods of law enforcement inquiry.

Compliance Reminders Associated with Price Transparency for COVID–19 Diagnostic Tests

As the pandemic continues, government enforcement has seemingly recently caught up, and various government agencies are focusing on COVID-19 fraud, waste and abuse, and violations of the myriad rules. Earlier this year, the Federal Trade Commission (FTC) testified before a Senate subcommittee that the agency would be taking aggressive steps to police violations of the rules and regulations related to the COVID-19 crisis. Price gouging, telemarketing, and robocalls have all been identified as concerns that will be enforced by the FTC or referred to

Data Integrity and Cybersecurity for Labs: How to Think about Privacy and Security

If you run a laboratory, you think about risk every day. From what materials to lock up at night, to ensuring availability of reagents and supplies to run the tests, every choice you make is a balancing act between safety, cost, usability, regulatory compliance, and countless other considerations. These tradeoffs apply to your data, too.

Laboratories collect lots of sensitive data. Besides employee and payroll information that every business manages, labs rely on the integrity of their test results. Questions about

other government agencies. As more and more focus is bearing down on COVID-19 and laboratories, it is important to take a breath and review regulations that are impacting your laboratory. One such rule that should garner another look is the requirement to publicly post a laboratory's cash price. *Read full article*

data integrity arising from a security breach could throw cold water on relationships with customers, cause reputational harm, and lead to costly penalties. Labs are at risk for corporate cyber-espionage, ransomware, and other high-profile cyber security attacks. *Read full article*

Compliance Check: Time to Review Clinical Laboratory and Hospital Relationships

Clinical laboratories and hospitals may wish to consider conducting a careful review of their existing arrangements in light of the government's continued focus on kickbacks. Although the U.S. Department of Health and Human Services (HHS) last issued a Special Fraud Alert warning against kickbacks for laboratory referrals in 2014, there are new headlines in this area that laboratories and hospitals should be aware of. The U.S. Department of Justice (DOJ) recently filed a False Claims Act complaint against individual CEOs of laboratories and a hospital, as well as other individuals, alleging violations based on patient referrals in contravention of the Anti-Kickback Statute and Stark Law, despite previously holding at least one of the clinical laboratories responsible in a prior settlement under the False Claims Act. In addition, HHS-OIG (Office of the Inspector General) posted Advisory Opinion No. 22-09 on April 28, 2022, that addressed a proposed arrangement pursuant to which a network of clinical laboratories contracts with and compensates hospitals to perform certain specimen-collection services related to testing. HHS-OIG concluded that the proposed arrangement presents a risk of fraud and abuse under the Anti-Kickback Statute. *Read full article*

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