STRATEGIC MANAGEMENT SERVICES

DOJ Continues Its Crackdown on Clinical Laboratory Fraud

Key Points:

- **Administrative action taken against 53 other providers**
- **Clinical laboratory fraud is in the cross hairs of enforcement agencies**
- **Common schemes noted and compliance advice for labs**
- **Challenges in investigating laboratory fraud schemes**

As part of a nationwide coordinated law enforcement action, the Department of Justice (DOJ) brought charges against 36 defendants for more than $1.2 billion in fraud, resulting from phony telehealth claims for advanced genetic testing and unnecessary DME. Among the defendants are a telemedicine company executive, owners and executives of clinical laboratories, DME companies, marketing organizations, and medical professionals.

DOJ also announced that separately, the Centers for Medicare and Medicaid Services, Center for Program Integrity, took administrative action against another 52 providers involved in similar schemes. More than "$8 million in cash, luxury vehicles, and other fraud proceeds" were seized.

The DOJ stated that its investigation "primarily targeted alleged schemes involving the payment of illegal kickbacks and bribes by laboratory owners and operators in exchange for the referral of patients by medical professionals working with fraudulent telemedicine and digital medical technology companies." One particular case was highlighted in which an operator of several clinical laboratories offered $16 million in kickbacks to telemedicine companies, call centers and doctors for genetic testing orders that were not medically necessary. In this case, DOJ is seeking "forfeiture of over $7 million in United States currency, three properties, the yacht, and a Tesla and other vehicles."

In another enforcement action involving clinical laboratories, Inform Diagnostics, Inc., (Inform), recently purchased by Fulgent Genetics, entered into a $16 million settlement to resolve

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allegations that it submitted false claims for payment to Medicare and other federal health care programs for medically unnecessary tests. The settlement involved a five-year period during which Inform routinely and automatically conducted additional tests on biopsy specimens before a pathologist's review and without an individualized determination regarding medical necessity. This strategy resulted in performing many tests that were not medically necessary.

These latest DOJ actions follow a series of government actions focusing on clinical laboratory and telehealth fraud that increased during the COVID Pandemic. Fraudsters have taken advantage of the increased funding and liberalization of regulations designed to protect the public against the disease. Laboratory testing globally has exploded since COVID-19 to over $200 billion a year in response to the need for sophisticated clinical tests to properly address patient conditions. Many have taken advantage of the weakened controls to engage in lucrative fraudulent practices. Among the most common types of laboratory fraud are: (1) unnecessary testing, (2) unauthorized testing, (3) unbundling tests, (4) kickbacks and bribes for referrals of business, (5) unlicensed testing, and (6) tests by unqualified persons.

Investigations of laboratories are complicated by several factors, including:

1. Laboratory services are provided in various settings and from a variety of providers, making the detection of irregularities more challenging;
2. Understanding the variety and complexities of lab testing requires in-depth knowledge to determine if specific tests should be performed and the quality of the results;
3. Tests recently approved for payment may be abused or fraudulently billed before payers are aware of their full billing implications;
4. The relationship between providers and laboratories is not evident merely from analyzing claims payments.

With the heightened scrutiny for fraud and abuse in this sector, it is well advisable for clinical laboratories to take measures to ensure they have an effective compliance program designed to reduce errors, especially patterned errors, and wrongdoing. This includes a compliance structure that is more than a paper program (e.g., code of conduct, policies, etc.). It must include effective ongoing monitoring and auditing to reduce the likelihood of errors and wrongful activity. If confronted by the DOJ, one of the first steps in their assessment of enforcement actions will be to ask questions to determine whether the wrongdoing encountered was by a rogue individual or as a result of the lack of a "compliance culture" that permitted or encouraged improper actions to take place. This determination will not only affect the level of actions taken against the laboratory but also its leadership.

In response to the heightened scrutiny over telehealth, the Department of Health and Human Services Office of Inspector General also released a Special Fraud Alert warning providers to "exercise caution when entering into arrangements with purported telemedicine companies." The alert includes "suspect characteristics" to help providers "identify potentially suspect arrangements with Telemedicine Companies."

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