

Unnecessary Laboratory and Diagnostic Tests

Tests must be “Reasonable and Necessary”

One of the more active areas in qui tam cases under the False Claims Act in recent years has involved unnecessary laboratory and diagnostic testing. In general, the Medicare program only pays for lab and diagnostic tests that are “reasonable and necessary for the diagnosis or treatment of illness or injury.” *See* 42 U.S.C. § 1395y(a)(1)(A) (“[N]o payment may be made under part A or part B of this subchapter for any expenses incurred for items or services. . . which. . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”). This general rule applies to tests performed by laboratories. Each time a claim for payment is submitted to a Federal healthcare program, the provider must expressly certify that the services performed were medically justified.

Medicare regulations provide that diagnostic lab tests “must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem.” 42 C.F.R. § 410.32(a). This requirement makes clear that only tests performed in connection with an appropriate diagnosis (with a specific ICD code) and whose results will be used to treat the patient are reimbursable as “reasonable and necessary” by Medicare. Additionally, if lab test performed by the lab is wholly unrelated to and not justified by the diagnosis given by a doctor, the lab cannot submit a claim for payment for that test to the Government, and the lab may be liable under the FCA if it does so.

How Labs Violate the FCA

Some of the ways laboratory and diagnostic testing facilities run afoul of the FCA are as follows:

- (a) utilizing a coding practice known as “unbundling” to maximize reimbursement from Government insurers which means that the provider bills separately for components of a related group of tests, when they should be billed under a single billing code per Medicare guidelines;
- (b) potential anti-kickback violations in cases where a provider is routinely referring patients to a lab for tests, and the lab provides a benefit to the referring provider to assist in the likelihood for the referrals;
- (c) billing patients for tests even though the tests have not been performed or fully performed;
- (d) potential Stark Law violations if the provider owns a financial interest in the lab to which the provider is referring patients, in which case both the lab and the referring provider may be violating the Stark Law as well as the FCA;
- (e) performing tests that the ordering physician believed were free of charge but the lab charges the patient for the extra tests; and
- (f) submitting claims for reimbursement for tests when the patient has diagnoses that are unrelated to the test.

Example of a Whistleblower recovery in Laboratory and Diagnostic Fraud Cases alleging violations of the FCA:

The **whistle-blower**, a former senior quality control analyst at the subsidiary, **received a Relator Fee of approximately \$5.6 million** of the recovered amount from an approximately **\$33.2 million Settlement** in March of 2018, in a case involving a medical device manufacturer with Alere agreeing to resolve claims that its subsidiary caused hospitals to submit false claims to government health care programs by knowingly selling materially unreliable point-of-care diagnostic testing devices. *See* Press Release, Office of Pub. Affairs, U.S. Dep't of Justice, Alere to Pay U.S. \$33.2 Million to Settle False Claims Act Allegations Relating to Unreliable Diagnostic Testing Devices (Mar. 23, 2018), <https://www.justice.gov/opa/pr/alere-pay-us-332-million-settle-false-claims-act-allegations-relating-unreliable-diagnostic>.

Blow the Whistle on Laboratory Testing Fraud

Individuals with knowledge of fraud committed by laboratories may be able to blow the whistle on this kind of fraud using the FCA, the TMFPA and other whistleblower reward programs. Whistleblowers play a critical role in bringing this type of laboratory testing fraud to light and holding wrongdoers accountable when they try to cheat the system.

To talk with me about your unnecessary lab or diagnostic testing case, call my Dallas law offices at 214-505-0097 or contact me online. Consultations with a Dallas County Qui Tam attorney are free and confidential. I handle these types of cases on a contingent fee basis, meaning you owe me no legal fees or expenses unless I obtain a recovery for you.