HCCA HEALTH CARE COMPLIANCE ASSOCIATION

Compliance TODAY

October 2016

A PUBLICATION OF THE HEALTH CARE COMPLIANCE ASSOCIATION

WWW.HCCA-INFO.ORG

Getting to the truth in internal investigations

an interview with Michael Johnson
CEO, Clear Law Institute

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A new era of LabScams? Part 2: The return of laboratory fraud

» The large settlements and corporate integrity agreements that resulted from Operation LabScam were supposed to deter fraud.

» The deterrent effect was temporary: Lab fraud is back with a vengeance.

» DOJ is pursuing individuals and corporate defendants criminally and civilly.

» In addition to the laboratories involved, physicians could be liable under the Anti-Kickback Statute if they receive payments intended to induce the referral of patients.

» Those who work in or benefit financially from labs should review the guidance promulgated by HHS-OIG and review their obligations under federal and state law.

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Part 1 of this article, which discussed the historical context of laboratory fraud, appeared in our September 2016 issue.

In the wake of Operation LabScam, the HHS Office of the Inspector General (HHS-OIG) rolled out compliance plans designed to educate labs and other healthcare providers about their obligations when billing programs like Medicare and Medicaid, in order to protect those programs from fraud, abuse, and waste. The federal government also promoted a "zero tolerance policy" concerning laboratory fraud. And whether due to education, reform, the deterrent effect of prosecution and litigation, or a combination of all those things, laboratory fraud appeared to recede significantly in the early 2000s.

But while the government focused its fraud-fighting efforts on other aspects of healthcare delivery, abuse in the laboratory industry began to percolate once more. Between 2005 and 2010, Medicare spending on laboratory services increased 29% while enrollment in Medicare rose only 10%. That discrepancy spurred HHS-OIG to conduct a study, which it released in a 2014 report entitled, "Questionable Billing for Medicare Part B Laboratory Services."[1] The title serves as a spoiler for the results of the study: HHS-OIG found that many labs engaged in questionable billing. It developed 13 measures by which to evaluate laboratories' billing practices, and then determined that in 2010 alone more than 48,000 labs (51% of all labs surveyed) exceeded high-billing thresholds for at least one of the measures. During the same year, 1,025 labs exceeded high-billing thresholds for at least five of the 13 measures. Among the questionable practices identified most often by HHS-OIG were:

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- Claims submitted to Medicare with invalid or ineligible ordering physician numbers,
- Unusually high numbers of tests per ordering physician,
- Claims for tests with no associated services covered by Medicare, and
- An unusually high percentage of claims for beneficiaries located more than 150 miles away from the ordering physician.

All told, the claims red-flagged by HHS-OIG cost Medicare $1.5 billion in 2010.

In its Work Plan for Fiscal Year 2014, HHS-OIG confirmed that the reduction of fraud, abuse, and overpayments resulting from claims for laboratory tests was an agency priority:

> Much of the growth in lab spending has resulted from the increased volume of ordered services. Part B covers most lab tests and pays 100 percent of allowable charges; Medicare beneficiaries do not pay copayments or deductibles for lab tests. Medicare should pay only for those lab tests that are ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary.[2]

The prevalence of questionable claims spurred concerns at HHS-OIG that laboratories were offering providers illegal remuneration and other benefits in exchange for referrals. Thus, in June 2015, HHS-OIG issued a Special Fraud Alert concerning laboratory payments to referring physicians. This was the first fraud alert touching on laboratory services that HHS-OIG had released since 2000. In the June 2015 alert, HHS-OIG reiterated its position that "providing free or below-market goods or services to a physician who is a source of referrals, or paying such a physician more than fair market value for his or her services, could constitute illegal remuneration under the Anti-Kickback Statute [AKS]."[3] In particular, it identified two practices that it believed were particularly likely to lead to fraud and abuse in violation of federal law: (1) blood-specimen processing arrangements and (2) registry payments.

As to the former, HHS-OIG expressed concern that laboratories were paying physicians for services related to the collection, packaging, and shipping of blood samples, a practice that implicates the AKS, regardless whether the payments reflected the fair market value of the services provided. The question under the AKS was whether one purpose of the payment was to reward referrals of federal healthcare beneficiaries.

With regard to registry payments, HHS-OIG detailed the circumstances under which laboratories can and cannot pay physicians for collecting and providing information concerning patients who undergo certain tests for inclusion in the laboratories' databases. Although payments to physicians related to data collection and other services may be reasonable in certain limited circumstances, such payments are impermissible if even one purpose is to induce referrals.

Twice in the fraud alert, HHS-OIG reminded physicians that, as the recipients of payments, they could be liable under the AKS if the payments constituted illegal inducements. Specifically, HHS-OIG noted that the provision of below-market goods or services or inflated payments raises the specter of the "four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal healthcare programs and beneficiaries, and unfair competition." The Biodiagnostics prosecutions (see Part 1 in our September issue), well underway at this time, imbued the warning with additional credibility.

The contemporary laboratory fraud cases

Due to the prison sentences and anecdotes of criminal largesse that it has generated, the Biodiagnostics case has grabbed more than its share of headlines. But it should not overshadow the many other laboratory fraud cases that have worked their way through the federal courts in recent years. Indeed, many are still being litigated. Like the Operation LabScam cases from years ago (and in contrast to the Biodiagnostics criminal prosecutions), they were spurred by *qui tam* actions under the False Claims Act (FCA). Below are snapshots of the most prominent cases from the new era of LabScams.

Quest Diagnostics and LabCorp

In a case that bridges Operation LabScam to the new wave of laboratory fraud, Quest Diagnostics paid the State of California $241 million to resolve whistleblower claims that, from 1995 to 2010, it had billed the state Medicaid program at a higher rate than other payers for the same tests and services.[4] The *qui tam* suit, which led to California's largest ever recovery under its state FCA, alleged that Quest would offer its services to private payers at deep discounts and then make up the difference by bilking Medicaid, charging the program as much as six times more than its other customers paid. The *qui tam* complaint also implicated the Laboratory Corporation of America (LabCorp), which settled for just short of $50 million, as well as other, smaller labs. In total, California recovered more than $310 million as a result of the whistleblower's case.

HDL and Singulex

In April 2015, Health Diagnostic Laboratories (HDL) and Singulex entered into ability-to-pay settlements with the United States and various state governments (for $47 million and $1.5 million respectively) to resolve allegations that, from 2009 to 2012, they violated federal and state FCAs and anti-kickback laws. According to three separate *qui tam* actions consolidated in the U.S. District Court for the District of South Carolina, HDL, Singulex, and Berkeley HeartLab induced physicians to send patients to their labs for blood testing, much of which was medically unnecessary, by offering the physicians unearned and illegal processing and handling fees ostensibly related to the drawing and packaging of the patients' blood.[5]

Prior to the case, Richmond-based HDL had enjoyed substantial growth. From early 2010 through 2011, its business increased at the rate of 5% a month, according to then-CEO Latonya Mallory. After the settlement, HDL filed for Chapter 11 bankruptcy and the bulk of its assets were purchased at auction by True Health Diagnostics in October 2015. The case persists against HDL and Singulex's marketing agent, BlueWave HealthCare Consultants; the aforementioned Mallory; and BlueWave's principles, Floyd Calhoun Dent and Robert Bradford Johnson, III. Berkeley HeartLab and the government filed a notice of settlement in principle in June 2016.

Millennium Laboratories

In October 2015, Millennium Health, formerly known as Millennium Laboratories, agreed to pay $256 million to resolve allegations that it violated the federal FCA by billing government healthcare programs for medically unnecessary genetic testing and urine drug tests and by providing free urine cups to physicians on the condition that those cups would be filled with specimens and sent back to Millennium for expensive testing. The alleged conduct spanned more than seven years (January 2008 through May 2015) and the settlement resulted in the dismissal of eight *qui tam* suits filed against Millennium in the District of Massachusetts.[6]

Pharmasan

In October 2015, Pharmasan Labs, Inc.; its CEO and owner, Mieke Kellermann; its third-party billing agent, Neuroscience, Inc.; and Neuroscience's CEO and owner (and Mieke's husband) Gottfried Kellermann settled an action under the FCA by agreeing to pay the United States $8.5 million.[7] As part of the settlement, the defendants forfeited the nearly $3 million that federal agents had seized from Pharmasan and Neuroscience bank accounts in 2014. They also signed a five-year corporate integrity agreement with HHS-OIG. Under the terms of the settlement agreement, the defendants conceded that the government could prove that Pharmasan had billed Medicare for food sensitivity testing for five years, despite knowing that Medicare prohibited payment for such testing, and that its employees had submitted false information to Medicare to conceal the type of testing for which the claims were being submitted.

Bostwick Laboratories

In January 2016, the CEO of Bostwick Laboratories settled with the federal government for $3.75 million to resolve allegations that, from 2006 to 2011, his company had submitted false claims to Medicare and Medicaid for bladder cancer screenings (among other tests) that were medically unnecessary and performed without a treating physician's order. The relator also alleged that Bostwick had violated the AKS by plying physicians with discounts and favorable billing arrangements to induce referrals.[8] The settlement followed a 2014 agreement pursuant to which the company agreed to pay more than $6 million to resolve similar allegations.

OPKO

In June 2016, OPKO Health (a.k.a. OurLab) and its president, James Oppenheimer, agreed to pay $9.35 million to resolve allegations that, from 2007 to 2015, the drug laboratory contributed to their customer-physicians' costs associated with their electronic health record (EHR) systems in exchange for patient referrals, in violation of the AKS and the Stark Law and thus the federal FCA. The AKS and the Stark Law contained safe harbors that, from 2006 to 2013, permitted a vendor to pay part of the purchase price of an EHR system on the behalf of a healthcare provider; the vendor could not condition its donation on referrals or otherwise consider the volume of referrals in determining whether and how much to contribute to a given provider. According to the relator, OPKO and Oppenheimer engaged in such behavior and thus lost the protection of the safe harbors.[9] Per the terms of the settlement, OPKO and Oppenheimer are jointly and severally liable for the settlement, and they cannot participate in federal healthcare programs for five years.

Are more laboratory fraud prosecutions on the way?

Although the government has yet to label its enforcement efforts with a catchy title suitable for a military offensive, it has identified combatting laboratory fraud as a priority. Its approach in the aforementioned cases signals that it may pursue these cases with greater vigor than it did in the Operation LabScam era.

In particular, the new wave of lab fraud cases demonstrates the government's commitment to pursuing criminal charges and to targeting individuals, in both the civil and criminal context. In Biodiagnostics, the DOJ has exhibited a heretofore unseen resolve to go after the recipients of kickbacks (the physicians) and not just the labs that dispense them. There is reason to believe Biodiagnostics is not *sui generis* (i.e.,

in a class by itself). Through a 2015 memorandum issued by Deputy Attorney General Sally Quinlan Yates[10] and subsequent policy statements, the DOJ announced its intention to hold individuals accountable for organizational misdeeds. Laboratory fraud cannot thrive without physicians willing to accept inducements in exchange for referring patients for the unnecessary testing. Therefore, in these cases, individual responsibility encompasses not only lab executives, but also the doctors they pay.

Laboratories, their executives, and the healthcare providers who do business with them must take notice of the investigations, criminal prosecutions, and *qui tam* lawsuits targeting the laboratory industry. Those who work in or benefit financially from labs should review the guidance promulgated by HHS-OIG to understand their obligations under the AKS, the Stark Law, the FCA, and other applicable statutes. Individuals and corporate entities who fail to act in accordance with the relevant law, as interpreted by HHS-OIG, may well be swept up in the new wave of LabScam enforcement actions.

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