Mintz Levin Health Care *Qui Tam* Update

Recently Unsealed Whistleblower Cases

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In this issue we report on recent *qui tam* activity and look at three unsealed cases.

One case involves allegations of "up coding" by a hospital that allegedly billed routine transport as emergency transport, reimbursed at a higher rate. The second involves a defendant that allegedly billed for medically unnecessary tests that it claims can identify susceptibility to opioid addiction, and purportedly engaged in a kickback scheme. In our third case, a company that processed prior authorization requests for MCOs allegedly used automated procedures to expedite processing and circumvent medical necessity determinations, resulting in submission of false claims.

Overview of *Qui Tam* Activity

- We identified 21 health care–related *qui tam* cases that were unsealed in May 2017.
- Of those cases, the government intervened, in whole or in part, in seven cases and declined to intervene in 10. There were four cases in which the intervention status could not be determined from the case docket.
- The 21 unsealed cases were filed in 17 different courts, with no court having more than two unsealed cases. The courts unsealing two cases were the Central District of California, the District of South Carolina, the Eastern District of Michigan, and the Northern District of California.
- The targeted entities included outpatient medical and psychological providers, laboratory testing companies, inpatient hospitals, and home health care providers.
- The ranks of relators consisted overwhelmingly of current and former employees and physicians. Ten relators were former employees and five were current employees. At least one relator was a patient. And, continuing a recent and troubling trend, one relator was an external auditor.
- Long delays in unsealing remain the norm. Only three cases were under seal for less than one year, with the shortest having been sealed for six months. The oldest case had been under seal for six and a half years before unsealing. The average time under seal for the 21 unsealed cases was two years and nine months.
- The most common alleged violation was billing fraud, which was claimed in two-thirds of the 21 unsealed cases. Eight cases alleged violations of the Anti-Kickback Statute, while four alleged Stark Law violations. Relators asserted retaliation claims in six of the 21 cases.

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United States ex. rel. Valentine v. Navicent Health, Inc., No. 5:15-cv-152 (M.D. Ga.)

Complaint Filed: May 1, 2015

Complaint Unsealed: May 9, 2017

Intervention Status: The United States and the State of Georgia intervened in part on May 8, 2017.

Claims: The complaint asserts claims under the federal False Claims Act, 31 U.S.C. § 3729 ("FCA"), and the Georgia False Medicaid Claims Act, O.C.G.A. §§ 49-4-168 *et seq.*, ("Georgia FMCA"), for false claims submitted to Medicare and Georgia's Medicaid program.

Name of Relator: Andre Valentine

Defendant's Business: Defendant Navicent Health, Inc. ("Navicent") is the second largest hospital in Georgia. Additionally, Navicent operates and owns its own ambulance services.

Relator's Relationship to Defendant: Former employee. The relator is a Georgia-licensed paramedic who was employed by Navicent for approximately one year. The relator alleges that he was terminated after he questioned Navicent's billing practices.

Relator's Counsel: Kevin A. Doyle of Lokey, Mobley and Doyle, LLP.

Summary of Case: The relator claims that Navicent engaged in several improper and fraudulent billing schemes in connection with its ambulance and emergency transport services, including the submission of reimbursement claims for emergency transportation services for patients who did not qualify for emergent transportation and who in fact did not receive emergency transportation. Navicent supervisors allegedly instructed paramedics and emergency medical technicians to change patient care reports to state that emergency transportation was required and provided. This alteration of the patient records enabled Navicent to receive increased payments for transporting Medicare- and Medicaid-eligible patients. By way of example, relator described five different occasions when he was dispatched to transfer patients between inter-facility hospitals. None of those transfers involved emergency transportation. Nonetheless, the relator alleges that his Navicent supervisor "ordered" him to change the service report to reflect level 1 emergency service.

In addition, the relator alleged that Navicent wrongfully terminated him because he questioned what he perceived to be improper and fraudulent billing practices for non-emergent services.

Current Status: Case pending.

Reasons to Watch: This case is an example of the government's continuing focus on "up coding" schemes, in which providers alter claims to seek higher reimbursement rates. Allegations that a provider has misrepresented the complexity or emergent nature of services provided in order to obtain increased reimbursement will always draw close scrutiny from the government. The unusually blatant fraud alleged in this case is not often seen at a major medical center. The government, however, determined after investigation that there was sufficient evidence to warrant intervention. It remains to be seen whether the allegations of altered medical records will be substantiated.

United States ex. rel. Gardner v. Proove Biosciences, Inc., No. 2:15-cv-9158 (C.D. Cal.)

Complaint Filed: November 25, 2015

Complaint Unsealed: May 10, 2017

Intervention Status: The United States intervened on May 9, 2017.

Claims: The complaint alleges violations of the FCA and the federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b ("AKS"), for false claims submitted to Medicare. The relator asserts that the defendants billed for medically unnecessary genetic tests and engaged in a

sophisticated kickback scheme with physicians.

Name of Relator: Bruce Gardner

Defendant's Business: Defendant Proove Biosciences, Inc. ("Proove") sells a number of genetic tests that help physicians determine whether a patient is at risk of addiction to opioid painkillers. Proove's most popular genetic tests are the Drug Metabolism Test and Opioid Risk Test. These two tests make up a significant portion of Proove's billings to Medicare and Medicaid.

Relator's Relationship to Defendant: Bruce Gardner is the Vice President of Strategic Operations.

Relator's Counsel: Aaron J. Kemp and Ronald W. Chapman II of Chapman Law Group

Summary of Case: The relator alleges that Proove engaged in fraudulent billing practices in connection with a series of genetic tests designed to determine patients' susceptibility to opioid addiction based on their genetic profiles. The testing method developed by Proove is an alternative to a conventional genetic testing methodology that is understood to be accurate in 50% of patients. Proove claimed that studies showed that its tests could accurately predict opioid sensitivity in 93% of cases. The relator contends that the 93% figure is untrue and is based on a misrepresentation of the results of certain clinical tests. According to the relator, Proove's CEO and CFO were both aware of that misrepresentation. In fact, the relator claims, the Proove test only evaluated 2% of the genes known to affect susceptibility to opioid addiction. He further asserts that the estimate of the Proove test's reliability rests on a faulty algorithm, developed by a physician retained by Proove, which was manipulated to yield efficacy results that would warrant government approval of use of the testing on Medicare and Medicaid patients. The relator charges that the doctor who devised the algorithm continues to collect payments for every test sold, purportedly as a kickback for his role in gaining government approval.

The complaint alleges that Proove's genetic tests are unsupported by medical evidence, and the defendant billed Medicare and Medicaid for medically unnecessary tests using billing codes that were inapplicable to the genetic tests it was actually performing but which generated higher reimbursements.

In addition, the complaint asserts that the defendant improperly induced physicians to sign a Professional Services Agreement to sell and administer Proove's tests to patients in exchange for a fee from Proove and reimbursement from Medicare. The relator alleges that this complicated kickback scheme resulted in Medicare's payment of millions of dollars for unnecessary and expensive testing.

Current Status: Still Pending

Reasons to Watch: In addition to the alleged billing scheme, this case is notable because of its connection to the opioid crisis. Approximately 91 Americans die each day from opioid overdoses; recently there has been a nationwide effort to reduce the availability of opioid-related painkillers. Many states are working in partnership to address opioid abuse. The allegations against Proove highlight the potential risk to the health care system of unscrupulous providers attempting to profit from this very serious public health threat.

United States ex. rel. Miller v. CareCore National, *LLC*, No. 1:13-cv-1177 (S.D.N.Y)

Complaint Filed: February 21, 2013

Complaint Unsealed: May 11, 2017

Intervention Status: The United States intervened in part on May 11, 2017.

Claims: The complaint asserts claims under the FCA based on the creation of false records and the presentation of false claims for payment to the Medicare and Medicaid programs.

Name of Relator: John Miller

Defendant's Business: Defendant CareCore National, LLC ("CareCore") enters into

outsourcing contracts with managed care organizations ("MCOs") to process physicians' requests for prior authorization of medical procedures based on established therapeutic criteria for medical necessity.

Relator's Relationship to Defendant: Former employee. The relator was a Clinical Reviewer and Supervisor for CareCore. Clinical Reviewers are responsible for reviewing or referring prior authorization requests.

Relator's Counsel: Matthew Gluck, Anna C. Dover, and Rolando G. Marquez of Milberg LLP and Stephen A. Weiss and TerriAnne Benedetto of Seeger Weiss LLP.

Summary of Case: To qualify for reimbursement by Medicare and Medicaid, treatment ordered by physicians must be medically necessary. Obtaining prior authorization for procedures is one way of assuring that treatment meets the medical necessity requirements. MCOs that administer programs for Medicare and Medicaid sometimes contract with providers such as CareCore to administer their prior approval process. Unfortunately, according to the government's complaint in intervention, CareCore's claim volume exceeded its processing capacity. In order to clear the prior approval backlog, CareCore instituted a program in 2005 that it called the "Process as Directed" or "PAD" program. Claims diverted to the PAD program circumvented individualized evaluation by medical professionals to determine whether medical necessity criteria were satisfied. Instead, the government charges, the claims submitted to the PAD program were simply auto-approved without any review for medical necessity. These automatic approvals were allegedly not based on the objective medical criteria established by the Centers for Medicare and Medicaid Services ("CMS") for Medicare and Medicaid claims.

CareCore allegedly referred to claims processed in that manner as "padded" claims. According to the government's complaint, CareCore padded claims to avoid contractual penalties it would have incurred for failure to conduct timely prior authorization reviews. Between 2005 and 2013, the government alleges that CareCore "padded" approximately 200,000 prior authorization requests. The government contends that each time CareCore relayed a "padded" request to the MCO, the auto-approval was a false statement on which the MCO relied to determine payment. The government alleges that MCOs relied on CareCore to conduct a valid prior authorization process and that the MCOs would never have paid padded claims had they known that a valid prior authorization process had not been conducted. The government characterizes the padded claims as false insurance claims, resulting in turn in the submission of false claims to the government in violation of the False Claims Act.

Current Status: On May 11, 2017, settlement was filed simultaneously with the United States complaint in intervention. CareCore agreed to pay a total of $54 million to all involved parties. The government stated that the relator, John Miller, had acted well beyond a typical relator and awarded him $9 million (16.66%) of the settlement amount. The FCA directs the government to pay relators in intervened cases between 15% and 25% of the government's recovery. CareCore also admitted responsibility for the PAD program in the settlement agreement, most likely at the government's insistence.

Reasons to Watch: This case raises the issue of whether auto-approval of insurance claims is beneficial or harmful to the health care system. The risk of federal funds being incorrectly used for procedures that are not medically necessary can potentially waste valuable tax payer dollars. However, an automated approval process can allow insurers to swiftly process claims and deliver patient care. The rapid review of insurance claims will ultimately lead to the quick payment of medical bills, benefitting medical providers. Even so, issues of medical necessity are an increasing focus of fraud and abuse scrutiny by government investigators. To the extent that automated approval processes potentially fail to incorporate adequate evaluation of medical necessity, such processes are likely to invite government scrutiny.

For more information, including details relating to the above cases, please contact **Hope S. Foster** at **202.661.8758** or HSFoster@mintz.com.

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