Mintz Levin Health Care *Qui Tam* Update

Recent Developments & Unsealed Cases

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Trends & Analysis

Since our last *Qui Tam* Update, we have identified 39 health-related False Claims Act ("FCA") *qui tam* cases that have been unsealed. Of those cases:

- 19 were filed between 2009 and 2013 (with seven filed in each of 2012 and 2013)
- 18 were filed in 2014
- 2 were filed in 2015

These cases were filed in federal district court in 20 states scattered across the country, plus the District of Columbia. Notably, seven cases were filed in California (with five being filed in the Central District of California (Los Angeles)). Four cases were filed in New York (three of them in the Southern District (Manhattan)), and three cases were filed in New Jersey.

Within the 39 cases we reviewed:

- The government elected to intervene in full in five cases.
- The government partially intervened in one case.
- The government declined to intervene in 21 cases.
- The government's decision on whether to intervene is still pending in two cases and cannot be determined from the docket in seven cases.
- Relators voluntarily dismissed seven cases.
- There have been settlements associated with five of the identified cases.
- 21 of the cases alleged state and federal claims, one of which also asserted claims under the municipal false claims acts of Chicago and New York City.
- Eight cases included claims for retaliation.

Subject matter of claims:

- A number of cases involved claims that the defendants billed for products or services that were not actually provided, engaged in upcoding, or billed for services of non-physician providers under physicians' names.
- One case alleged the use of unqualified and unlicensed personnel to serve as x-ray technicians, allegedly in knowing violation of the conditions applicable to payment for claims submitted by x-ray technicians.

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- In a few cases, the government declined to intervene and the relator sought to dismiss the allegations voluntarily. In one case, the relator asked the court to maintain the seal, but the court unsealed the complaint anyway.
- This month's cases include yet another case brought by serial relator Fox, Rx, parent company of Fox Insurance, Inc., both of which were in the business of sponsoring Medicare Part D prescription drug plans. Now, both seem to be engaged primarily in bringing *qui tam* actions. (Previous Fox, Rx *qui tam* actions were discussed in the November 2013, October 2014 and March 2015 Updates). Fox allegedly conducted an internal audit of its claims and determined that AccessHealth, a pharmacy service provider, had purportedly dispensed hundreds of thousands of Schedule II controlled substances without prescriptions.
- Another case, which the relator voluntarily dismissed with the government's agreement, alleged false certifications of compliance with conditions for the receipt of payment from the Medicare Shared Savings Program through participation in an Accountable Care Organization.
- The relator in one case was a limited liability company formed for the sole purpose of filing the *qui tam* action. The practice of forming legal entities solely for the purpose of bringing *qui tam* cases is a trend that we are seeing with increasing frequency, and it appears to us that they are created, at least in some instances, to conceal the relator's identity.
- The relators in many of the cases were former employees, although some relators came from defendants' competitors or service providers.

Recently Unsealed Cases

United States of America ex rel. Mazurek v. Garden State Cardiovascular Specialists, P.C., No. 2:10-cv-04734 (D.N.J.)

Complaint Filed: September 14, 2010

Complaint Unsealed: June 1, 2015

Intervention Status: The federal government intervened as to Garden State Cardiovascular Specialists P.C. ("Garden State") for purposes of settlement. The government declined to intervene as to defendant Medigain, Inc. ("Medigain").

Claims: False claims to Medicare and Tricare in violation of the 1986 and 2009 versions of the FCA for false claims (31 U.S.C. § 3729(a)(1)(1986), 31 U.S.C. § 3729(a)(1)(A)(2009)); false statements (31 U.S.C. § 3729 (a)(2) (1986), 31 U.S.C. § 3729(a)(1)(B)(2009)); and conspiracy (31 U.S.C. § 3729 (a)(3)(1986), 31 U.S.C. § 3729(a)(1)(C)(2009)). The relator also asserted violations of the federal Anti-Kickback Statute ("AKS") as the basis for an FCA violation. The relator sued under the New Jersey False Claims Act for false claims to Medicaid, as well. In addition, the relator brought a retaliation claim against Medigain, alleging that it terminated her after she raised concerns about certain Garden State billing practices.

Name of Relator: Cheryl Mazurek

Defendants' Businesses: Garden State is a cardiology practice that owns and operates several facilities. Medigain provides services related to billing, reimbursement, and revenue cycle management.

Relator's Relationship to Defendants: The relator was a Medigain employee.

Relator's Counsel: Begelman & Orlow, P.C.

Summary of Case: Garden State allegedly contracted with Medigain to provide electronic billing services. Medigain submitted electronic claims for Garden State to Medicare, Medicaid, and Tricare, among other government health care programs. The relator worked for Medigain and asserted that

she identified allegedly improper claims through a number of means, including an "office audit" of Garden State's claims (some of which she attached to her complaint). The relator asserted that she informed Medigain of certain alleged billing improprieties. The complaint charged that Garden State's claims were false in several different ways, including (1) using the NPI number of a physician who did not perform the service for which Garden State sought payment; (2) billing federal health care programs for medically unnecessary cardiology diagnostic tests and procedures, including stress tests, cardiac catheterizations, and external counterpulsation services; and (3) "upcoding" services to obtain higher reimbursement rates.

The complaint further alleged that Garden State asked Medigain to file false claims and that Medigain purportedly filed false claims in exchange for payment from Garden State.

Current Status: On May 28, 2015, Garden State and its principals, Jasjit Walia, M.D., and Preet Randhawa, M.D., settled the medical necessity case against them for $3.6 million. The relator received $648,000 of the settlement proceeds. The relator advised the court on June 25, 2015 that she would serve the complaint against Medigain and that she would proceed with that portion of the lawsuit on her own.

Reasons to Watch: This case is another reminder that relators are often billing and coding specialists who may work for third-party billing or auditing companies. Companies can mitigate the risk that employees will become *qui tam* relators by instituting processes and procedures that can be used to surface and act on issues identified by employees. Where a company uses a third-party vendor, the company might want to consider adopting contractual provisions obligating the vendor to implement similar controls so that compliance issues come to light in the course of the company-vendor relationship, and not through an OIG subpoena or the unsealing of a *qui tam* action.

In addition, the case exemplifies a trend that we are seeing with increasing frequency: relators are more willing than ever to press ahead with claims on their own, even if the government declines to intervene as to certain, or even all, claims. In this case, even though the government intervened in part, and settled a portion of the case, it appears that the relator will continue the litigation as to certain claims that the government declined to pursue itself.

United States of America ex rel. Morris v. Brevard Eye Center, Inc., No. 6:14-cv-01460 (M.D. Fl.)

Complaint Filed: September 5, 2014

Complaint Unsealed: Not clear from the docket.

Intervention Status: No reference to intervention or declination in the docket.

Claims: Submission of false claims in violation of the FCA (31 U.S.C. § 3729(a)(1)(A)); false statements (31 U.S.C. § 3729 (a)(1)(B)); and concealing and avoiding an obligation to pay money to the United States (31 U.S.C. § 3729(a)(1)(G)). The relator also alleged that the defendants had violated the Florida state statutes applicable to false claims and concealing or avoiding the obligation to pay money to the state. Finally, the relator included a retaliation claim against the defendants in the lawsuit.

Name of Relator: Carrie L. Morris, M.D.

Defendants' Business: Brevard Eye Center, Inc. ("BEC") is a medical eye care facility with seven locations in Brevard County, Florida. Brevard Surgery Center, Inc. (the "Surgery Center") is an ambulatory surgery center affiliated with BEC. The relator also named several individuals as defendants, including the president of the Surgery Center, the CEO of BEC and the Surgery Center, the vice president and treasurer of both BEC and the Surgery Center, the president of BEC and the Surgery Center, and several individual optometrists either currently or formerly employed by BEC.

Relator's Relationship to Defendant: The relator was a BEC employee.

Relator's Counsel: Jill S. Schwartz & Associates, P.C.

Summary of Case: The relator asserted that the CEO of BEC orchestrated a number of schemes to defraud federal health care programs with the cooperation and assistance of other named defendants (who were also executives or employees of BEC). In pertinent part, the relator alleged

that BEC:

1. Engaged in fraudulent anesthesia billing by packaging cosmetic and medically necessary procedures together, but intentionally failed to deduct the cost of anesthesia for the cosmetic portion of the procedure (as legally required to do) before billing federal health care programs;
2. Paid optometrists $100 for every patient referred to BEC's ophthalmologists for the evaluation and treatment of cataracts in violation of the AKS;
3. Ordered unnecessary procedures related to cataract surgery and falsified medical records to support this practice as a matter of course (specifically, scheduling nearly every patient who had undergone cataract surgery for a procedure within three months of that surgery when those patients who develop this post-cataract-surgical complication—and many do not—do not do so for one to three years after cataract surgery);
4. Employed optometrists who exceeded their licensed scope of practice by performing surgical (or certain other) procedures that may only be performed by medical doctors; and
5. Billed federal health care programs for Botox injections (using the CPT code for actual Botox, not the generic versions) after obtaining the Botox on the "black market" to save money or using a non-FDA-approved Botox-like substance for some of those injections.

When the relator expressed her concerns about these practices to BEC executives, they purportedly often acknowledged the issues but did nothing to remedy them. Instead, according to the relator, she experienced significant retaliation in response, including: denial of a bonus she had previously been awarded (and which BEC had already begun paying), verbal abuse, physical intimidation (including one BEC partner who raised his hand as if to strike the relator), harassing telephone calls and excessive monitoring of the relator's computer and whereabouts. She was eventually put on probation, and she was then terminated.

Current Status: A significant portion of the docket in this case continues to be sealed, but the unsealed remainder shows that in the last month Notices of Pendency of Related Cases, Certificates of Interested Persons and Notices to Counsel have been filed. It remains to be seen whether the government will elect to intervene in, or any related cases will be joined with, this case.

Reasons to Watch: While the misconduct alleged by the relator is not necessarily unique in the context of health care fraud enforcement, this case may be one to watch because it involves several allegations regarding specific patients who were exposed to unnecessary, sometimes dangerous, procedures. Given the government's continued (and growing) interest in prosecuting cases that involve allegations of harm to patients, it will be interesting to see whether the egregious risk of harm alleged in this case captures the government's attention. In addition, while the retaliatory conduct alleged is on the extreme end of the spectrum, this case serves as yet another reminder that the vast majority of relators are former employees and that fair treatment and following up on employees' complaints may go a long way toward limiting the risk of being sued by a relator under the FCA's *qui tam* provisions.

United States of America and State of New York ex rel. Jamie Cantor v. Option Care, Inc., et al. No. 1:09-cv-06970 (S.D.N.Y.)

Complaint Filed: August 6, 2009

Complaint Unsealed: June 26, 2015

Intervention Status: Declination by the federal government; partial intervention by New York State.

Claims: Submission of false claims and false statements in violation of the federal (FCA, 31 U.S.C. §§ 3729 (a)(1)(A), and (a)(1)(B)); submission of false claims, false statements, and conspiracy to defraud by false claims in violation of the New York False Claims Act, New York State Finance Law §§ 187-194.

Name of Relator: Jamie Cantor

Defendant's Business: Nursing, pharmaceutical, home care services

Relator's Relationship to Defendant: The relator was a former sales manager for defendant Option Care, Inc. ("Option Care").

Relator's Counsel: Law Offices of Weiner & Weiner, LLC

Summary of Case: The relator was a former employee of Option Care and Trinity Home Care, LLC, a company that Option Care had acquired. Option Care provided nursing, pharmaceutical, and home care services to patients. The relator alleged that Option Care defrauded, and conspired with others to defraud, Medicare, Medicaid, and private insurance companies by sending patients excess medication and by providing patients with medication for which they did not sign receipts.

Current Status: The case settled in June 2015. The defendant agreed to pay $2,551,062.32 to the State of New York; the State agreed to pay the relator $459,191.22.

Reasons to Watch: This case contains a common factual scenario in *qui tam* actions where the relator is a former employee who had access to billing records during employment. However, the case provides an important reminder that even where federal intervention may not occur, a state government can choose to intervene, especially in states such as New York that are active in the enforcement arena.

Here, Option Care agreed to a multi-million dollar settlement with the State of New York after the State intervened ("State Settlement Agreement") (and a few weeks later agreed to a $22.4 million settlement with the State of New York for claims involving a different drug). Even though the federal government did not intervene, the State Settlement Agreement covered both the federal and state shares of the Medicaid reimbursements, providing that "the State shall tender to the United States a percentage of the Settlement Amount as agreed by the State and the United States in accord with the Federal Medicaid Assistance percentage rate." The State Settlement Agreement also made clear that neither the State nor the relator could release any claims brought on behalf of the United States. Separately, the relator—not including any defendants—entered into a stipulation and release with the United States. The federal release recognizes that the relator received a share of the proceeds of the State Settlement Agreement, and the relator stipulated that the settlement of the State claims was a fair settlement. Under the federal stipulation and release, the relator agreed to release the United States from (1) any claims for a share of the state settlement, including claims under the federal FCA; and (2) any claims arising from or relating to the relator's lawsuit against any of the defendants.

Although the defendant resolved the State claims, as discussed by our colleague Ellyn Sternfield, state settlements without federal government intervention pose a risk for defendants. Even though the federal government did not object to the State Settlement Agreement in this case, the United States did not provide the defendants with a federal release. In addition, HHS-OIG was not a party to the settlement, so the defendants did not obtain a release from OIG's exclusion authority. As a result, the defendants remain subject to potential additional liability.

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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