Qui Tam Defense

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Health Care Enforcement Defense Practice | *Health Law & Policy Matters* blog

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Mintz Levin Health Care *Qui Tam* Update

Recent Developments & Unsealed Cases

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Trends & Analysis

- We have identified 18 health care–related *qui tam* cases unsealed since last month's *Qui Tam Update.* Of those, 10 were filed from 2012 to the present. The remaining cases, filed before 2012, date back as far as December 2009.
- These 18 cases were filed in 14 states. As we commonly observe, several of the recently unsealed cases were filed in historically active jurisdictions for false claims act cases, including the District of Massachusetts, the District of New Jersey, and the Southern and Eastern Districts of New York.
- Among the 18 recently unsealed cases, the government declined to intervene in about half of the cases in which the unsealed filings disclosed the government's decision on intervention. In two cases, the government intervened only for settlement purposes after having initially declined to intervene.
- Subject matter of claims:
    - Roughly 40% of the recently unsealed cases involved both state and federal claims.
    - Claims for relief under state or federal anti-whistleblower retaliation provisions appeared in 4 of the 18 recently unsealed cases.
- Identity of relators:
    - Over 80% of the relators were employees or former employees of the defendants in these 18 cases.
    - One case, brought against a home health care company and its physician-owner, was filed by a relator with no prior connection to the defendants. This relator is employed as a patient advocate by an unrelated company and, as he alleged in his complaint, he brought the case after becoming concerned about several close relationships he observed between a number of doctors and home health care agencies in his market area. *See United States ex rel. Stephens v. Haddadin*, No. 2:12-cv-00475 (N.D. Ind.).

Recently Unsealed Cases

***United States ex rel. Schmasow v. EndoGastric Solutions, Inc.*, No. 1:12-cv-00078 (D. Mont.)**

Complaint Filed: June 26, 2012.

Complaint Unsealed: December 2, 2013.

Intervention Status: The United States initially declined to intervene in November 2013, but on February 11, 2014 moved to intervene for the purpose of settlement pursuant to 31 U.S.C. § 3730(c)(3).

Claims: Marketing and causing the upcoding of a surgical procedure to induce hospitals and physicians to purchase products from EndoGastric Solutions, Inc. ("EndoGastric"), in violation of the Civil False Claims Act ("FCA"), 31 U.S.C. § 3729. In addition, EndoGastric allegedly implemented co-marketing agreements with physicians to induce them to perform surgical procedures using EndoGastric's products, in violation of the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)-(2).

Name of Relator: Glenn Schmasow.

Defendant's Business: EndoGastric is a medical device company that develops surgical products and instruments used for treating gastroesophageal reflux disease ("GERD"), which includes chronic acid reflux, and other gastrointestinal diseases.

Relator's Relationship to Defendant: Relator was employed by EndoGastric as a program development manager for approximately three months in 2010 before his resignation, allegedly for "ethical reasons."

Relator's Counsel: Edwards, Frickle & Culver (Billings, Montana).

Summary of Case: EndoGastric developed an incisionless procedure to treat GERD, which traditionally has been treated with either open or laparoscopic surgeries. The incisionless procedure is only performed using EndoGastric's proprietary surgical medical devices. The relator alleged that EndoGastric induced the erroneous coding of its incisionless procedure as either an open or laparoscopic procedure in order to increase reimbursement amounts. In some cases, EndoGastric purportedly convinced physicians to place trocars (devices placed in the body during laparoscopic surgery to serve as portals for surgical instruments) in their patients during procedures, which require incisions, even though the main advantage of EndoGastric's procedure is that it is incisionless. Trocars were allegedly placed in patients to convert the procedure from an incisionless case to a so-called "hybrid case" and thereby facilitate upcoding to a laparoscopic procedure, which is reimbursed at a higher amount than an incisionless case.

Current Status: On February 25, 2014, the United States and the relator jointly moved to dismiss the action in accordance with the terms of a settlement agreement filed concurrently with the motion. Under the settlement agreement, EndoGastric will pay up to $5.25 million, with the relator receiving up to $945,000. EndoGastric will also be subject to a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

Reasons to Watch: The case illustrates the risks facing medical device manufacturers whose sales efforts incentivize the billing of procedures at unjustified high reimbursement rates. Such activity may be expected to attract the attention of both would-be whistleblowing employees and the federal government. Assistant Attorney General for the Justice Department's Civil Division Stuart F. Delery commented on the settlement: "Health care providers that cause the government to pay more than it should for medical devices not only cost us money as taxpayers, they raise the cost of health care for everyone." This case reflects the latest example of the interagency cooperation between the Justice Department and the Department of Health and Human Services under the Health Care Fraud Prevention and Enforcement Action Team ("HEAT") initiative launched in 2009.

***United States ex rel. Hinestroza v. Ralex Services, Inc.*, No. 1:10-cv-00822 (E.D.N.Y.)**

Complaint Filed: February 24, 2010.

Complaint Unsealed: December 26, 2013.

Intervention Status: Both the United States and the State of New York elected to intervene in part as to defendants Ralex Services, Inc. d/b/a Glen Island Care Center ("Glen Island") and Leah Friedman.

Claims: Submitting false or fraudulent claims for payment for services that allegedly were not provided to patients at Glen Island and unlawful retaliation in violation of the Civil False Claims Act, 31 U.S.C. § 3729, as well as the analogous false claims law of New York.

Name of Relator: Carolyn Hinestroza.

Defendants' Business: Glen Island is a nursing home facility in New Rochelle, New York, co-owned by defendant Friedman.

Relator's Relationship to Defendants: Relator was a full-time resident nurse employed by Glen Island before she was terminated in December 2004.

Relator's Counsel: Valli Kane & Vagnini LLP (Garden City, New York).

Summary of Case: Relator alleges that Glen Island falsified Patient Review Instruments ("PRIs") that it is required to submit to the government to receive Medicare and Medicaid reimbursement. The PRIs describe patient needs and services that Glen Island either has provided or plans to provide. Glen Island allegedly forged certain PRIs using the relator's name when she neither reviewed nor approved the PRIs. When the relator investigated these PRIs, she discovered that they indicated that patients had received services that were not actually rendered and that were allegedly not supported by doctors' notes and orders. When the relator complained to management about these PRIs, defendant Friedman allegedly asked her when she had become "not a team player." The following month after the relator's complaint to management, she was terminated.

Current Status: The United States and the State of New York partially intervened in the case at the end of 2013 and the case is currently pending.

Reasons to Watch: The partial intervention by both the United States and the State of New York show the ongoing interest the government has demonstrated in the billing practices of skilled nursing facilities ("SNFs"). As has been noted previously in this space, SNFs provide fertile ground for false claims litigation because most patients in SNFs are beneficiaries of either Medicare or Medicaid, and therefore the majority of services rendered are potentially subject to a false claims action. The Department of Justice continues to hold SNFs accountable for "the provision of excessive and medically unnecessary therapy services."

***United States ex rel. Garcia v. Louisiana Sleep Diagnostics, LLC*, No. 6:12-cv-01225 (W.D. La.)**

Complaint Filed: May 14, 2012.

Complaint Unsealed: January 5, 2014.

Intervention Status: On January 2, 2014, the United States partially intervened in that portion of the case alleging defendant's FCA violations through the submission of claims to Medicare for independent diagnostic testing services that were not reimbursable because the services were performed at undisclosed locations or at locations other than the location identified in the bill.

Claims: Submitting non-reimbursable claims to Medicare for independent diagnostic testing services, failing to disclose change of address information to Medicare, sharing practice locations with other Medicare-enrolled individuals, and submitting false billing codes in violation of the Civil False Claims Act, 31 U.S.C. § 3729, and the Louisiana False Claims Act.

Name of Relator: Haley Garcia.

Defendant's Business: Louisiana Sleep Diagnostics, LLC ("LSD") is an independent diagnostic testing facility ("IDTF") specializing in polysomnographic technology (testing for sleep disorders).

Relator's Relationship to Defendant: Relator has been employed by LSD since 2006, first as the marketing director and subsequently as the human resources and operations director.

Relator's Counsel: L. Clayton Burgess (Lafayette, Louisiana).

Summary of Case: Relator alleges that LSD has failed to disclose all its practice locations to Medicare, as required in order to maintain its certification as an IDTF. Further, LSD purportedly submitted fraudulent claims for payment for services rendered in certain of LSD's facilities that are not qualified to receive Medicare reimbursement by billing for those services as if LSD had rendered them in one of its other approved locations. LSD allegedly billed Medicare for services rendered at ineligible practice locations by intentionally entering codes from one of its eligible practice locations to make it appear as though the services were performed there. Relator also alleges that several of LSD's facilities are located in shared offices with Medicare-enrolled health care providers in violation of CMS certification standards. Finally, the relator alleges that LSD used a false billing code for obstructive sleep apnea for every patient's initial test, even though a

physician had not yet diagnosed every patient as having obstructive sleep apnea.

Current Status: The case is currently pending. LSD filed its answer on February 18, 2014.

Reasons to Watch: During its investigation, the government sought and received four separate extensions of time to consider its election to intervene. The docket entries on these motions suggest some impatience with the pace of the government's investigation and perhaps signify a growing reluctance by some courts to grant serial *ex parte* motions for extension by the government. In granting the government's third motion, at which point the case had been pending for fifteen months, the Court noted on the docket that "this is the third extension sought by the government and granted by the Court. The government is hereby notified that additional extensions are unlikely to be granted absent specific articulable circumstances that the government can show warrant an additional extension." The government nevertheless sought and received one final extension just four months later, when the Court finally noted, "This motion is reluctantly granted. NO ADDITIONAL EXTENSIONS WILL BE GRANTED."

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

About Our Health Care Enforcement Defense Practice

Mintz Levin's Health Care Enforcement Defense Practice is comprised of health law, employment, and white collar defense attorneys with experience in government investigations and health care regulatory compliance matters. We regularly help clients conduct internal investigations designed to detect and correct problems before the government becomes involved. We have represented clients in federal and state government investigations and litigation across the country in matters initiated by the Criminal and Civil Divisions at the Department of Justice, United States Attorneys, the Office of Inspector General for the Department of Health and Human Services, the Drug Enforcement Administration, State Attorneys General, Medicare and Medicaid contractors, and the 50 Medicaid Fraud Control Units. We have helped clients avoid potentially ruinous civil fines, incarceration, other criminal and administrative penalties, and exclusion by combining our regulatory knowledge with our investigative, employment-related and litigation capabilities.

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