Mintz Levin Health Care *Qui Tam* Update

Recently Unsealed Whistleblower Cases

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Trends & Analysis

- We have identified 42 health care–related *qui tam* cases that have been unsealed in whole or in part since the cases covered in our last *Qui Tam Update*. Included in that count is one proceeding (the "Consolidated Case") in which three separate actions were consolidated into a single case.

- A substantial majority of the unsealed cases had been under seal for periods well in excess of the required statutory period. Of the 44 complaints filed in those 42 cases, three quarters of the complaints (33 of 44) were filed before 2015, with one unsealed complaint dating back to November 2008 and two others dating back to 2010 and 2011, respectively. Of the remaining complaints, five were filed in 2012, fourteen in 2013, eleven in 2014 and eleven in 2015. As these cases illustrate, extensions of the seal on *qui tam* actions continue to be routine.

- The cases identified were filed in federal district courts in 15 states and the District of Columbia, including California (6), New York (6), Florida (4), New Jersey (4), Ohio (4), Tennessee (3), Texas (3), Indiana (2), South Carolina (2), Wisconsin (2), Alabama (1), the District of Columbia (1), Georgia (1), Oregon (1), Pennsylvania (1), and Utah (1).

- The federal government declined to intervene in 25 of the 42 cases.[1] In another case, the state governments of New York and New Jersey declined to intervene while the federal government's intervention decision was not made clear by the unsealed filings. Six more cases were voluntarily dismissed before any action was taken by the government. The federal government intervened, in whole or in part, in seven cases. In the remaining cases, the government's intervention status could not be discerned from the unsealed filings.

- Nature of the Claims

    - Twenty-seven of the recently unsealed cases involved both state and federal claims.

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[1] Although the government declined to intervene in the three individual cases compromising the Consolidated Case, it did intervene in the Consolidated Case. Accordingly, the three consolidated individual actions are omitted from the 25 cases in which the government declined to intervene, but the Consolidated Case accounts for one of the seven cases in which the government intervened.

- Thirteen involved allegations of unlawful kickbacks. Of these, five also alleged violations of the Stark Law.
- Claims for relief under state or federal anti-whistleblower retaliation provisions appeared in 19 of the 42 recently unsealed cases.

- In over two-thirds of the unsealed cases (30 of 42), relators were current or former employees of the defendant. In two cases, the relator's relationship to the defendant was not revealed by the unsealed filings.

Featured Unsealed Cases

United States of America ex rel. Doe v. Specialty RX, No. 1:12-cv-05983 (D.N.J.)

Complaint Filed: September 25, 2012

Complaint Unsealed: January 8, 2014

Intervention Status: The states of New Jersey and New York declined to intervene. The case was voluntarily dismissed by the Relator with the consent of the United States, New Jersey and New York before the United States' intervention status was docketed.

Claims: The Relator brought claims under the federal False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1)(A), and the New Jersey and New York False Claims Acts for false claims submitted to Medicare Part D and New Jersey's and New York's State Medicaid Programs. The Relator alleged that the claims were false because they arose from a discount program that violated the federal Anti-Kickback Statute ("AKS") (42 U.S.C. § 1320a-7b).

Name of Relator: Unknown (Relator was permitted to proceed anonymously as a "Jane Doe" plaintiff.)

Defendants' Businesses: SpecialtyRx ("Specialty") is a long-term care pharmacy that provides pharmacy services to nursing homes and other long-term care facilities known as skilled nursing facilities ("SNFs"). In June 2011, Specialty acquired Advantage Pharmacy Solutions, LLC ("Advantage"), another pharmacy, focused on serving SNFs.

Relator's Relationship to Defendant: The Relator's relationship to the defendant is not entirely clear from the Complaint. The Relator states that she "has significant experience in the pharmacy business" along with experience submitting claims to private insurers, Medicare and Medicaid. Additionally, she has worked "at several smaller pharmacies and as a pharmacist who served various nursing homes, assisted living facilities [and] group homes located in New Jersey."

Relator's Counsel: Schnader Harrison Segal & Lewis LLP (formerly of Trujillo, Rodriguez & Richards, LLC); Berger & Montague

Summary of Case: The Relator alleges that Specialty engaged in an unlawful "swapping" scheme to induce SNFs to use Specialty as their exclusive pharmacy provider. Specialty allegedly offered SNFs deeply discounted rates for pharmaceuticals provided to their Medicare Part A patients. The Relator claimed that this discount yielded a profit to the SNFs because they are reimbursed by Medicare Part A at a fixed daily rate for medical care and pharmaceuticals provided to Part A patients. As a result of the discount, SNFs purportedly were incentivized to use Specialty as the exclusive provider of

pharmacy services for all patients. Specialty recouped the losses caused by the Part A discounts, and earned a profit on non Part A business, by providing pharmaceuticals to Medicare Part D and privately insured residents of the same facilities at a more lucrative market rate. The Relator alleged that Specialty's Part A discounts to the SNFs unlawfully induced SNF referrals of Medicare Part D and other patients in violation of the AKS. According to the Relator, this kickback scheme tainted all of Specialty's claims to Medicare Part D and state Medicaid programs in violation of federal and state law. The Relator charged that thirty-seven SNFs in New York and New Jersey accepted the discounts and provided the specific discounted rate for each. Additionally, the Relator appended to her complaint twenty-two pages of Specialty's financial reports enumerating the specific discounted rates provided for various patients at various facilities. Notably, the Relator alleged that Advantage started this unlawful discounting practice in 2007 and asserted that Specialty was liable not only for its own violations after the 2011 acquisition of Advantage but also as a successor-in-interest for Advantage's violations prior to the acquisition by Specialty.

Current Status: After New Jersey and New York declined to intervene in this case, the Relator filed notice of a Voluntary Dismissal based on a settlement agreement reached with the defendant. The terms of the settlement are not currently available.

Reasons to Watch: This case is notable, in part, for the allegations of successor liability against Specialty resulting from the alleged conduct of Advantage prior to its 2011 acquisition by Specialty. These allegations provide a reminder to health care companies of the importance of due diligence regarding compliance with the FCA and AKS during merger and acquisition negotiations.

Additionally, although the Relator's relationship to the defendant here is not entirely clear, the Relator's access to Specialty's billing records is a reminder that relators are often employees of a defendant or may be employees of other entities with whom a defendant does business. Companies can mitigate the risk that employees will become whistleblowers by implementing policies and procedures to ensure that employee concerns are identified and addressed early and internally. Companies may also seek to ensure that vendors and even institutional customers have similar policies and procedures in place so that notice of these concerns will be provided in the course of the business relationship – not in a *qui tam* suit.

United States ex rel. Kelly Oxendine v. HCA Holdings, Inc., No. 2:13-cv-03042 (D.S.C.)

Complaint Filed: November 8, 2013

Complaint Unsealed: November 16, 2015

Intervention Status: The United States intervened on November 13, 2015.

Claims: The Relator alleged that defendants had: submitted false claims in violation of the federal FCA, 31 U.S.C. § 3729 (a)(1)(A); used false statements in violation of § 3729(a)(1)(B); failed to disclose material facts that would have resulted in repayments to the Government under § 3729(a)(1)(G); and violated the related state laws of Florida, California, Colorado, District of Columbia, Georgia, Indiana, Louisiana, Nevada, Oklahoma, Tennessee, Texas, and Virginia.

Name of Relator: Kelly Oxendine

Defendants' Businesses: HCA Holdings, Inc. ("HCA") is the largest hospital chain in the United States, owning and operating approximately 164 hospitals and 113 free standing surgery centers in twenty states and in the United Kingdom, and employing approximately 199,000 people worldwide. The other

named defendant, Parallon Business Solutions, LLC ("Parallon"), is a wholly owned subsidiary of HCA.

Relator's Relationship to Defendants: Relator is an employee in the Revenue Integrity Department of Parallon Business Performance Group, a business unit of defendant Parallon.

Relator's Counsel: Rikard & Protopapas, LLC; Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.; Morgan & Morgan Complex Litigation Group; Merricks Law Group, P.A.

Summary of Case: The complaint charged that the defendants violated the FCA and related state laws by overbilling and failing to refund Medicare, Medicaid, and TRICARE for such overpayments and by failing to adequately audit medical billing practices. The complaint alleged six examples of systematic overbilling: (1) "stacking" intravenous ("IV") services so that when a more complex service, like a chemotherapy infusion, was provided along with a less complex service, such as IV hydration therapy, both services were billed separately when only the more complex procedure should have been billed; (2) double billing obstetric procedures when two departments both billed for the same procedure; (3) overbilling fluoroscopy services by billing for such services both as part of a bundled code and as a separate code for the same service; (4) overcharging for services by billing for setting up ventilation treatments as part of the initial setup of the ventilator and also including it in the charge for the procedure or patient room; (5) erroneously billing for IV infusions by not accurately recording the start and stop times; and (6) billing for unordered low-density lipoprotein ("LDL") tests when a physician had ordered a generic lipid panel but had not ordered an LDL.

The complaint also alleged that the Revenue Integrity Department in which Relator works was created as part of a Corporate Integrity Agreement ("CIA") that HCA had entered into with the Office of Inspector General of the Department of Health and Human Services ("HHS OIG") and which was in place from 2000 to 2008. The complaint charged that the defendants used revenue integrity resources, which were centralized in response to the CIA to allow for more corporate control over billing, to conceal overbilling through selective auditing and to facilitate under-reporting of systemic overbilling practices.

Current Status: The government intervened in the case on November 13, 2015. On November 14, 2015, the case was unsealed, dismissed with prejudice and settled for $2 million.

Reasons to Watch: This case is notable because the allegations were based not only on the purported submission of false claims but also on the dearth of corrective measures taken once persistent and widespread billing errors were discovered. The complaint's allegations were grounded in the defendants' asserted failures to adequately implement the safeguards set up under a prior CIA. In addition to raising the alleged overbilling practices, the complaint focused on the defendants' failures either to respond to audit data uncovering repeated billing errors or to implement comprehensive audits beyond discrete data sets or periods of time. In response, as noted in its press release announcing the settlement, the Department of Justice ("DOJ") emphasized its enforcement "goal to make the consequences more than just the cost of doing business."

Abc v. Def (United States ex. rel. David Heisler v. CenterLight HealthCare); and State of New York ex. rel. David Heisler v. CenterLight HealthCare, No. 1:13-cv-8502 (S.D.N.Y.)

Complaint Filed: November 27, 2013

Complaint Unsealed: The complaint has not been unsealed.

Intervention Status: The United States intervened, in part, on January 21, 2016.

Claims: The Relator alleged that the defendant had filed false claims in violation of the FCA, 31 U.S.C.

§ 3730(b), and the New York State false claims act and the New York State Finance Law.

Name of Relator: David Heisler

Defendant's Business: CenterLight Health System, Inc. is a New York not-for-profit corporation organized to support the provision of health care services principally in New York State and to provide financial and administrative assistance to its affiliated organizations, including CenterLight Healthcare, Inc. ("CenterLight Healthcare"). Pursuant to a contract with the New York State Department of Health, CenterLight Healthcare administers a long-term care plan, under which CenterLight Healthcare arranges and reimburses for health and community-based long-term care services provided to Medicaid beneficiaries.

Relator's Relationship to Defendant: Although the complaint is under seal, the New York Attorney General's press release acknowledges that the relator "provided valuable information through [his] 'qui tam' action."

Relator's Counsel: Yankwitt LLP; Law Offices of Andrea M. Paparella, Esq.

Summary of Case: The Relator alleged, among other things, that CenterLight Healthcare (1) improperly solicited individuals to join the CenterLight Managed Long Term Care Plan by offering gifts and incentives and making false promises; and (2) enrolled individuals who were not eligible for membership in the CenterLight Managed Long Term Care Plan ("CenterLight MLTCP").

The United States intervened in the case to pursue claims arising from Relator's allegations that CenterLight submitted false claims for payment to the Medicaid program as a result of the following conduct: (1) enrolling, or failing to identify and dis-enroll in a timely manner, 1,241 ineligible members who were referred by or received services from social adult day care centers; (2) using social adult day care centers to provide personal care services to CenterLight MLTCP members as the members' primary source of personal care services where (a) such services did not qualify as personal care services or (b) such services were provided by social adult day care centers that were not legally permitted or competent to provide such personal care services; and (3) engaging in improper marketing practices specifically directed toward enrolling members through social adult day care centers and inducing such members to use social adult day care centers as the members' primary source of personal care services.

As part of a settlement agreement with the DOJ and the New York Attorney General's Office, CenterLight Healthcare admitted that it received monthly capitation payments for the 1,241 ineligible members, many of whom were not eligible at the time of their enrollment, while others were not eligible to remain in the CenterLight MLTCP at the time of their re-assessment. CenterLight agreed to pay $46,751,086.74 to settle the case. Approximately $18.7 million of the settlement amount is for the federal Medicaid share.

Current Status: The settlement resolves only part of the claims in this case. The remaining allegations are under investigation by the United States and New York's Attorney General. On January 28, 2016, New York State moved to partially intervene with respect to the alleged state false claims act violations.

Reasons to Watch: This case is notable because the allegations are based not only on the submission of false claims but also on the failure to take corrective measures to ensure billing compliance. This case is also significant for its hefty settlement amount, which, as described by New York's Attorney General, is intended to send the message that the state and federal governments will "not tolerate companies that seek to exploit the system for profit."

United States ex rel. Jane Doe v. Heart Solutions PC, No. 2:14-cv-3644 (D.N.J.)

Complaint Filed: June 6, 2014

Complaint Unsealed: November 3, 2015

Intervention Status: The United States intervened on November 18, 2015.

Claims: The Relator (1) alleged (i) violations of the FCA, 31 U.S.C. § 3729 (a)(1)(A) and (a)(1)(B) (presenting false claims for payment and making or using false records or statements); (ii) common law fraud; (iii) unjust enrichment; and (iv) payment under mistake of fact; and (2) sought disgorgement.

Name of Relator: Unknown (Relator was permitted to proceed anonymously as a "Jane Doe" plaintiff)

Defendants' Businesses: Heart Solutions PC and Biosound Medical Services are mobile medical diagnostic companies and registered Medicare providers located in Parsippany, New Jersey. The companies provided mobile diagnostic testing, including ultrasounds, echocardiograms and nerve conduction studies. The other named defendants, Kirtish Patel and Nita Patel, are a husband and wife who owned and operated defendants Heart Solutions PC and Biosound Medical Services.

Relator's Relationship to Defendant: Employee of Heart Solutions PC and/or Biosound Medical Services from approximately February 2013 to approximately October 2013.

Relator's Counsel: Brickfield & Donahue

Summary of Case: The complaint alleges that the defendants violated the FCA by knowingly billing Medicare for fraudulent diagnostic test reports that were not prepared by a physician and for diagnostic tests that were used solely to generate these fraudulent test reports. The complaint listed six examples of systematic fraudulent billing: (1) fabricating test results on medical reports; (2) using only technicians, rather than physicians, to review tests and write medical reports; (3) forging purported reading physicians' names and facsimile signatures on medical reports; (4) billing for tests not done; and (5) paying unlawful kickbacks to referring physicians in exchange for patients.

The government's complaint in intervention is based on the conduct to which defendants Kirtish Patel and Nita Patel admitted in their criminal guilty pleas, specifically, that they created fraudulent diagnostic test reports, forged physician signatures on these reports, and then billed Medicare for the fraudulent reports and the underlying tests. Defendants Kirtish Patel and Nita Patel also admitted in their criminal pleas that they had billed Medicare for neurological testing that they conducted without the required physician supervision after falsely representing to Medicare that the tests would be supervised by a physician. The government's FCA complaint in intervention alleges that this conduct violated the FCA because the defendants were not entitled to Medicare reimbursement for fraudulent diagnostic test reports that were not prepared by an appropriate specialist physician and for diagnostic tests that were used solely to generate the fraudulent test reports.

Current Status: The case is currently pending.

Reasons to Watch: The civil case was originally terminated on December 11, 2014 but was reopened on December 12, 2015 after Kirtish Patel and Nita Patel pled guilty in a separate criminal enforcement action to one count of criminal health care fraud. The allegations in the government's complaint in intervention are based on these guilty pleas in which they admitted that defendants Biosound Medical Services and Heart Solutions PC were paid at least $1,668,954.95 by Medicare for the fraudulently billed diagnostic testing and reports and for neurological diagnostic testing that was never supervised by

a licensed neurologist. This case is notable because it is another example of DOJ's recent trend of pursuing criminal sanctions against individuals for submitting false claims, in addition to civil damages against the corporate entity. As noted in the press release, the New Jersey U.S. Attorney's Office's Health Care and Government Fraud Unit dedicates itself to both criminal and civil investigations and prosecutions of health care fraud offenses. Since 2010, the New Jersey office has recovered "more than $640 million in health care fraud and government fraud settlements, judgments, fines, restitution, and forfeiture under the False Claims Act" and other statutes.

United States ex rel. Andrew Gelbman v. All Metro Home Care Services, Inc., No. 1:14-cv-6461 (S.D.N.Y.)

Complaint Filed: August 13, 2014

Complaint Unsealed: December 2, 2015

Intervention Status: The United States declined to intervene on October 26, 2015.

Claims: The Relator alleged violations of both the FCA, pursuant to 31 U.S.C. § 3729 (a)(1)(A) and(a)(1)(B) (presenting false claims for payment and use of false statements), and the New York State Finance Law.

Name of Relator: Andrew Gelbman

Defendant's Business: Defendants offered either home care services or a variety of services to people with developmental or other disabilities.

Relator's Relationship to Defendant: Relator was employed by the New York State Department of Health ("DOH") as an Information Specialist II and performed a wide variety of duties including operating as a Data Warehouse Interrogator. His responsibilities in that role required him to perform business and systems analysis and fraud detection for eMedNY (the New York Medicaid Management Information System used to adjudicate Medicaid claims).

Relator's Counsel: Law Office of Richard B. Ancowitz

Summary of Case: Relator alleges that the defendants presented Medicaid claims, generally for services rendered to persons with special needs, that defendants knew or reasonably should have known were legally and/or factually false because the individuals to whom the services were provided were not eligible to receive them. According to Relator, the services typically included intermediate day care for developmentally disabled persons, day care programs for developmentally disabled persons, and related services.

Relator's allegations stem solely from data in the eMedNY system and are purportedly supported by a spreadsheet detailing each defendant's Medicaid billings for services allegedly rendered to ineligible recipients. This spreadsheet includes information about the services and supplies, the dates on which defendants allegedly provided them, each patient's Medicaid number, the rate code billed, the amount paid for the claims, the procedures performed, and each patient's diagnosis. Relator also asserts that each defendant had "a non-delegable duty and responsibility to determine recipient eligibility for receiving the Medicaid benefits claimed by the provider."

Relator explains that eMedNY determines whether a claim should be paid, denied or pended based on certain "edits." He includes as an exhibit a list of "edits" from the eMedNY system that describes billings by the defendants that Relator alleges were "falsely and improperly presented [and paid in an amount that exceeded $335,981,859]." After making several highly technical allegations, Relator charges that the defendants submitted claims in violation of applicable regulations, despite knowing that the

providers and/or recipients of the services were ineligible to provide and/or receive them.

Relator's entire complaint is comprised of similar allegations regarding Medicaid Coverage Codes, Rate Codes, Provider Category of Service Codes, and Procedure Code Modifiers. Nowhere does the complaint allege specific actions by specific providers apart from the submission of claims that violated certain regulatory provisions based on Relator's review of the underlying claims data.

Current Status: Both New York State and the United States declined to intervene on October 26, 2015. On December 2, 2015, the court unsealed the complaint and ordered Relator to serve it on the defendants within 45 days. That same day, Relator requested an extension of the service deadline.

Reasons to Watch: The complaint's allegations – that the defendants billed for certain services they were not qualified by Medicaid to perform and provided services to Medicaid beneficiaries who were not eligible to receive them – are not unusual. What is unique is the manner in which Relator discovered and reported the alleged misconduct. Relator's responsibilities as a DOH employee included data analysis related to Medicaid fraud and detection – on behalf of the state – but he used the information he obtained from performing these duties for the state to file a private *qui tam* action. Although the complaint does not indicate whether Relator brought the information he had found through his analysis to the attention of his superiors before filing suit, the fact that both New York and the United States declined to intervene raises questions about the validity of his assertions. From the docket, it appears that Relator is considering whether to move forward with this case on his own. It will be interesting to follow whether such data–driven allegations will support a viable FCA action.

United States Of America ex rel. Maria Valladares Kadzielawa v. Millennium Health, LLC, No. 3:15-cv-01063-BAS-RBB (S.D. Cal.)

Complaint Filed: May 12, 2015

Complaint Unsealed: January 22, 2016

Intervention Status: The case was dismissed shortly after the government declined to intervene.

Claims: The Relator alleged violations of the FCA under 31 U.S.C. § 3729(a)(1)(A), (a)(1)(B), and (a)(1)(G) through the submission of false claims to Medicare based on fraudulent billing and claims submission practices.

Name of Relator[s]: Maria Valladares Kadzielawa.

Defendant's Business: Defendant Millennium Health, LLC (f/k/a Millennium Laboratories) is a urine drug testing laboratory offering services in all 50 states.

Relators' Relationship to Defendant: Relator Kadzielawa is a registered nurse, certified professional coder, and certified professional medical auditor. Relator Kadzielawa became aware of Millennium Health's alleged fraudulent billing practices while auditing Millennium Health's bills covering multiple years.

Relators' Counsel: Blood Hurst & O'Reardon, LLP and Morgan & Morgan Complex Litigation Group.

Summary of Case: Relator alleged that defendant billed for specimen validity testing that is not required or allowed by Medicare and performed medically unnecessary confirmatory testing on nearly every urine drug test.

Relator asserted that, for each patient urine sample defendant tested, it submitted reimbursement claims for four distinct CPT codes covering specimen validity testing. According to the Relator's complaint, CMS considers this type of testing to be uncovered as it is part of a laboratory's quality assurance program and is not required in the management of a patient's medical problem. Relator contended that

defendant billed Medicare $25 for each specimen validity testing service. When multiplied by the approximately 300,000 urine samples that defendant tests on an annual basis, Relator estimated that defendant had overbilled Medicare each year by $7.5 million.

Relator also alleged that defendant had billed Medicare for services that were not related to a patient's illness or injury by submitting reimbursement claims for medically unnecessary confirmatory testing on nearly every urine drug test sample. According to Relator, Medicare expects confirmatory testing to be performed by a laboratory only after a physician first establishes the medical necessity of such testing through the use of initial screening tests, which cover many drugs and drug classes. The physician then orders additional confirmatory tests from a drug testing laboratory for specific drugs which have tested positive on the initial screening test. Relator alleged that, during her audit of defendant's bills, she met with some of defendant's employees who told her that defendant did not rely on the initial screening results submitted by physicians; instead, defendant chose to test each sample for every drug separately even if the initial screening test results were negative for many of the drugs. Thus, Relator alleged that Medicare was overbilled by as many 15 to 20 drug tests per patient urine sample. For example, during her audit of defendant's bills, Relator claims to have found that in 2012, defendant allegedly billed Medicare for 232,000 confirmatory drug tests for phencyclidine ("PCP"), which amounted to approximately $4.7 million in Medicare reimbursement.

Current Status: The case was dismissed on February 10, 2016.

Reasons to Watch: This case is unusual as Relator, a certified medical auditor, was a trusted advisor to defendant who, through her audit of defendant's Medicare bills, claims to have discovered potential red flags and then subsequently filed this *qui tam* suit. Further, the Relator's complaint provided significant detail regarding the complex nature of defendant's testing of urine samples, allegedly to facilitate the billing of uncovered and medically unnecessary testing. This case also presents a cautionary tale regarding conduct that may provide a basis for a *qui tam* suit. Thus, one basis for Relator's claims was that defendant's employees had told her that the company did not rely on the initial screening results that it had received from physicians due to a perceived high number of false positives and false negatives. In auditing defendant's bills, Relator concluded that defendant's practice of running confirmatory testing for multiple drugs on every urine sample allegedly had caused Medicare to reimburse millions of dollars for purportedly medically unnecessary services. This case provides an example of how a provider's trusted advisors can become whistleblowers.

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