Mintz Levin Health Care *Qui Tam* Update

Recently Unsealed Whistleblower Cases

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Overview of *Qui Tam* Activity

- We identified 60 health care related *qui tam* cases that were unsealed in December 2017 and January 2018.
- The government intervened in 14% of those unsealed cases, which is consistent with the longer term trends we have seen over the prior twelve months.
- Of the 60 unsealed cases, only 28 were at least initially being litigated. The other 32 were docketed as closed or dismissed.
- The 60 unsealed cases were filed in 38 different courts. Jurisdictions with the most unsealed cases were the Central District of California (which includes Los Angeles) with six, the Middle District of Florida (including Jacksonville, Orlando, and Tampa) with four, and the District of Connecticut and Eastern District of Louisiana (New Orleans) with three apiece.
- Pharmaceutical companies, hospitals, and healthcare systems were the most frequently targeted types of defendants, with each accounting for 9 of the 60 unsealed cases. Seven cases were brought against physicians and physician practice groups, six against home health and hospice providers, and five against outpatient clinics.
- Former employees were again the most frequent relator type, accounting for 23 of the 60 unsealed cases. Current employees only brought two of the cases. Experts accounted for seven cases.
- Only one of the cases was unsealed within the 60-day period specified by statute. That case was under seal for 55 days. The longest time under seal was almost eight-and-a-half years. Average time under seal for this cohort was 700 days, though half of these cases were unsealed in 16 months or less, and 23 of these 60 cases were unsealed in less than a year.

Featured Cases

***United States ex rel. Vensel v. Naples Community Hospital, Inc.*, No. 16-cv-00189-SPC-CM (M.D. Fla.)**

Complaint Filed: March 11, 2016

Complaint Unsealed: November 7, 2017

Intervention Status: The government declined to intervene.

Claims: False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*.

Defendants' Businesses: Defendant Naples Community Hospital, Inc. ("NCH") is a community hospital system in Collier County, Florida and is a wholly owned subsidiary of defendant NCH Healthcare System, Inc. Defendant NCHMD, Inc. ("NCHMD") is a physician practice group, which employs physicians at NCH hospitals and clinics and is a wholly owned subsidiary of defendant NCH Healthcare System, Inc.

Relator: Eric Vensel, M.D.

Relator's Relationship to Defendants: Dr. Vensel is a radiologist and a partner in Naples Radiologists, P.A. ("Naples Radiologists"), which co-owned three outpatient imaging centers with NCH. Naples Radiologists had a contract with NCH to provide all radiology services for the co-owned imaging centers. NCH terminated its contract with Naples Radiologists in 2010.

Relator's Counsel: Bryan A. Vroon of Vroon & Crongeyer, LLP and Jonathan Kroner of Jonathan Kroner Law Office

Summary of Case: The relator alleged that NCH's employed physicians were required to refer only to NCH and that each physician's compensation was based on the volume of referrals that each physician made to NCH. The relator generally asserted that NCH absorbed significant losses to pay exorbitant physician compensation in order to generate more revenue through referrals. For example, NCH purportedly compensated one cardiologist more than $920,000 in one year when the 90th percentile of cardiologist compensation was $826,933. The relator contended that NCH also illegally compensated the cardiology group, which referred a high volume of patients, by permitting the cardiologists to work fewer hours than physician groups that referred fewer patients. NCH also allegedly compensated one orthopedic surgeon $2.2 million annually for two consecutive years, when the 90th percentile of orthopedic surgeon compensation was around $1.2 million. According to the relator, NCH's scheme to increase referrals by compensating its employed physicians based on the volume of referrals violated the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b (the "AKS"), the Stark Law, 42 U.S.C. § 1395nn, and the FCA because the arrangements with physicians did not constitute bona fide employment relationships.

Current Status: On October 31, 2017, the United States declined to intervene in the case, and the complaint was unsealed one week later on November 7, 2017. On November 16, 2017, the United States consented to dismissal of the case, and the relator voluntarily dismissed the action on November 22, 2017.

Reasons to Watch: Although this case has been dismissed, it reflects a growing trend in which relators are bringing *qui tam* actions against hospitals and health care systems for allegedly providing excessive compensation to employed physicians based on anticipated or actual volume of referrals. The U.S. Court of Appeals for the Fourth Circuit held in *United States ex rel. Drakeford. v. Tuomey Healthcare System, Inc.*, 675 F.3d 374 (4th Cir. 2012), that a jury could find that a health care system violated the Stark Law by entering into a medical services agreement with a physician that bases compensation on the anticipated volume of referrals the physician could generate in a year. *See also United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 792 F.3d 364 (4th Cir. 2015). Cases such as *Tuomey* and *Vensel* that target physician compensation under the Stark Law and AKS pose particular risks for hospitals located in underserved areas that need to offer highly competitive compensation to attract physicians. In such circumstances, consideration should be given as to whether the compensation can be structured to comply with applicable regulations and safe harbors.

United States and the Commonwealth of Massachusetts ex rel. Collins v. Molina Healthcare, Inc., No. 3:16-cv-30177-MGM (D. Mass.)

Complaint Filed: October 28, 2016

Complaint Unsealed: January 9, 2018

Intervention Status: The federal government and the Commonwealth of Massachusetts declined to intervene.

Claims: FCA, 31 U.S.C. § 3729 *et seq*. and various state health care fraud statutes and false claims acts.

Defendants' Businesses: Defendant Molina Healthcare, Inc. ("Molina") is a managed care company operating in multiple states, including Massachusetts, and the District of Columbia. Defendant Pathways of Massachusetts, LLC ("Pathways") is a wholly owned subsidiary of Molina and operates mental health centers in Massachusetts.

Relators: Jennifer Collins, Ermelinda Cardona, Iris Castro, and Migdalia Rosaso

Relator's Relationship to Defendants: The relators are former employees of Molina and Pathways.

Relator's Counsel: Thomas J. O'Connor, Jr. of O'Connor Martinelli

Summary of Case: The relators allege the following violations of Massachusetts regulations and credentialing requirements of MassHealth (the Massachusetts Medicaid agency): (1) Molina failed to employ a board-certified psychiatrist on the staff of the Pathways clinics, (2) the psychiatrist supposedly employed by Molina was not on-site at the Pathways clinics for at least eight hours per week, (3) patients were not afforded access to psychiatric medical treatment, and (4) the psychiatrist supposedly employed by Molina failed to adequately supervise Pathways psychiatric nursing staff. The relators contend that, by consistently filing claims for reimbursement under MassHealth, Molina knowingly submitted false claims for reimbursement to federal and state government health care programs in violation of the FCA and Massachusetts false claims statutes.

Current Status: This case is still in the early stages. On December 29, 2017, the United States declined to intervene, and the Commonwealth of Massachusetts also declined to intervene five days later on January 3, 2018. The court then unsealed the complaint six days later on January 9, 2018. Defendants were served on April 9, 2018 and, by agreement of the parties, the defendants' deadline to respond to the complaint was extended to June 25, 2018.

Reasons to Watch: This case presents issues mirroring those presented in *Universal Health Services, Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016). In *Escobar*, the relators alleged that defendant Universal Health did not employ sufficient licensed mental health counselors and was submitting false claims to the government because every time it submitted a claim it certified its compliance with MassHealth mental health facility requirements. The relators prevailed at the pleading stage in the lower courts, and the U.S. Supreme Court upheld those decisions, ruling that a misrepresentation about legal compliance must be material to be actionable under the FCA. This case was filed after *Escobar* was decided and shows an attempt by relators to model a complaint against a MassHealth provider on the *Escobar* materiality theory. Although *Escobar* has strengthened the ability of defendants to assert materiality as a defense against FCA liability arising from regulatory noncompliance, this case evidences the ability of relators to rely on *Escobar* to define what types of regulatory noncompliance might satisfy the materiality element of an FCA claim.

Given the parallels to the successful allegations in *Escobar*, it is unclear based on the unsealed materials why the government declined to intervene here. It is possible that the government concluded based on its investigation that there was insufficient factual support for relators' allegations to warrant intervention. Interestingly, the parties' joint motion for extension of the defendants' response deadline to June 25, 2018, indicates that "[t]he Parties' counsel plan to discuss this matter in detail before Defendants respond to the Complaint." Presumably, such discussions would allow the defendants to share with relators any information provided to the government that would weigh against moving forward. Whether the case will be litigated notwithstanding the parties' discussions will become clear by the June 25 deadline.

United States of America ex rel. Medrano v. Diabetic Care RX, LLC, No. 15-cv-62617-BLOOM (S.D. Fla.)

Complaint Filed: December 14, 2015

Complaint Unsealed: December 19, 2017

Intervention Status: Partial intervention by the United States on December 15, 2017.

Claims: FCA, 31 U.S.C. § 3729 *et seq.*, AKS, 42 U.S.C. § 1320a-7b

Defendants' Businesses: Diabetic Care Rx, LLC dba Patient Care America ("PCA") is a compounding pharmacy. Riordan, Lewis & Haden, Inc. ("RLH") is a private equity group and majority owner of Patient Care America. Patrick Smith, Matthew Smith, and Thomas Buscemi are executives at Patient Care America.

Relators: Marisela Carmen Medrano ("Medrano") and Ada Lopez ("Lopez")

Relators' Relationship to Defendants: Medrano was Patient Care America's Director of Marketing from September 2, 2014, to July 8, 2015; Lopez was Patient Care America's Reimbursement Services Manager from April 2014 to June 2015.

Relators' Counsel: Relators' counsel not listed (U.S. Attorney's Office representing the government in the part of the case in which there was intervention.)

Summary of Case: As previously detailed in Mintz Levin's *Health Law Policy Matters* blog, the government's complaint in intervention alleges that PCA's purported wrongdoing began shortly after RLH's investment in 2012. PCA was then in the business of providing intravenous nutritional therapy to dialysis patients. Soon thereafter, two RLH partners became officers, directors – or both – of PCA. The government alleges that, while in these roles, they directed PCA to aggressively pursue an entirely new line of business – topical compounding – to increase the company's value in anticipation of selling PCA in five years. The government claims that PCA then brought in a new CEO (despite the fact that a talent consultant allegedly cautioned PCA

that the candidate would require “careful management”), and the CEO then hired a licensed pharmacist to lead the new business line because of his ability to “generate immediate referrals.” The CEO and the pharmacist are the individuals named in the complaint.

The government claims that PCA engaged marketing companies as independent contractors to generate prescriptions for its topical compounds, and these companies were compensated through a 50% commission on profits generated from the prescriptions they submitted to PCA, despite PCA allegedly receiving legal advice from multiple attorneys cautioning against such compensation arrangements. According to the government, PCA exercised little or no oversight over the marketing companies, essentially giving them the freedom to generate prescriptions as they pleased.

The complaint asserts that the marketers misled TRICARE beneficiaries to induce them to obtain the prescriptions, paid kickbacks to physicians who submitted prescriptions without seeing the patients, and set up a sham charitable organization with the help of PCA to pay for beneficiary copayments. The government further alleges that PCA exploited TRICARE’s practice at the time to reimburse pharmacies for all ingredients in a compounded drug by repeatedly modifying its compounding formulas to increase reimbursement for its pain management products. The government claims that PCA received more than $68 million during the period of the alleged fraud and that amount constituted nearly all of PCA’s revenue by March 2015.

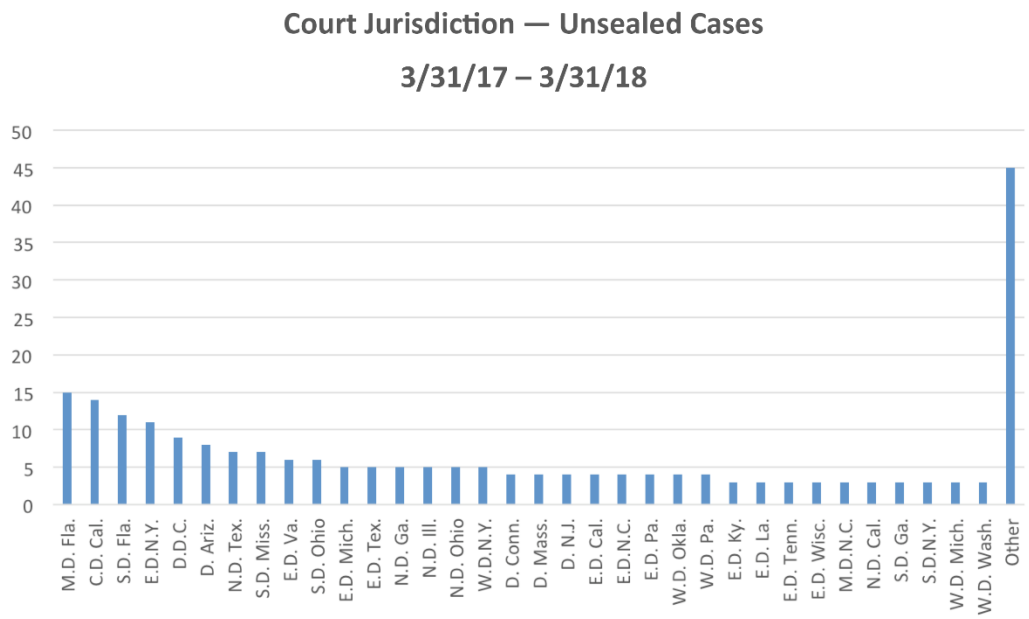
Current Status: Defendants have moved to dismiss the complaint. The motion is still pending. Meanwhile, the court has adopted a scheduling order that has set a trial date for August 2019.

Reasons to Watch: What is particularly noteworthy is that the complaint names a private equity firm that holds a majority ownership stake in the company as one of the defendants. Ordinarily, owners and shareholders are not named as defendants in FCA cases. However, some private equity companies actively participate in the management of their portfolio companies, and this case highlights the risk that close involvement in such management could create.

Health Care *Qui Tam* Litigation Trends

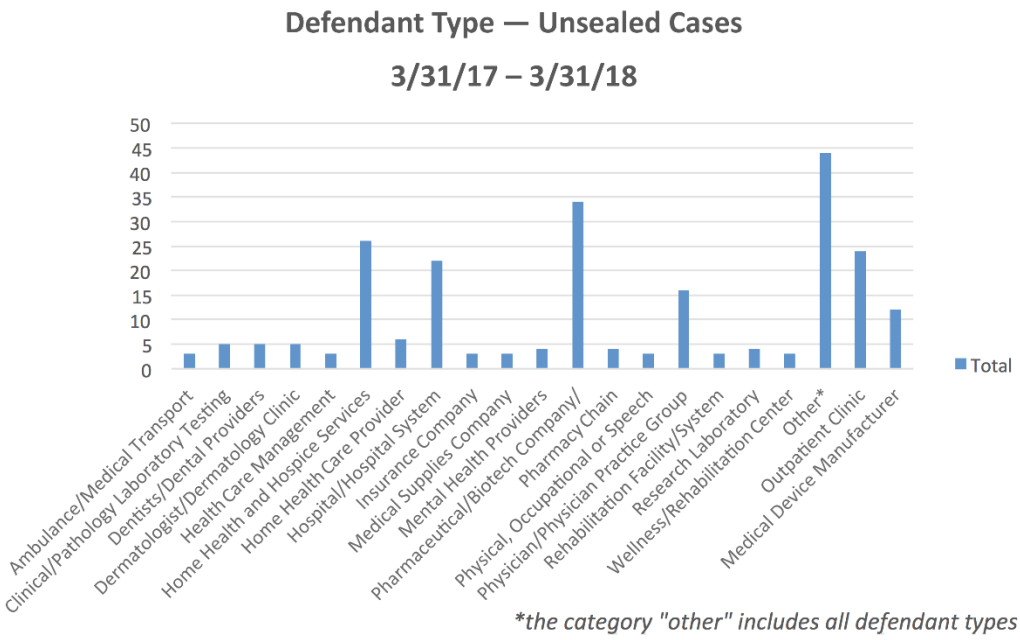
Mintz Levin maintains a database of unsealed health care *qui tam* actions. This enables us to follow and analyze trends in the cases that have been unsealed. The following are some trends in *qui tam* filings against health care-related entities in the twelve months ended March 31, 2018:

Where were cases filed? Although cases were unsealed in jurisdictions throughout the country, some interesting trends have emerged as to jurisdictions where the most cases have been unsealed:

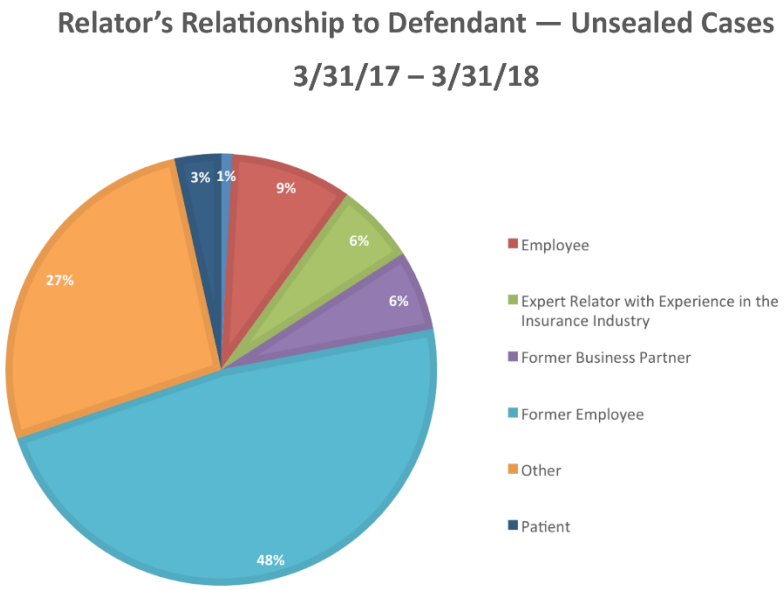


Over the twelve months ended on March 31, there was significant activity in Florida, with fifteen cases being unsealed in the Middle District (Tampa, Orlando, and Jacksonville), and twelve being unsealed in the Southern District (Miami and West Palm Beach). California also has seen a large number of filings, with the Central District – which includes Los Angeles – leading the way. Also particularly active is the Eastern District of New York, which includes Brooklyn, Queens, and Long Island.

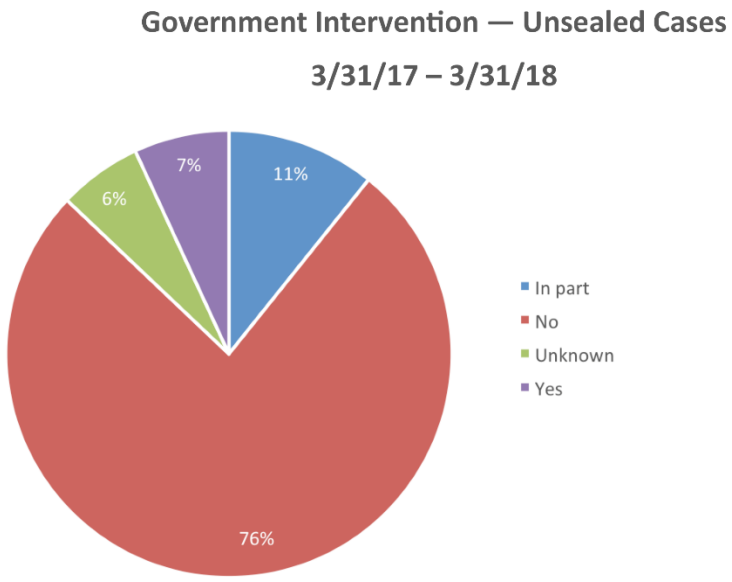
What kinds of businesses were targeted? Hospitals, pharmaceutical manufacturers, outpatient clinics, hospices, and pharmacies continue to be most frequently sued:



Who brought the cases? Current and former employees – mostly the latter – dominate the ranks of relators, accounting for 57% of all case filers. So-called “expert” relators are making up a growing portion of the *qui tam* docket, accounting for 6% of the filers in cases unsealed in the twelve months ended March 31, 2018.



How frequently did the government intervene?



Intervention rates continue to be extremely low, with the government declining to intervene in fewer than four out of every five cases unsealed over the twelve months ended March 31, 2018.

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 includes 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.