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

Mintz Levin Health Care *Qui Tam* Update

Recent Developments & Unsealed False Claims Act Cases

OCTOBER 2014

BY KEVIN MCGINTY, STEFANIE GIULIANO ABHAR, SEAN GRAMMEL, SAMANTHA KINGSBURY, AARON TIDMAN, BRIDGETTE WILEY, AND STEPHANIE WILLIS

Trends & Analysis

Between our last *Qui Tam Update* and the end of June, 65 health care–related *qui tam* cases were unsealed (28 in April, 18 in May, and 19 in June). Within those 65 cases:[1]

- The government declined to intervene in 34 cases (16 in April, 9 in May, 9 in June).
- The government filed Notices of Non-Intervention in 10 cases (1 in April, 3 in May, 6 in June).
- The government partially intervened in 10 cases (7 in April, 1 in May, 2 in June).
- The government fully intervened in 7 cases (4 in April, 3 in June).
- 19 cases were dismissed prior to settlement (9 of which were dismissed voluntarily by the relator).
- 12 cases were settled and/or dismissed pursuant to a Settlement Agreement (8 in April, 4 in June)[2]

Notably, a majority of the unsealed cases were filed within the last two years, but about one-third of the cases predate 2012:

- Before 2012: 23 cases (35%)
- In 2012: 15 cases (23%)
- In 2013: 26 cases (40%)
- In 2014: 1 case (2%)

While the cases were filed in a wide variety of jurisdictions, historically active jurisdictions for False Claims Act ("FCA") enforcement (marked with an * below) typically saw a higher concentration of cases filed. Some of the districts involved include:

- District of Arizona (2)
- C.D. California (3)*
- M.D. Florida (4)*
- S.D. Florida (3)*
- W.D. Missouri (2)
- E.D. New York (2)*
- S.D. New York (2)
- W.D. New York (2)
- E.D. Pennsylvania* (7)
- M.D. Pennsylvania
- W.D. Pennsylvania
- District of South Carolina (2)
- M.D. Tennessee (2)
- E.D. Texas
- N.D. Texas
- W.D. Texas
- District of Utah
- E.D. Wisconsin

Featured Cases

United States ex rel. Fox Rx, Inc. v. Managed Health Care Associates, Inc., No. 2:13cv6154 (C.D. Cal.) ("Fox I").

United States. ex rel. Fox Rx, Inc. v. Managed Health Care Associates, Inc., No. 2:13cv8433 (C.D. Cal.) ("Fox II")

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Complaints Filed: *Fox I*: August 21, 2013; *Fox II*: November 14, 2013

Complaints Unsealed: *Fox I*: April 14, 2014; *Fox II*: April 11, 2014

Current Status: The court entered Joint Stipulations to Dismiss *Fox I* and *Fox II* on July 21, 2014. (See below for further discussion.)

Intervention Status: The United States declined to intervene in *Fox I* and *Fox II* on April 11, 2014.

Name of Relator: Fox Rx, Inc. ("Fox")

Name of Defendants: Managed Health Care Associates, Inc. and its wholly owned subsidiary, MHA LTC, Inc. (collectively, "MHCA")

Defendants' Business: MHCA is a pharmacy provider to long-term care facilities.

Relator's Relationship to Defendants: Fox is a private Medicare Part D plan sponsor with which MHCA contracted to receive Medicare Part D reimbursement for prescription drugs.

Relator's Counsel: Engstrom, Lipscomb, and Lack

Our featured cases include two *qui tam* actions, unsealed in April, that were brought by serial relator Fox against MHCA. Fox is a private insurer that acts as a federally reimbursed Medicare Part D Plan sponsor ("PDP"). MHCA, in turn, contracts with PDPs like Fox to provide prescription drugs to the PDPs' Medicare Part D beneficiaries through MHCA's network of independent pharmacies. MHCA is one of the largest providers of pharmacy services to long-term care facilities ("LTCFs").

Fox premised its first FCA case and part of its second case against MHCA on an underlying theory that MHCA improperly billed Fox (instead of its LTCF clients) for drugs that MHCA's LTCF clients prescribed to their patients for off-label purposes. Fox argued that because the drugs were prescribed for off-label purposes, they were not medically necessary and thus were not covered by Medicare Part D. As such, Fox alleged that MHCA should have billed its LTCF clients, not Medicare (through Fox), for these prescriptions. According to Fox, the claims that MHCA submitted improperly to Fox for these off-label prescriptions were false claims.

Fox contended that based on the mechanisms through which the Medicare Part D program calculates the amount it will pay for prescription drugs, MHCA's submission of claims for off-label prescriptions directly affected the amount spent by the Centers for Medicare & Medicaid Services ("CMS"). In short, Fox asserted, the more a PDP spends on drugs for each beneficiary, the more the federal government will pay either through (1) the direct monthly capitated payments made to cover the PDP's cost of providing benefits; (2) the low-income cost-sharing subsidy (to cover the federal government's portion of cost-sharing payments for certain low-income beneficiaries); or (3) the reinsurance subsidy that comprises the federal government's share of drug costs for beneficiaries who have reached catastrophic coverage.

Fox also alleged that most Medicare Part D enrollees who reside in LTCFs reach the annual catastrophic coverage trigger, after which the federal government directly reinsures the PDP on an individual enrollee basis against 80% of further prescription drug costs. As such, the majority of LTCF patients enrolled in Medicare Part D have the bulk of their claims reimbursed directly and individually to the PDP by the federal government through catastrophic coverage reinsurance or low-income cost-sharing payments. For those Medicare Part D enrollees who had reached the level of catastrophic reinsurance and to whom MHCA had dispensed off-label prescriptions, MHCA's submission of claims to Fox allegedly caused Fox, in turn, to submit each such false or fraudulent claim for reimbursement to CMS in violation of the FCA.

Fox I

Claims: The relator brought claims against MHCA for various alleged violations of the FCA for false claims, false statements, conspiracy, and "reverse" false claims (under, 31 U.S.C. §§ 3729(a)(1)(A), (B), (C), and (G)), among others, and also accused MHCA of violating the state False Claims Acts of California, the District of Columbia, Florida, New Jersey, New York, and Texas.

Summary of Case: Fox alleged that from 2006 to August 2013, MHCA billed for atypical antipsychotic drugs dispensed to Medicare Part D beneficiaries (1) who did not suffer from a condition for which the U.S. Food and Drug Administration ("FDA") had approved the drugs or (2) who suffered from conditions that were the subject of FDA "black box" warnings (i.e., warnings that patients with certain specified conditions were at an increased risk of death if they used the product bearing the warning). Because there was no medically accepted indication for these prescriptions, Fox argued, the claims should have been

submitted to the LTCF, not the Medicare Part D program (Fox made similar claims regarding Depakote in *Fox II*, discussed below).

Fox further alleged that MHCA was induced to commit the improper dispensing of atypical antipsychotic drugs, and in turn the submission of claims to CMS in violation of the FCA, because MHCA received volume-based rebates directly from the manufacturers of those drugs, which it then shared with its member pharmacies so they would also dispense atypical antipsychotics. According to Fox, MHCA failed to report these rebates to Fox (as it is required to do by Medicare Part D program rules), which would then have reported the rebates to CMS so CMS could take those amounts into account when calculating Medicare Part D beneficiary premium amounts. Fox alleged that MHCA's failure to report these rebates and its payment of rebates to member pharmacies violated the Anti-Kickback Statute ("AKS").

Another alleged AKS violation arose in MHCA's failure to collect required co-payments from beneficiaries in an effort to induce those beneficiaries to purchase or receive prescription drugs. According to Fox, MHCA's knowing submission of claims rendered false by the underlying AKS violations constituted a violation of the FCA.

Fox also accused MHCA of violating the AKS by offering financial inducements to LTCFs to contract with its member pharmacies. Specifically, Fox asserted that by not billing the LTCFs (as it should have) for drugs that were prescribed to beneficiaries for off-label purposes, MHCA incentivized those LTCFs to continue to write off-label prescriptions for atypical antipsychotics.

Fox argued (as it also did in *Fox II*, below) that by submitting such allegedly false claims to Medicare, MHCA affected the amounts paid by CMS on each such claim (based on the mechanisms CMS uses to calculate the amount paid to PDPs under the Part D Program). Fox also asserted that because states are required to pay a portion of the costs associated with providing federal Medicare drug coverage to beneficiaries who are eligible for both Medicare and Medicaid, MHCA's conduct also affected the plaintiff states as a result of their involvement with Medicaid.

Fox II

Claims: The relator brought claims against the defendants for alleged violations of the FCA for false claims; false statements and "reverse" false claims (under 31 U.S.C. §§ 3729(a)(1)(A), (B), and (G)); and also for violations of the state False Claims Acts of California, the District of Columbia, Florida, New Jersey, New York, and Texas.

Summary of Case: Fox alleged that between January 1, 2006 and November 2013 MHCA violated the FCA by submitting claims to Fox seeking reimbursement for dispensing the anticonvulsant Depakote and its generic equivalents to Medicare Part D beneficiaries for off-label uses. MHCA's alleged failure to bill the LTCFs resulted in significant financial benefits to those LTCFs in terms of costs shifted from the LTCF (i.e., MHCA's clients) to the federal government (which, Fox argued, was an unlawful kickback to MHCA's clients that rendered false the resulting claims submitted to Medicare Part D).

Fox also alleged that based on the mechanisms through which the Medicare Part D program calculates the amount it will pay for prescription drugs (explained above), MHCA's submission of claims for Depakote directly affected the amount spent by CMS, as the majority of LTCF patients enrolled in Medicare Part D have most of their claims reimbursed directly and individually to the PDP by the federal government through catastrophic coverage reinsurance or low-income cost-sharing payments. For those Medicare Part D enrollees who had reached the level of catastrophic reinsurance and to whom MHCA had dispensed Depakote, MHCA's submission of claims to Fox allegedly caused it, in turn, to submit each such false or fraudulent claim for reimbursement to CMS in violation of the FCA.

In addition to harming CMS and the federal government, Fox argued that MHCA's practices harmed the plaintiff states because they are responsible for paying a portion of the Medicare Part D coverage of patients who are eligible for both Medicare and Medicaid benefits.

Reasons to Watch: The cases filed by Fox are noteworthy for a few reasons, the first being the relator. While relators in *qui tam* cases come in all shapes and sizes, sponsors of Medicare Part D prescription drug plans have not, in the past, frequently served as relators. Fox, however, appears to have embraced the role of *qui tam* relator, to the point of becoming a serial relator bringing multiple claims against pharmacy providers. One of Fox's other cases was noted in our *November 2013 Qui Tam Update*, in which we discussed an earlier-

unsealed case brought by Fox alleging that Walgreen Company overcharged Fox's subsidiary insurance company, other Medicare Part D plan sponsors, and state Medicaid programs for prescription drug claims dispensed to beneficiaries because Walgreen Company failed to substitute generic drugs for brand-name drugs in states that require such substitution and submitted claims for drugs that were expired in violation of state and federal laws.[3]

While Fox asserts a different theory of liability in the instant cases, these are not the first cases in which Fox has alleged that an LTCF pharmacy provider has violated the FCA by seeking reimbursement under Medicare Part D for prescriptions written for off-label uses. Fox filed similar claims against Omnicare, Inc. in a suit initiated in March 2011. In that case, Fox accused Omnicare of engaging in various schemes across the country to defraud the Medicare Part D program by seeking reimbursement for prescriptions for atypical antipsychotic drugs for off-label use (the same claims it made in *Fox I*). In late May 2014, the U.S. District Court for the Northern District of Georgia granted Omnicare's motion for summary judgment on the grounds that the evidence Fox presented did not support its claim that Omnicare knowingly submitted to CMS false claims for thousands of off-label prescriptions for atypical antipsychotics. This ruling, in turn, prompted Fox (and MHCA) to agree to the Joint Stipulations of Dismissal entered in *Fox I* and *II*.[4]

While it is notable that the United States has declined to intervene in each of these cases — and perhaps more notable that Fox entered into Joint Stipulations of Dismissal in both *Fox I* and *II* — the fact that one PDP sponsor has served as the relator in at least four *qui tam* cases (three of which were unsealed within the last eight months) may signal a growing willingness on the part of some PDPs to bring FCA enforcement actions.

Other Recently Unsealed Cases

United States ex rel. Angel v. Alliance Rehabilitation LLC, No. 1:10cv2124 (D.D.C.).

Complaint Filed: December 16, 2010

Complaint Unsealed: April 7, 2014

Current Status: Joint Notice of Voluntary Dismissal and Settlement entered on April 7, 2014.

Intervention Status: The United States intervened in part on April 4, 2014 for the purpose of effectuating the Settlement Agreement. The government did not file a complaint.

Name of Relators: Kathya Angel and Alexis Natal

Defendants' Business: The defendants provide physical therapy services in Washington, D.C., Maryland, and Virginia and include five corporate entities and three associated individuals.

Relators' Relationship to Defendants: Former employees

Relators' Counsel: The Employment Law Group

Claims: Among other things, the relators brought claims against the defendants for alleged violations of the FCA for false claims, false statements, and conspiracy (under 31 U.S.C. §§ 3729(a)(1)(A), (B), and (C)), and also for retaliation (31 U.S.C. § 3730(h)).

Summary of Case: The relators alleged that the defendants engaged in fraudulent and improper billing practices when submitting claims to the Medicare and TRICARE programs. The allegations included assertions of billing for work performed by unlicensed providers and other unqualified personnel, "upcoding" or misrepresenting services provided, submitting claims for services never provided, and recommending services that were not in the patient's best interests (i.e., "not medically necessary").

Ultimately, the government chose to intervene in part to effectuate a settlement, and the parties agreed to a joint voluntary dismissal. The defendants agreed to pay the United States $2.78 million to settle allegations that the defendants had falsely represented that the physical therapy services being billed were rendered or supervised by the provider whose National Provider Identifier ("NPI") was listed on the claim, when, in some cases, the provider identified had no involvement in the treatment.

The defendants also entered into a five-year Corporate Integrity Agreement ("CIA") with the Office of Inspector General for the Department of Health and Human Services ("OIG"). Among other obligations, the CIA requires the defendants to obtain an independent review of coding, billing, and claims submissions to federal health

care programs.

Reasons to Watch: This case is yet another example of a Settlement Agreement being filed promptly after the unsealing of a *qui tam* complaint. It should be noted that the resulting CIA imposes obligations on both the corporations and the three individual defendants. This case is also interesting as an example of a *qui tam* relator being represented by what is nominally — and in this case, quite literally — an employment law firm. Many whistleblowers start out as disgruntled current and former employees. Plaintiff-side employment law firms are increasingly capitalizing on that dynamic to bring whistleblower claims in addition to traditional discrimination or wrongful termination actions. Growth in the number of *qui tam* actions being filed may both incentivize and be fueled by entry of traditional employment firms into the field of whistleblower litigation.

United States ex rel. Madany v. Shahab, No. 2:09-cv-13693 (E.D. Mich.)

Complaint Filed: September 17, 2009 (original); May 14, 2014 (Complaint in Intervention)

Complaint Unsealed: April 30, 2014

Current Status: Pending

Intervention Status: The United States intervened in part against a subset of the named defendants (24 individual defendants and 8 home health service providers) on April 17, 2014. The relators dismissed their claims against the remaining individual and corporate defendants against whom the government did not intervene on July 7, 2014.

Name of Relators: Ruqiayah Madany and John B. Collins

Defendants' Business: Multiple home health corporations and their individual owners and operators in the Detroit metropolitan area, as well as hundreds of named and unnamed individual physicians, physical therapists, patients, patient recruiters, and marketers/consulting entities for these entities who were allegedly involved in the scheme.

Relators' Relationship to Defendants: Employees (billing and administrative staff)

Relators' Counsel: Vezina Law, PLC and Nacht, Roumel, Salvatore, Blanchard & Walker, P.C.

Claims: Among other things, the relators brought claims against the defendants for alleged violations of the FCA for false claims, false statements, conspiracy, concealment of an obligation to repay the government (31 U.S.C. §§ 3729(a)(1)(A), (B), (C), and (G)), and for common law unjust enrichment.

Summary of Case: The relators alleged that the defendants submitted false claims for home health services based on underlying violations of the AKS. Specifically, the relators accused the principal defendants both of conspiring to provide kickbacks to a vast network of marketers, patient recruiters, and physicians, and also of engaging in a complex patient transfer scheme that allowed the owners of the various home health agencies ("HHAs") to "churn" patients from agency to agency (or from facility to facility) based on false certifications of eligibility for home health services. In addition, the home health providers involved in the scheme allegedly often did not provide the services they claimed patients received, inflated the level of services provided to patients, and filed false cost reports with the government. The alleged churning of patients among the conspiring home health providers also concealed that patients were receiving multiple 60-day episodes of home care without being properly certified or recertified for such services. Relators asserted FCA claims premised on both false certification of compliance with federal law (due to the purported illegal kickbacks) and factually false claims (based on billing for services allegedly not provided or billing for different and more expensive services than those actually provided).

Reasons to Watch: This case exemplifies the government's continuing focus on HHA-related fraud schemes. The relators in this case alleged a large-scale conspiracy closely resembling past cases that the Medicare Fraud Strike Force ("Strike Force") for the Eastern District of Michigan pursued and won. The government has focused its investigatory resources on large-scale investigations to get "more bang for the buck" and to maximize public visibility of health care fraud enforcement efforts. For instance, in the most recent "mega-takedown," the Strike Force charged 90 individuals who were purportedly responsible for $260 million in false billings to federal health care programs. [5] Seven of these 90 individuals were located in Detroit and were charged for their roles in fraud schemes involving approximately $30 million in false claims for medically unnecessary services, including home health services, psychotherapy, and infusion therapy. It is unclear

whether this case was linked to the existing Strike Force's efforts or whether it was brought to the government's attention independently.

Of note, the government whittled down the number of defendants in the case in electing to intervene only in part.

United States ex rel. Brown v. Holy Spirit Hospital of the Sisters of Christian Charity, No. 1:12-cv-1197(M.D. Pa.)

Complaint Filed: June 22, 2012

Complaint Unsealed: May 15, 2014

Current Status: Dismissed

Intervention Status: The United States declined to intervene on May 14, 2014.

Name of Relators: Natalie Brown and Renee Connor

Defendants' Business: Holy Spirit Hospital of the Sisters of Christian Charity is an acute care, nonprofit hospital operating in Camp Hill, Pennsylvania. The relators also sued Holy Spirit Health System, which owns and operates Holy Spirit Hospital, and Quantum Imaging and Therapeutics Associates, Inc., which provides physician services for interpreting nuclear imaging studies.

Relators' Relationship to Defendants: Brown and Connor are former employees of Holy Spirit Hospital. Brown was the hospital's Charge Master Coordinator and Connor worked as the Denial Management Coordinator.

Relators' Counsel: Kline & Specter, PC

Claims: The relators brought claims against the three defendants for alleged violations of the FCA for false claims, false statements, and "reverse" false claims (31 U.S.C. §§ 3729(a)(1)(A), (B), and (G)).

Summary of Case: The relators independently discovered that Holy Spirit Hospital had been allegedly improperly billing several diagnostic tests without actually performing them. After notifying colleagues of these alleged improprieties, the relators contended that the administration decided to stop billing for the tests, but also decided not to repay the government. The complaint alleges that, in response to a discussion about repaying the government, one relator's supervisor supposedly commented, "[i]f they want it, they can come get it."

The relators alleged that Holy Spirit Hospital engaged in what was called "explode billing" or "bundling." They asserted that the hospital's radiology department would always bill for a certain diagnostic test, in addition to three underlying imaging examinations. However, the radiology personnel would allegedly only perform the underlying examination, not the additional diagnostic test. Automatically pairing this unperformed diagnostic test with the imaging examination allegedly led to overpayments by the government. The relators also contended that the Emergency Department and Sleep Diagnostic Center would bill for unperformed diagnostic tests, for which Holy Spirit Hospital never repaid the government.

Reasons to Watch: The relators in this case asserted that Holy Spirit Hospital acknowledged that several of its billing practices resulted in overpayments by the government but chose not to report or repay that amount. Although Holy Spirit Hospital did end those allegedly problematic billing practices, it still faces potential liability under the FCA for failing to report the overpayment to the government within 60 days. For entities that encounter an internal report of potential overpayment, this case may serve as another factor to consider: not only should the practices resulting in overpayment be stopped, but also the overpayment should be reported and refunded within 60 days to avoid potential FCA liability.

United States ex rel. Mahmood v. Elizabethtown Hematology Oncology, PLC, et al., No. 3:11-cv-00376 (W.D. Ky.).

Complaint Filed: June 27, 2011

Complaint Unsealed: June 3, 2014

Current Status: Settled on June 3, 2014

Intervention Status: The United States intervened (but the date of intervention is unclear because part of the docket is still sealed).

Name of Relator: Dr. Ijaz Mahmood

Defendants' Business: The defendant Elizabethtown Hematology Oncology, PLC is a health care provider specializing in the treatment of medical conditions related to hematology and oncology. Individual defendants are doctors and partners at Elizabethtown.

Relator's Relationship to Defendants: Dr. Mahmood was formerly employed as a hematologist/oncologist at Elizabethtown.

Relator's Counsel: Caudill Law Firm

Claims: The relator brought claims against the defendants for alleged violations of the FCA for false claims and conspiracy to submit false claims (under 31 U.S.C. §§ 3729(a)(1) and (3)) and also for an AKS violation (under 42 U.S.C. § 1320a-7(b)(1) and (2), and § 1395nn).

Summary of Case: Elizabethtown Hematology Oncology, PLC, and its owners agreed to pay $3.7 million to resolve allegations that they submitted or caused to be submitted false claims to the Medicare, Medicaid, TRICARE, and the Federal Employee Health Benefit Program ("FEHBP") for unnecessarily extending the duration of chemotherapy infusion treatments to patients and inappropriately billing office visits for infusion therapy treatments. The relator will receive $283,412 as part of the settlement.

Specifically, according to the settlement agreement, the United States and the Commonwealth of Kentucky alleged that, from January 1, 2005 through December 31, 2010, the defendants billed Medicare, Medicaid, TRICARE, and FEHBP for unnecessary office visit evaluations at the same time patients were receiving chemotherapy or other types of infusion treatments. The defendants allegedly did this by improperly billing evaluation and management codes using Modifier-25, which allows for billing evaluation and management necessary prior to the performance of a procedure.

The United States and the Commonwealth of Kentucky also alleged that, from January 1, 2006 through December 31, 2012, the defendants unnecessarily and improperly extended the duration of chemotherapy infusion treatment times for their patients in order to improperly bill Medicare, Medicaid, TRICARE, and FEHBP for the additional hours of chemotherapy infusion treatments. As part of his *qui tam* lawsuit, the relator alleged that the defendants developed written protocols that increased chemotherapy infusion times by a factor of three or more beyond generally recognized standards of medical practice.

In addition to the $3.7 million payment, Elizabethtown Hematology Oncology entered into a three-year CIA with the OIG. The agreement requires enhanced accountability and wide-ranging monitoring activities, to be conducted by both internal and independent external reviewers.

Reasons to Watch: This settlement is noteworthy for several reasons. First, the nature of the alleged conduct — manipulating cancer treatment protocols to unsafe levels in order to increase reimbursement — is, as stated by the government, "utterly unconscionable." The conduct described in the relator's complaint likely contributed in part to the government's decision to intervene.

Second, as stated above, the alleged conduct involved the extension of actual services rendered and the provision of potentially unnecessary evaluation services. By intervening, the government put itself in the position of having to prove what treatments and evaluations were medically necessary and appropriate.

Third, this settlement is a worthwhile reminder that the FCA applies not only to Medicare and Medicaid, but also to all other government payors, including TRICARE, which covers uniformed service members and their families, and FEHBP, which covers federal government employees.

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.

Endnotes

[1] Please note that due to overlap in categories discussed below, the sum of the totals for the various sub-categories of cases addressed below does not add up to 65 cases.

[2] These 12 cases dismissed pursuant to a Settlement Agreement are not included in the 18 cases listed as having been dismissed prior to settlement.

[3] In yet another case, Fox filed suit in January 2012 against Omnicare Inc. and NeighborCare Inc. ("Omnicare"), PharMerica Corp., and MHA Long Term Care Network (a named defendant in *Fox I* and *II*), all of which provide drugs to long-term-care facilities, accusing them of violating the federal False Claims Act and state false claims laws by not providing generics when they were requested and by dispensing expired drugs (*United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 1:12-cv-00275-DLC (S.D.N.Y.)). The U.S. District Court for the Southern District of New York dismissed the suit and rejected Fox's theory that by engaging in such practices (which were prohibited by state law), the defendants had falsely indicated in submissions to a federal agency that the drugs they dispensed were covered by Medicare. The court dismissed the Fox claim in reliance on settled Second Circuit precedent, first established in *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001), holding that a claim based on an implied false certification is only actionable if the underlying statute or regulation explicitly conditions payment on a provider's compliance with that statute or regulation. *See Court Dismisses Lawsuit Alleging Pharmacies Submitted False Claims*, BNA Bloomberg Health Law Resource Center (Aug. 14, 2014), http://healthlawrc.bna.com/hlrc/4225/split_display.adp?fedfid=51545069&vname=hcenotallissues&jd=a0f4q2d4e1&split=0.

[4] *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, No. 1:11-cv-00962-WSD (N.D. Ga.). *See also* Joint Stipulation of Dismissal, *United States ex rel. Fox Rx, Inc. v. Managed Health Care Associates, Inc.*, No. 2:13cv6154 (C.D. Cal.); Joint Stipulation of Dismissal, *United States ex rel. Fox Rx, Inc. v. Managed Health Care Associates, Inc.*, No. 2:13cv08433 (C.D. Cal.).

[5] Press Release, "Medicare Fraud Strike Force charges 90 individuals for approximately $260 million in false billing," (May 13, 2014) *available at* http://www.hhs.gov/news/press/2014pres/05/20140513b.html. Detroit, in fact, is one of the cities subject to the six-month moratorium on new HHA provider enrollment in the Medicare program. Centers for Medicare & Medicaid Services, "Second wave of CMS' enrollment moratoria extended for home health and ground ambulance suppliers; four new geographic areas added, (Jan. 30, 2014) *available at* http://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-Releases/2014-Press-releases-items/2014-01-30-2.html

4338-1014-NAT-HL