

Mintz Levin Health Care *Qui Tam* Update

Recent Developments & Unsealed Cases

MARCH 2015

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Trends & Analysis

- We have identified 19 health care–related *qui tam* cases unsealed in November and December 2014. Of those cases, 17 were filed from 2012 to the present. The remaining two cases were filed in April 2008 and May 2011.
- These 19 cases were filed in federal district courts in 13 states. Five of the unsealed cases were filed in the Middle District of Florida.
- Unsealed filings show that the government affirmatively declined intervention in 10 of those 19 recently unsealed cases. The government intervened – sometimes in part – in 3 of the cases, and the government’s intervention was unclear from the unsealed filings in the remaining 6 cases.
- Subject matter of claims:
 - Ten of the 19 recently unsealed cases involved both state and federal claims.
 - Claims for relief under state or federal anti-whistleblower retaliation provisions appeared in 3 of the recently unsealed cases.
- Almost 70% of the relators were current or former employees of the defendants.

Featured Unsealed Cases

[United States ex rel. Fox Rx, Inc. v. Managed Health Care Associates, Inc., No. 2:14-cv-00073-JLR \(W.D. Wash.\)](#)

Complaint Filed: January 16, 2014

Complaint Unsealed: November 26, 2014

Intervention Status: The government declined to intervene on November 19, 2014.

Claims: Falsely billing for Schedule II prescription drugs that were dispensed without a proper prescription, in violation of the Civil False Claims Act (FCA), 31 U.S.C. § 3729 and the false claims acts of Colorado, Connecticut, Florida, Massachusetts, New Jersey, New York, North Carolina, Virginia, and Washington.

Name of Relator: Fox Rx, Inc.

Defendants’ Business: Managed Health Care Associates, Inc. (“MHA”) is one of the country’s largest pharmacy services providers, with a significant part of its business focused on providing pharmacy services to long-term care facilities, including nursing homes. MHA contracts with insurers to fill prescriptions and then

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submit a claim to the insurer for payment. Medicare Part D is the primary payor of prescription drugs for many of the beneficiaries residing in long-term care facilities, such as the ones serviced by MHA.

Relator's Relationship to Defendant: Defendant MHA was the pharmacy services provider for Relator Fox Rx, Inc., which is a Medicare Part D Plan Sponsor.

Relator's Counsel: Hagens Berman Sobol Shapiro, LLP (Seattle, WA).

Summary of Case: Relator Fox Rx alleges that MHA submitted claims for Schedule II controlled substances that were dispensed by MHA without a proper prescription. MHA is responsible for the dispensing and billing of pharmaceutical products for long-term care facility residents where the facility has contracted with MHA for pharmacy services. Like all pharmacy services providers, MHA must comply with several legal obligations before dispensing and billing for controlled substances. Schedule II controlled substances are the most tightly regulated class of drugs, and include drugs such as oxycodone and fentanyl. To dispense Schedule II controlled substances, the pharmacist must have a proper prescription that includes a DEA registration number. This prescription is also necessary for the payor to reimburse for the cost of the drug. Despite this legal requirement, MHA allegedly dispensed and billed for Schedule II controlled substances that lacked valid prescriptions and so were not covered by Medicare Part D.

Relator Fox Rx asserts that, from 2008 to the date of the complaint, MHA submitted or caused the submission of claims for reimbursement for thousands of Schedule II controlled substances provided without valid, lawful prescriptions to elderly Medicare Part D beneficiaries residing in long-term care facilities. MHA allegedly caused the filing of false claims by characterizing these drugs as "covered," despite the absence of a proper prescription. The percentage of these allegedly improper claims for payment reached upwards of 50% in certain states. Relator Fox Rx contends that it learned of these improper claims after performing a comprehensive data audit that revealed that MHA had submitted claims for reimbursement for drugs that were provided without proper prescriptions. Because MHA is one of the nation's largest pharmacy services providers, Relator Fox Rx alleges that the damage to Medicare Part D could be vast.

Current Status: The government has declined to intervene, the court has unsealed the pleadings, and the case is currently pending with the relator litigating on behalf of the United States

Reasons to Watch: Fox Rx, described by one federal judge as a "serial *qui tam* relator," has brought a number of *qui tam* cases nationwide under various theories alleging that pharmacies that had dispensed drugs to participants in Fox Rx's Medicare Part D plans had engaged in practices that had caused false claims to have been submitted to the federal government in violation of the FCA. Two previous cases against MHA – both of which resulted in government declinations – were profiled in the [October 2014 Mintz Levin Health Care Qui Tam Update](#). A third case brought jointly against MHA, Omnicare, Inc., Neighborcare, Inc., and Pharmacia Corp. resulted in dismissal of Fox Rx's claims and, in addition to eliciting the above-quoted description of Fox Rx as a serial relator, led to an award of sanctions against Fox Rx for bringing a claim that "was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment." [United States ex rel. Fox Rx, Inc. v. Omnicare, Inc., No. 1:12-cv-00275-DLC, slip op. at 2 \(S.D.N.Y. Dec. 1, 2014\)](#). Still another case brought by Fox Rx against Walgreen was profiled in the [November 2013 Mintz Levin Health Care Qui Tam Update](#).

As we have previously commented in this space, the billing practices of long-term care facilities continue to spawn false claims litigation, in part because most residents in such facilities are beneficiaries of Medicare or Medicaid. Entities involved in billing for long-term care facilities should expect that they may be scrutinized for FCA violations, by the government or other business entities, as in this case.

One other development of potential interest is Fox Rx's choice of counsel in this latest case. The Hagens Berman firm is primarily known for class action litigation focused on consumer protection, unfair business practices, and antitrust cases. Significantly, many of Hagens Berman's class actions have targeted the pharmaceutical industry, including both litigation alleging fraudulent practices stemming from the setting of Average Wholesale Prices for prescription drugs and numerous antitrust cases involving alleged conspiracies between branded and generic drug manufacturers to delay entry of generic drugs into the marketplace. They have also been active in the *qui tam* area for several years and so Fox's choice of representation may signal an effort to add a veneer of credibility to its remaining *qui tam* cases.

United States ex rel. Rew v. Mission Health of Georgia, LLC, No. 8:14-cv-00648-JSM-MAP (M.D. Fla.)

Complaint Filed: March 17, 2014

Complaint Unsealed: December 1, 2014

Intervention Status: The intervention status is unclear from the public filings.

Claims: Falsely certifying that the various nursing homes and assisted living facilities under Mission Health's corporate umbrella had obtained and kept on file certifications of need for skilled nursing care, in violation of the federal False Claims Act.

Name of Relators: Leslie Rew

Defendants' Business: There are 32 defendants in this action, 28 limited liability corporations and the 4 individuals who run and own those corporations. The defendants operate nursing homes and assisted living facilities throughout the southern United States. Defendant Mission Health of Georgia provides management services to the other corporate defendants.

Relators' Relationship to Defendants: Relator Leslie Rew is a registered nurse and was employed by one of the defendants, Mission Health of Georgia, as its Vice President of Clinical Reimbursement.

Relators' Counsel: Kwall, Showers & Barack, P.A. (Clearwater, FL)

Summary of Case: Relator Leslie Rew was formerly employed by Mission Health, which manages the other corporate defendants. Because the defendants' nursing homes and assisted living facilities bill Medicare, the program's regulations require that they obtain from an attending physician or physician on staff a certification of need for skilled nursing care for each admitted beneficiary for whom Medicare reimbursement is sought. The first certification is required no later than 14 days after inpatient care services have started, and recertification must occur every 30 days thereafter. Nursing homes and assisted living facilities do not transmit these certifications to Medicare, but rather certify that the required physician certifications have been obtained and are on file.

Relator Leslie Rew alleges that the defendants did not obtain these required certifications from 2008 through May 2010. This, the relator contends, would render any services provided during this time medically unnecessary and thus uncovered by Medicare. The relator asserts that she urged the defendants to determine if the certifications had been obtained and to refund payments if necessary, but the defendants refused. Because of this alleged failure to obtain the proper certifications, the relator charges that the defendants received \$32 million in Medicare reimbursement without the requisite documentation of the need for care.

Current Status: The Complaint has been unsealed and the case is currently pending.

Reasons to Watch: As we have previously remarked in this space, the United States has demonstrated its close monitoring of, and ongoing interest in, the billing practices of SNFs. As we have observed before, 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."

For more information, including details relating to the above cases, please contact [Hope S. Foster](mailto:HSFoster@mintz.com) 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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4751-0315-NAT-HL