Health Law Alert: Department of Justice Intervenes in False Claims Act Case Naming Private Equity Firm as Co-Defendant

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In February 2018, the Department of Justice (DOJ) intervened in a False Claims Act (FCA) case accusing a compounding pharmacy, and its private equity fund owner, of paying illegal kickbacks to induce prescriptions for compounded drugs reimbursed by TRICARE, a federally funded health care program for military personnel and their families. This case sends an alarming message to companies that invest in health care, as it demonstrates that the DOJ is not afraid to hold investors directly liable for compliance with complex health care laws and regulations. It also shows that DOJ will take action under the FCA and Anti-Kickback Statute even where Medicare or Medicaid payments are not involved.

I. The Allegations

The lawsuit, *United States ex rel. Medrano et al. v. Diabetic Care RX, LLC d/b/a Patient Care America et al.*, was originally filed by two former employees of the compounding pharmacy (PCA). The complaint alleges that in July 2012, private equity firm Riordan, Lewis & Haden (RLH) invested in PCA with the goal of increasing PCA's value and selling it for a profit within five years.

Although PCA's business was originally focused on providing intravenous nutritional therapy to end stage renal disease patients who received dialysis, PCA and RLH decided to pursue a new product line—compounding topical creams, including pain creams, scar creams, and vitamins. PCA's CEO hired a licensed pharmacist, Matthew Smith, to lead the new topical compounding business.

According to the complaint, PCA and RLH used Mr. Smith's connections to generate referrals. Notably, PCA entered into contracts with three marketing companies under which the marketing firms agreed to solicit orders for PCA, market PCA's products, and complete prescriptions on patients' behalf. In exchange for this work, PCA agreed pay the marketing firms a commission of 50% of the profit made on each referral.

The DOJ alleges that the Defendants and its marketers manipulated the compound formulas to ensure the highest possible reimbursement from TRICARE. The DOJ also claims that the Defendants paid telemedicine physicians to prescribe the creams and vitamins without seeing patients, and even paid patients themselves to accept the prescriptions. In addition, the DOJ alleges that PCA formed a charity with

one of the marketing firms to pay for patient co-pays if the patient was hesitant to make an order because of associated upfront costs. This charity consisted of PCA expensing 100% of the co-payment and then requesting the marketing firm to send cashier's checks to PCA to cover half of those expenses.

The alleged kickback scheme generated a significant amount of revenue in a short amount of time. From September 2014 through August 2015, PCA generated more than $68 million in reimbursements from TRICARE.

II. DOJ Intervention

The lawsuit was filed under the qui tam (also known as "whistleblower") provisions of the FCA, which permit private parties to sue for false claims submitted to the United States and to receive a significant share (up to 25%) of any recovery. The FCA's qui tam provisions have been highly lucrative for many individuals who have filed these cases. In 2017, the federal government recovered $3.4 billion from lawsuits filed under the qui tam provisions of the FCA; $392 million of this was awarded to the individuals that filed these cases. The FCA permits the United States to "intervene," or join the lawsuit as a party, in such cases. The DOJ typically only does so after investigating the allegations to determine whether they may, in the DOJ's opinion, have merit.

In this case, claims were brought against PCA, RLH, and two of PCA's chief executives. The government alleges that all defendants knew their actions implicated federal fraud and abuse laws, including the federal Anti-Kickback Statute. PCA and RLH were familiar with such laws, and allegedly received complaints from patients that they had not ordered the creams they received or ever spoken to the prescribing physician. In addition, PCA and RLH were advised by their attorneys that they should not be billing government programs for prescriptions referred by the marketing firms.

III. Implications for Private Equity Firms and Other Investors

This case marks a significant shift in health care enforcement. Although private equity firms have, on a few occasions, been involved in FCA cases, to our knowledge this is the first time the DOJ has named a private equity firm as a co-defendant.

The decision to name RLH is likely due, in part, to the level of control and oversight RLH had over PCA operations and the alleged kickback scheme. That said, it serves as a strong reminder that investors are not shielded from liability under the FCA. This is particularly troubling for investors that are new to the health care industry, and therefore unfamiliar with the complex laws and regulations that apply. Business arrangements or marketing practices that may be legitimate in other markets are often illegal in the health care field. Health care investors must ensure that their control and management of a company does not violate fraud and abuse laws and, at the very least, must be familiar with the unique regulatory environment

to which they are subject. Investors should understand that any time reimbursement from any "federal health care program" is part of their business model, a significant level of regulation is likely to apply.

In addition, while Medicare and Medicaid tend to get most the of the attention in health care fraud enforcement, the Anti-Kickback Statute, the False Claims Act and many other important federal health care laws apply to many other "federal health care programs" (like TRICARE). As a result, business strategies that seek to "carve out" Medicare or Medicaid are not always a path to compliance.

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