Guidance to Avoid FCA Liability for Firms Investing in Healthcare

May 8, 2018 Neil Issar

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The United States recently intervened in a lawsuit alleging that a pharmacy violated the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (FCA), by paying millions in kickbacks to marketers and submitting false claims for medically unnecessary prescriptions. Notably, the lawsuit named as a defendant the private equity firm that owns the pharmacy based on the firm's involvement in the alleged kickback scheme and the pharmacy's management. The government's intervention indicates that firms investing in healthcare companies could be liable under the FCA and, therefore, must exercise best practices and conduct due diligence with respect to the management of portfolio companies.

Key Points

- In an unusual case, the government filed a complaint against a pharmacy, its private equity firm majority owner and two principals of that firm based on a kickback scheme conducted by the portfolio company.
- The private equity firm's conduct was directly related to the scheme – its partners allegedly directed the change in strategy to focus on high reimbursing product lines such as compounded pain creams, scar creams, and vitamin supplements and directly funded commission payments that led to medically unnecessary claims.
- The conduct alleged demonstrates the high legal bar for a portfolio healthcare company to create FCA liability for its owners but highlights the risk that exists for investors in this industry. That risk can be minimized by taking some key precautions when investing in healthcare companies.

Background

On March 7, 2016, two former employees of Diabetic Care Rx, LLC d/b/a Patient Care America (PCA), a compounding pharmacy located in Florida, filed a *qui tam* suit alleging that PCA violated the FCA by paying approximately $40 million in kickbacks to marketing agencies in exchange for securing TRICARE patients.[1] The defendants allegedly paid telemedicine doctors to issue medically unnecessary prescriptions for compounded pain creams, scar creams, and vitamins and waived patients' copayments to induce them to accept the prescriptions. After two years of investigation, the government filed a complaint in intervention against the defendants on February 16, 2018.

Notably, the government's complaint named two pharmacy executives and the private equity firm that owns a controlling interest in PCA as defendants in the action.[2] The government's complaint alleges that the private equity firm conspired with PCA, approved and bankrolled the alleged kickback scheme, and was actively involved in PCA's management. For example, after it purchased

PCA for $25 million in 2012, the complaint alleges that the private equity firm shifted the pharmacy's focus towards compounded topical drugs to take advantage of high federal reimbursement rates and installed two of its partners as PCA officers and board members. These partners were allegedly involved in the payment of independent marketers as well as the selection and hiring of PCA executives.

Practical Takeaways

The government's intervention in the case against PCA should serve as a reminder that FCA liability may apply to any person or entity that "causes" a false claim to be submitted, and not just to those that submit claims themselves. The press release accompanying the government's complaint noted that the Department of Justice sought to hold liable all entities that paid kickbacks to maximize reimbursement at the expense of taxpayers and federal healthcare beneficiaries, including pharmacies *and those companies that manage them*.[3]

This means private equity firms, venture capitalists, and individual owners should be particularly conscientious about FCA compliance if they actively manage their portfolio companies' strategies, operations, or board decision-making. Taking preventative steps in the purchase, sale, and management of these companies can minimize this risk.

These include:

- When conducting due diligence, obtaining legal analysis of business structures, particularly those involving sales, marketing, payment of commissions, and financial relationships with healthcare providers or referral sources.
- Ensuring portfolio companies have adequate internal compliance policies and procedures to identify problematic conduct or business relationships, especially if the healthcare company participates in federal government programs.
- Carefully scrutinizing relationships with healthcare providers, marketing agents, or company executives that are based on revenue or referral volume.
- Comparing portfolio companies' product or service offerings to published government enforcement priorities.
- Obtaining experienced legal counsel with healthcare expertise, whether in-house or externally, to support management and board members.

While the PCA case is likely an unusual case that will remain an outlier in healthcare enforcement, taking appropriate measures to ensure compliance and being proactive in due diligence will help protect investors against FCA liability while still allowing them to add value to their portfolio companies through control and oversight.

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[1] The case is *United States ex rel. Medrano v. Diabetic Care Rx, LLC*, No. 15-CV-62617 (S.D. Fla.).

[2] The complaint did not name as defendants' minority owners of PCA.

[3] *See* Press Release, Dep't of Justice, United States Files False Claims Act Complaint Against Compounding Pharmacy, Private Equity Firm, and Two Pharmacy Executives Alleging Payment of Kickbacks (Feb. 23, 2018).