PE Firms Should Prepare For Increased False Claims Scrutiny

By **Christopher Nasson, Hayley Trahan-Liptak and Anna L'Hommedieu** (August 5, 2024)

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Private equity investment in healthcare has grown significantly over the past two decades, and the U.S. government is starting to pay attention. Recent announcements by the U.S. Department of Justice and proposals by Congress and state attorneys general show that the impact private equity firms may have over medical decisions and care is increasingly under scrutiny.

The False Claims Act appears to be the first avenue of enforcement, but private equity firms should be prepared for state investigations and congressional action as government focus gains steam.

FCA Enforcement Against Private Equity in Healthcare

Claims brought under the FCA by both the DOJ and private parties, known as relators, have proliferated in recent years. Fiscal year 2023 saw a record number of FCA settlements and judgments, 543, and civil investigative demands, 1,504, with $2.7 billion recovered by the DOJ.[1]

The FCA allows for treble damages and penalties, creating massive exposure in these cases and major payments for the government and relators. Healthcare has consistently represented the largest focus of enforcement under the FCA and has accounted for the highest recovery.[2] This focus on healthcare has continued to grow.

On June 27, the DOJ announced the National Health Care Fraud Enforcement Action, which included charging 193 defendants for a variety of alleged healthcare fraud schemes involving billions in alleged losses. And earlier in the year, DOJ announced that private equity involvement in the healthcare sector will be a priority moving forward.[3]

The FCA imposes liability for knowingly submitting, or causing to submit, false claims to the government. While traditionally DOJ focused on parties that knowingly submitted claims,the DOJ is increasing directing its attention to parties that fall in the latter category — those that "cause the submission" of false claims.

Courts have found that a defendant "causes" a submission of a false claim if the conduct was a substantial factor inducing submission of the claim, and the submission was reasonably foreseeable as a result of the conduct.[4]

Under this standard, even if private equity firms are not themselves submitting claims to the government, their actions may still subject them to liability under the FCA.

Take, tor example, in the U.S. v. Diabetic Care matter, which was resolved in 2019 in the U.S. District Court for the Southern District of Florida.

There, the DOJ brought FCA claims against a compounding pharmacy, its private equity firm manager and two executives of the pharmacy on the theory that the firm and its officers caused the company to implement a business strategy aimed to create kickbacks and submit false claims to the government for reimbursement.[5]

The private equity firm allegedly knew of the plan and paid for the kickbacks.

Holding third parties accountable, specifically private equity firms, through FCA enforcement is one of DOJ's strategic priorities.

In February remarks, the principal deputy assistant attorney general called out the influence private equity firms can have on healthcare providers, from setting benchmarks and revenue targets to express direction to prioritize reimbursement.

Such influence may impact medical judgment and subsequent billing and claim submission. This new target increases the possible liability for third parties who do not themselves submit the false claims to the government.

Senate Bill Highlights New Focus on PE Healthcare Investments

The DOJ is not alone in its focus on private equity in the healthcare industry. On June 11, Massachusetts Senators Ed Markey and Elizabeth Warren, both Democrats, introduced the Corporate Crimes Against Health Care Act, aimed specifically at private equity investors in the healthcare industry.[6]

Key aspects of the bill would include requiring healthcare providers that receive federal funding to publicly report changes in ownership and financial data, allowing regulators to claw back executive compensation if the purchased entities experience "serious, avoidable, financial difficulties," and creating criminal penalties where so- called private equity looting of the healthcare entities results in a patient's death.

The bill follows the opening of a bipartisan investigation by the Senate Budget Committee into private equity ownership at hospitals across the country.[7] Some state legislatures are also moving to regulate private equity investment in the healthcare industry.

Last year, New York enacted a law requiring qualifying healthcare entities to publicly disclose material transactions to the New York Department of Health to review and publish for public comment.[8]

Meanwhile, a pending California bill would allow the attorney general to grant, deny or prescribe conditions on ownership and control changes between equity groups and healthcare entities, while in Massachusetts a pending healthcare oversight bill would ban hospitals from leasing buildings from real estate investment trusts.[9]

Other State and Federal Action Aimed at Private Equity Investments

The DOJ's Antitrust Division, the Federal Trade Commission and the U.S. Department of Health and Human Services issued a request for information seeking public comment on the effect of private equity and other private payor transactions involving healthcare providers.[10]

The RFI cited three practices of private equity funds in the healthcare space that were of particular interest:

- Investors buying multiple competitors in the field, leading to limited competition;
- Serial acquisitions to roll up the market; and
- Purchasing facilities for a quick resale.

In response to this request for comment, 11 state attorneys general joined in submitting a comment laying out their concerns and urging the FTC, DOJ and HHS to curb conduct by these investors.[11] The recommendations from the state attorneys general include:

- Implementing more mechanisms for transparency of private equity ownership and payments associated with healthcare services;

- Prohibiting anticompetitive contractual provisions affecting healthcare services; and

- Coordinating state and federal efforts to maximize enforcement against conduct.

Circuit Split on Applicable Causation Standard

With the increased focus on private equity healthcare investments, it is important to highlight that the scope of the FCA is not settled law. Courts are split over the standard to apply in determining whether claims "resulting from" kickbacks are actionable under the FCA.[12]

A 2010 amendment to the Anti-Kickback Statute expanded liability under the FCA, adding that "claim[s] that include items or services resulting from a violation" of the AKS are also false or fraudulent claims under the FCA.[13]

The U.S. Court of Appeals for the Third Circuit has held plaintiffs only need to prove a causal link between kickbacks and medical care, while the U.S. Court of Appeals for Eighth Circuit and the U.S. Court of Appeals for the Sixth Circuit have interpreted the "resulting from" language to require but-for causation, a stricter standard.

An interlocutory appeal to the U.S. Court of Appeals for First Circuit in United States v. Teva Pharmaceuticals USA, Inc. was expected to shed additional light on the issue, however Teva Pharmaceuticals recently requested a stay of the appeal, indicating the possibility the parties will settle.[14]

The matter stems from allegations that Teva Pharmaceuticals violated the AKS and FCA by issuing over $350 million in payments to two charities and contracted vendors to cover Medicare copay obligations for a particular drug.

The government alleged that by subsidizing the cost of the drug, patients were incentivized to purchase the drug, resulting in higher prices for wholesalers, and ultimately yielding greater revenue for Teva.

At summary judgment, the U.S. District Court for the District of Massachusetts in Teva applied the Third Circuit standard, granted the government's motion for partial summary judgment, and held the government did not need to prove but-for causation at trial.[15]

Teva Pharmaceuticals appealed, seeking resolution of the issue of what standard applies. With a potential settlement looming, this issue will likely remain unresolved.

Key Takeaways and Considerations for Equity Investors

Private equity investors can expect that regulators will be paying close attention to their actions in the healthcare space as they seek to address perceived investor influence over the healthcare industry.

Private equity firms should approach management of healthcare investments with care, assessing how their operations could be perceived by motivated regulators because the government has made clear that its sights are set not just on portfolio companies but also on their private equity owners. How active private equity investors are in operations, especially regarding the influence of submission of claims to the government, will drive potential liability under the FCA. Investors should consider the following best practices as they expand and manage healthcare investments:

- Conduct due diligence on their investments, both before and after acquisitions, to ensure compliance with industry regulations;
- Include subject matter experts with FCA, AKS and healthcare fraud and abuse experience as part of due diligence reviews and prior to key decision making;
- Seek guidance on possible FCA implications when influencing policies or making decisions for their portfolio companies, especially those in the healthcare sector;
- Evaluate the risk of involving firm employees in management of healthcare portfolio companies — involvement of investors in direct management increases the likelihood that the government may seek to hold them liable for any misconduct;
- Ensure decision-makers are aware of the implications of setting benchmarks and revenue targets, and understand whether such targets are achievable or have the potential to lead to false claims; and
- Respond quickly if potential misconduct is identified to investigate the issue and make any necessary remediation, as the potential exposure and expense associated with addressing misconduct early is far more limited than the risk of a high-profile FCA litigation that may result in a significant damages calculation.

As FCA enforcement and other legal actions in this space develop, guidance on this issue will also grow. Private equity firms should continue to understand the role they may play in

their investments and evaluate whether their influence may subject them to government investigations.

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[1] Principal Deputy Assistant Attorney General Brian M. Boynton, Remarks at the 2024 Federal Bar Association's Qui Tam Conference (February 22, 2024), available at https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-brian-m-boynton-delivers-remarks-2024.

[2] Press Release, Dept. of Justice, National Health Care Fraud Enforcement Action Results in 193 Defendants Charged and Over $2.75 Billion in False Claims (June 27, 2024), available at https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-193-defendants-charged-and-over-275-0.

[3] Principal Deputy Assistant Attorney General Brian M. Boynton, Remarks at the 2024 Federal Bar Association's Qui Tam Conference (February 22, 2024), available at https://www.justice.gov/opa/speech/principal-deputy-assistant-attorney-general-brian-m-boynton-delivers-remarks-2024.

[4] See, e.g., United States v. Marder, 208 F. Supp. 3d 1296 (S.D. Fla. 2016).

[5] United States ex rel. Medrano and Lopez v. Diabetic Care Rx LLC dba Patient Care America et al., No. 15-CV-62617 (S.D. Fla.).

[6] Press Release, Senators Warren, Markey Introduce the Corporate Crimes Against Health Care Act of 2024 (June 11, 2024), available at https://www.warren.senate.gov/newsroom/press-releases/senators-warren-markey-introduce-the-corporate-crimes-against-health-care-act-of-2024.

[7] Press Release, US Senate Committee on the Budget, Senate Budget Committee Digs into Impact of Private Equity Ownership in America's Hospitals (December 7, 2023), available at https://www.budget.senate.gov/chairman/newsroom/press/senate-budget-committee-digs-into-impact-of-private-equity-ownership-in-americas-hospitals.

[8] NYS Dept. of Health. Reporting of Transactions https://www.health.ny.gov/facilities/material_transactions/#:~:text=

[9] See Press Release, Attorney General Bonta, Assembly Speaker pro Tempore Wood Introduce Legislation to Strengthen Review of Private Equity Healthcare Transactions and Abuses (February 20, 2024), available at: https://oag.ca.gov/news/press-releases/attorney-general-bonta-assembly-speaker-pro-tempore-wood-introduce-legislation; Bloomberg News, High-profile hospital collapse sparks

legislative action to ban REITs as landlords that experts say misses the mark, Investment News (June 24, 2024),:https://www.investmentnews.com/regulation-and-legislation/news/massachusetts-moves-to-limit-reits-hospital-ownership-254719.

[10] Press Release, Department of Justice, Justice Department, Federal Trade Commission and Department of Health and Human Services Issue Request for Public Input as Part of Inquiry into Impacts of Corporate Ownership Trend in Health Care (March 5, 2024), available at https://www.justice.gov/opa/pr/justice-department-federal-trade-commission-and-department-health-and-human-services-issue.

[11] Comments of Eleven Attorneys General in Response to the February 29, 2024 Request for Information on Consolidation in Healthcare Markets (June 5, 2024), available at: https://oag.ca.gov/system/files/attachments/press-docs/Comments%20by%2011%20Attorneys%20General%20in%20Response%20to%20Feb.%2029%20RFI%20on%20Consolidation%20in%20Healthcare%20%281%29%5B2%5D.pdf.

[12] The AKS imposes criminal liability on anyone who directly or indirectly, knowingly or willfully, offers to pay to purchase, arrange, or recommend purchasing any item where payment is made in whole or in part pursuant to a federal health care program.

[13] 42 U.S.C. § 1320a-7b(b)(2).

[14] See United States v. Teva Pharms. USA Inc., No. 23-1958(1st Cir.).

[15] United States v. Teva Pharms. USA Inc., 682 F. Supp. 3d 142 (D. Mass. 2023).