PRIVATE EQUITY FIRMS SHOULD PREPARE FOR INCREASED SCRUTINY AS DOJ PUTS FALSE CLAIMS VIOLATIONS UNDER THE MICROSCOPE

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US Policy and Regulatory Alert

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Private equity investment in health care has grown significantly over the past two decades, and the US government is starting to pay attention. Recent announcements by the US Department of Justice (DOJ) 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 (FCA) 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 HEALTH CARE

Claims brought under the FCA by both 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 US$2.7 billion recovered by DOJ.[1] The FCA allows for treble damages and penalties, creating massive exposure in these cases and major payments for the government and relators. Health care has consistently represented the largest focus of enforcement under the FCA and has accounted for the highest recovery.[2] On the heels of this record year, DOJ announced in February that private equity involvement in the health care 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, 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. For example, in one matter resolved in 2019, 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 health care providers, from setting benchmarks and revenue targets to express

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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.

PROPOSED SENATE BILL HIGHLIGHTS HEIGHTENED GOVERNMENT FOCUS ON PRIVATE EQUITY HEALTH CARE INVESTMENTS

DOJ is not alone in its focus on private equity in the health care industry. On 11 June 2024, Massachusetts Senators Ed Markey and Elizabeth Warren introduced the Corporate Crimes Against Health Care Act, aimed specifically at private equity investors in the health care industry.[6] Key aspects of the bill would include requiring health care 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 private equity “looting” of the health care 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 health care industry. Last year, New York enacted a law requiring qualifying health care 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 health care entities, while in Massachusetts a pending health care oversight bill would ban hospitals from leasing buildings from real estate investment trusts.[9]

OTHER STATE AND FEDERAL ACTION AIMED AT PRIVATE EQUITY INVESTMENTS

DOJ's Antitrust Division, the Federal Trade Commission (FTC), and the Department of Health and Human Services (HHS) issued a Request for Information (RFI) seeking public comment on the effect of private equity and other private payor transactions involving health care providers.[10] The RFI cited three practices of private equity funds in the health care 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 state attorney generals' recommendations include implementing more mechanisms for transparency of private equity ownership and payments associated with health care services, prohibiting anticompetitive contractual provisions affecting health care services, and coordinating state and federal efforts to maximize enforcement against conduct.

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CIRCUIT SPLIT ON APPLICABLE CAUSATION STANDARD IN FCA AND ANTI-KICKBACK STATUTE LITIGATION

With the increased focus on private equity health care 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 (AKS) 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 Third Circuit has held plaintiffs only need to prove a causal link between kickbacks and medical care, while the Eighth and Sixth Circuits have interpreted the "resulting from" language to require but-for causation, a stricter standard.

An interlocutory appeal to the First Circuit in U*nited States v. Teva Pharms. 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 US$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 District Court 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 health care space as they seek to address perceived investor influence over the health care industry. Private equity firms should approach management of health care 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 health care 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 health care 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 health care sector;

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- Evaluate the risk of involving firm employees in management of health care portfolio companies. Involvement of investors in direct management increases 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. 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.

FOOTNOTES

[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] DOJ's focus on healthcare continues to grow. On June 27, 2024, DOJ announced the National Health Care Fraud Enforcement Action, which included charging 193 defendants for a variety of alleged health care fraud schemes involving billions in alleged losses. 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] *Required Reporting of Material Transactions*, NY STATE DEPARTMENT OF HEALTH,

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https://www.health.ny.gov/facilities/material_transactions/#:~:text=New%20York%20State%20Public%20Health,the%20closing%20of%20the%20transaction.

[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(1)[2].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) (emphasis added).

[14] *See United States v. Teva Pharms. USA, Inc.*, No. 23-1958 (1st Cir.). Update on October 29, 2024: On October 18, 2024, the First Circuit voluntarily dismissed the case followinga settlement between the parties, leaving the interpretation of the "resulting from" language unresolved in the First Circuit. Teva Pharmaceuticals agreed to pay $450 million to settle two claims, the ongoing litigation regarding the FCA and AKS claims, as well as separate allegations related to price fixing allegations. *See* Press Release, Department of Justice, Drug Maker Teva Pharmaceuticals Agrees to Pay $450M in False Claims Act Settlement to Resolve Kickback Allegations Relating to Copayments and Price Fixing (October 10, 2024), available at https://www.justice.gov/opa/pr/drug-maker-teva-pharmaceuticals-agrees-pay-450m-false-claims-act-settlement-resolve-kickback.

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

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