



Enforcement Trends and Caution Points in Health Care Private Equity Investing

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The first [piece](#) in this series of articles about private equity investment in health care outlined key compliance considerations for private equity investors. Compliance programs are necessary for protecting private equity (and health care providers) from legal liability, and federal government enforcement agencies have not ignored the operations of private equity-backed health care providers, with the investors themselves facing increasing risk of liability.

In fact, private equity-backed health care has been on the radar of several government enforcement agencies for nearly 15 years. For example, the U.S. Department of Health and Human Services Office of the Inspector General (OIG) documented its awareness of the increase in private equity investment in the nursing home industry in work plans as early as 2009. Fast forward 13 years, and President Biden turned the spotlight on outside investors entering more aggressively into the nursing home space in his 2022 State of the Union address stating, “And as Wall Street firms take over more nursing homes, quality in those homes has gone down and costs have gone up.” He pledged to put an end to that trend during his administration.

While it is early yet to see significant action coming from the U.S. Department of Justice (DOJ) since Biden’s State of the Union, there are many prior actions for private equity investors to regard as cautionary tales. One need only consider the government enforcement trends, recent False Claims Act actions, and antitrust concerns that have focused on private equity health care in the last several years.

[Ongoing government scrutiny of private equity health care transactions](#)

As the volume and value of transactions in this space have risen dramatically over the past several years—and show few signs of slowing—government focus has adjusted accordingly.

Nursing homes have increasingly been a target recently with heightened scrutiny stemming from the COVID-19 pandemic. In a February 2022 fact sheet, the Biden Administration noted that “Too often, the private equity model has put profits before people—a particularly dangerous model when it comes to the health and safety of vulnerable seniors and people with disabilities.” As a result of this finding, the administration promised to “crack down on bad actors” and ensure government funding is directed to providing quality care versus growing investors’ pocketbooks.

Further, the OIG investigations are not limited to the nursing home industry. The OIG has also closely examined, among other types of medical practices, dental groups, which are often run under a dental support organization (DSO) model (e.g., financial investors administrating the dental practices). In 2015, for example, the OIG conducted a four-state study, finding that dental practices operated in chains, or DSOs, were more likely to have “questionable billing practices” as compared to their independent peers, raising concerns over corporate pressure to overtreat and overbill while ignoring safety concerns.

Government agencies are not alone in the conclusion that where outside private investment is involved in health care, costs increase and quality of patient care decreases. Studies published in outlets like the “Journal of the American Medical Association” have found significant increases in cost of care for private equity-backed health care when compared to their independent peers, further encouraging agency concern.

False Claims Act recent actions

Private equity firms and the providers they partner with have been targets in several recent False Claims Act (FCA) actions, facing the possibility of significant civil and criminal penalties. Under the FCA, companies and individuals can be held liable for presenting a false claim or causing a false claim to be presented to the federal government.

The knowledge requirement for liability under the FCA is divided into three categories: actual knowledge, deliberate ignorance, and reckless disregard. In some cases, private equity firms have settled government actions for millions of dollars after allegations of mere knowledge rather than direct involvement in false claim submissions.

Here are three examples from the past three years:

- In November 2020, the DOJ announced that a private equity company agreed to pay \$1.5 million, of a total \$11.5 million settlement under the FCA, settling claims under *U.S. ex rel. Johnson, et al. v. Therakos, Inc. et al.* (E.D. Pa. No. 12-1454). In this case, the allegations against the private equity company were not that it actively caused a change in practice that led to the submission of a false claim. Rather, it was alleged that a medical device company engaged in improper promotion of a device, and that this practice continued after the device company was acquired by the private equity company.
- In *U.S. ex rel. Ebu-Isaac, et al. v. Insys Therapeutics, Inc., et al.*, Case No. 2:16-CV-07937-JLS-AJW, 2021 WL 3619958 (C.D. Cal. June 9, 2021), a private equity company's motion to dismiss was denied by the Central District of California, finding that the private equity company could be found liable through its portfolio company, in this case, a specialty pharmacy. The court noted that the use of separate business entities, and the fact that the private equity company did not submit the false claims itself, was not enough to shield the company from liability under the FCA. In making this determination, the court relied on evidence such as emails from the managing partner of the fund that failed to distinguish among the entities under the fund's portfolio and the initial press release announcing the acquisition of the pharmacy group, referring to the entities as partners. This case is pending.
- In a settlement agreement announced in 2021, where a private equity company agreed to pay \$1.8 million, the government alleged that the private equity company caused false claims to be submitted when it learned of alleged wrongful conduct

by an electroencephalography (EEG) company during the due diligence process and proceeded with its investment in that company. In this case, the private equity company was a minority shareholder holding two board seats and had also entered into a Management Services Agreement with the EEG company. The basis of the allegation against the private equity group in this case was that it “allowed the alleged conduct... to continue” (*U.S. ex rel. Mandalapu, et al. v. Alliance Family of Companies LLC, et al.*).

Antitrust concerns

The DOJ and the U.S. Federal Trade Commission (FTC) have also noted antitrust concerns with private equity-backed health care, announcing an increased focus on this area as one of four areas of prioritized enforcement. This is an unusual move as, historically, many of these transactions have avoided scrutiny because they fall beneath the \$101 million limit that prompts an antitrust review by the FTC and DOJ. However, as antitrust concerns in this area continue to grow, enforcement agencies are taking a more critical look at deals even though they may not automatically trigger review.

Why? Private equity deals in health care exceeded \$1 trillion in 2021. In a forum hosted by the FTC and the DOJ, health care professionals recounted their experiences with consolidation, citing concerns of patient safety, staffing, employee benefits and well-being, costs of care, and overall quality of patient care. This large deal volume, coupled with concerns from health care professionals regarding consolidation in the health care industry, has led the DOJ and the FTC to target these transactions from an antitrust perspective.

The DOJ’s Antitrust Division and the OIG signed a memorandum of understanding in December of 2022, aiming to promote competitive health care markets and ensure that patients have access to care. The memorandum allows the agencies to make referrals to each other and to utilize the resources of the other agency to “...better protect health care consumers and workers from collusion, ensure compliance with laws enforced by OIG and the Antitrust Division, and promote competitive health care markets.” Such cooperation should undoubtedly increase governmental scrutiny in the private

equity-backed health care space to address the FTC and DOJ concerns previously mentioned.

Conclusion

Enforcement trends indicate that private equity companies should exercise healthy caution when acquiring, controlling, or otherwise being involved in health care entities. With government agencies targeting not only misrepresentation but the knowledge of misrepresentation, private equity companies should ensure careful compliance with all aspects of state and federal law, including billing regulations, corporate practice of medicine prohibitions, and antitrust concerns. A robust due diligence process is essential in selecting an appropriate and compliant health care partner.

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