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Enforcement of Private Equity Investment in Healthcare

Past, Present, and Future Trends

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Significant private equity investment in the healthcare space has resulted in increased regulatory scrutiny and enforcement. From False Claims Act (FCA) settlements to bipartisan [congressional inquiries](#), concerns by the [Office of Inspector General of the U.S. Department of Health and Human Services](#) (HHS-OIG), and lawsuits by the [Federal Trade Commission](#) (FTC) and [Department of Justice](#) (DOJ), the private equity healthcare sector has been rocked by the rising enforcement pace. ¹ This scrutiny suggests that private equity firms may not be insulated from the actions of their healthcare portfolio companies. But given the reduced volume of private equity healthcare investments in 2022 and 2023, will the enforcement climate similarly abate? Evolving FCA legal standards for “knowledge” and “causation” mean that each side of the “v” will have arguments, and it will take adjudications on the merits to ferret out trends. ² In the meantime, private equity firms can take steps to mitigate their potential FCA exposure.

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FCA Settlements

Private equity deal volumes slowed after peaking in 2021, potentially because of elevated interest rates and regulatory scrutiny. ³ Since at least 2019, private equity firms have settled FCA actions, alleging that the private equity firms failed to adequately address practices at their portfolio companies that risk contravening healthcare laws.

Amid legal actions spanning several years, themes have emerged highlighting the nexus between private equity investments and allegations of healthcare regulatory non-compliance:

- In 2023, a private equity firm, along with its three managing partners and two portfolio pharmacies, agreed to pay \$9 million to resolve whistleblower allegations in a non-intervened case. ⁴ The private equity firm was accused of actively promoting and facilitating the widespread off-label use of a fentanyl spray, Subsys, in violation of the Controlled Substances Act. ⁵
- In 2022, a health maintenance organization offering Medicare Advantage and other plans in Oklahoma and Texas agreed to pay \$4.2 million to resolve FCA and Anti-Kickback Statute allegations. ⁶ These allegations involved the distribution of gift cards to administrative assistants during private equity ownership to allegedly induce Medicare Advantage referrals, recommendations, and enrollment. ⁷
- In 2021, a private equity sponsor agreed to pay nearly \$20 million to settle state FCA allegations brought by the Massachusetts Attorney General's Office. ⁸ These allegations centered on a portfolio company's submission of false claims to the Massachusetts Medicaid program, seeking reimbursement for mental healthcare services rendered by unlicensed and improperly supervised clinic staff. ⁹
- In 2019, a private equity firm and its portfolio company reached a settlement with the DOJ, agreeing to pay \$21.05 million to resolve accusations that the private equity firm aided its portfolio company in

an illegal kickback scheme to prescribe compounded creams and vitamins to military veterans in the TRICARE health program. ¹⁰

Congressional Inquiries

Congress has also intervened, demanding information regarding private equity investments, particularly in hospitals, to investigate concerns about prioritizing revenue before clinical care. In December 2023, Sen. Sheldon Whitehouse (D-RI) and Sen. Chuck Grassley (R-IA) launched an [inquiry](#) into private equity firms that own hospitals. ¹¹ To evaluate whether quality of care suffers in hospitals under private equity ownership, the senators are focusing on these hospitals' related-party transactions and private equity firms' operational control.

This bipartisan investigation builds upon a previous one, launched in March 2023 by Sen. Grassley, that sought [information](#) about the extent to which private equity ownership of an Iowa hospital contributed to events involving potential care mismanagement. ¹² Sen. Grassley and Sen. Whitehouse are expanding that investigation to include companies that currently own or operate, or formerly owned or operated, hospitals in California, Pennsylvania, Rhode Island, and other states, given their increasing concern about the growth of private equity in healthcare.

Agency Oversight and Enforcement

HHS-OIG

In November 2023, [HHS-OIG](#) issued General Compliance Program Guidance, in which it recognized the “growing prominence of private equity and other forms of private investment in health care.” ¹³ Signaling potential future oversight audits, the agency cautioned that such investment “raises concerns about the impact of ownership incentives (e.g., return on investment) on the delivery of high quality, efficient health care.” ¹⁴

Federal Trade Commission

In September 2023, the FTC sued an anesthesia practice and its private equity owner, alleging that the private equity fund, its affiliates, and its portfolio company engaged in anticompetitive conduct to consolidate and monopolize the anesthesiology market in Texas through a series of “roll-up” acquisitions over several years, along with price-setting and market allocation arrangements between defendants and certain competitors. ¹⁵ Just three months later, in December 2023, the government announced a joint data-sharing effort across the FTC, DOJ, and HHS to combat potentially anti-competitive acquisitions in the healthcare space. ¹⁶

Department of Justice

In December 2023, DOJ intervened in a whistleblower qui tam alleging FCA violations against a private equity-backed hospital system for allegedly violating the Physician Self-Referral Law (commonly referred to as the “Stark Law”) and submitting or causing the submission of false claims and statements to the Medicare program. ¹⁷ The private equity-backed hospital system not only paid approximately \$4.8 million to settle, but it also entered into a Corporate Integrity Agreement with HHS-OIG. ¹⁸ This agreement mandates annual reviews of its financial arrangements to ensure compliance with healthcare laws.

Future Trends

Time will tell whether the declining trend in private equity investment in healthcare will continue or reverse course, but regulatory scrutiny remains active for now. To prepare for and manage enforcement risks across the areas outlined below, private equity firms and their portfolio companies should stand up a compliance function (if one does not already exist) and routinely evaluate its efficacy.

Federal and State Legislation

Congress has been proposing legislation that would require greater transparency from private equity firms with healthcare investments. ¹⁹

Whether new legislation will gain the kind of traction this term that was lacking last term remains uncertain. Meanwhile, several states have recently introduced or promulgated legislation concerning significant ownership changes in healthcare companies, including through private equity investment. In 2023 alone, [New York](#), [Illinois](#), and [Minnesota](#) enacted such laws. ⁽²⁰⁾ [Oregon](#) did so in 2021 and [California](#) followed suit in 2022. ⁽²¹⁾ Additional states are preparing similar legislation in 2024. Some of these bills focus on transparency, requiring disclosure of impending deals and information for state agency review, while others grant states broader powers to approve, conditionally approve, or reject transactions . ⁽²²⁾

Investigations, Audits, Litigations

Investigations, audits, and litigations focusing on private equity's role in alleged healthcare fraud will continue. As the head of the Civil Division of the Department of Justice remarked in February 2024, investment firms that “influence patient care by providing express direction for how a provider should conduct their business, or more indirectly by providing revenue targets or other indirect benchmarks intended to prioritize reimbursement... may subject themselves to liability.” ⁽²³⁾ This increased scrutiny is likely to result in a higher volume of whistleblower complaints cycling through the qui tam process.

Furthermore, the FTC is expected to persist in investigating additional roll-up healthcare acquisitions, including based on self-reported disclosures and whistleblowers following the precedent set by the anesthesia roll-up case. ⁽²⁴⁾ The recent FTC-DOJ-HHS collaboration, coupled with state legislation, signals an intensified focus on addressing healthcare combinations that may have previously gone relatively undetected.

Internal Compliance Enhancements

Expect diligence red flags to be addressed either before or after transactions, in accordance with the DOJ's October 2023 updated voluntary corporate self-

disclosure policies. ²⁵ In January 2023, [the DOJ Criminal Division](#) updated the Corporate Enforcement and Voluntary Self-Disclosure policy to incentivize companies to promptly and voluntarily disclose misconduct, offering benefits like avoiding criminal penalties or receiving reduced penalties. ²⁶

Consequently, anticipate strengthened compliance infrastructure at both the private equity firm and portfolio company levels, and a potential uptick in self-disclosures.

Conclusion

Despite recent downward trends in private equity healthcare investments, the regulatory landscape remains active, prompting private equity firms to consider early investments in compliance functions. Additionally, ongoing legislative proposals at the federal and state levels seek to enhance transparency and oversight of private equity firms' healthcare investments. Investors and operators should heed the diverse regulatory risks and evolving requirements. Looking ahead, continued vigilance and proactive compliance measures will be crucial for navigating evolving regulatory challenges and mitigating potential risks in the healthcare sector.

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Endnotes



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