Healthcare Enforcement Compliance Conference

Enforcement & Private Equity

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GOVERNMENT ENFORCEMENT, INITIATIVES AND OVERSIGHT

- "As Wall Street firms take over more nursing homes, quality in those homes has gone down and costs have gone up. That ends on my watch," President Biden-2022 State of the Union
- White House released a fact sheet detailing new reforms, including requirements for "adequate staffing," greater accountability for "chain owners of substandard facilities," and increased scrutiny of the "poorest performers."
- GAO Study---CMS Should Make Ownership Information More Transparent for Consumers—January 2023

CONGRESSIONAL INVESTIGATIONS

- "It's past time for a bright light to be shined on how private equity ownership in our healthcare system affects patient safety, costs, and jobs. Private equity's influence stretches like an octopus.... Private equity's arms through the American health care system are borne heavily by the most vulnerable: communities of color, rural underserved areas, the elderly, people with disabilities."
- Congress Member/ Chair Bill Pascrell at House Ways and Means Subcommittee Hearing on private equity in healthcare 3/25/21

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GOVERNMENT ENFORCEMENT, INITIATIVES AND OVERSIGHT

- SEC rules proposed February 9, 2022:
 - Quarterly reports with specific performance measures and accounting for all costs
 - · Eases suits against fund managers for breach of fiduciary duty
 - No side letters, no indemnification provisions
- FTC "looking closely at the role of private equity in health care." (death rates in nursing homes, roll-ups)
- DOJ-investigation of overlapping board seats/interlocking directorates:
 - "We saw a problem. It's pervasive." AAG Kanter, DOJ Antitrust

PRIVATE EQUITY DUE DILIGENCE

- Reps and disclosures
- Pending or threatened litigation
 - Regulatory reporting, certifications, oversight, inspections, penalties, plans of correction.
 - Insuror relationships/Hospital relationships/record systems
 - Credentialing/exclusion
- Corporate practice of medicine under Medical Practice Act of 1985 (63 P.S. § 422.1 et seq.)
- Stark Law, Anti-Kickback Statute, False Claims Act, and HIPAA, as well as the state law equivalents.

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THE DOJ COMPLIANCE MANDATE

The compliance mandate is defined in the Department of Justice's (DOJ) Evaluation of Corporate Compliance Programs to include "three 'fundamental questions":

- 1. "Is the corporation's compliance program well designed?"
- 2. "Is the program being applied earnestly and in good faith?" In other words, is the program adequately resourced and empowered to function effectively?
- 3. "Does the corporation's compliance program work" in practice?

[T]he "critical factors in evaluating any program are whether the program is adequately designed for maximum effectiveness in preventing and detecting wrongdoing by employees and whether corporate management is enforcing the program or is *tacitly encouraging or pressuring employees to engage in misconduct.*" U.S. DEPARTMENT OF JUSTICE CRIMINAL DIVISION, EVALUATION OF CORPORATE COMPLIANCE 1–2 (2020) (quoting JUSTICE MANUAL 9-28.800(B), CORPORATE COMPLIANCE PROGRAMS).

NEW YORK OMIG GUIDANCE—MARCH 2023

New York Office of Medicaid Inspector General considers an "effective compliance program" to be a compliance program that is adopted and implemented by the provider that, at a minimum, satisfies the compliance program requirements, and that is **designed to be compatible with the provider's characteristics** (emphasis added). Being compatible with the provider's characteristics means that the compliance program:

- is well-integrated into the company's operations and supported by the highest levels of the organization, including the chief executive, senior management, and the governing body;
- 2. promotes adherence to the provider's legal and ethical obligations; and
- is reasonably designed and implemented to prevent, detect, and correct noncompliance with Medicaid program requirements, including fraud, waste, and abuse most likely to occur for the provider's risk areas and organizational experience

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COMPLIANCE AND RISK-PRIVATE EQUITY DEALS

 Kaiser Health News found that companies owned or managed by private equity firms have agreed to pay fines of more than \$500 million since 2014 to settle at least 34 lawsuits filed under the False Claims Act "Sick Profit: Investigating Private Equity's Stealthy Takeover of Health Care Across Cities and Specialties" Fred Schulte, KHN November 14, 2022

PRIVATE EQUITY: ENFORCEMENT ACTIONS

- United States ex rel. Martino-Fleming, v. South Bay Mental Health Ctr., Inc.--\$25 million settlement
- North Carolina Ambulance Complaint and settlement
- United States ex rel. Medrano v. Diabetic Care RX,LLC, case against a PE firm for its involvement in its portfolio's conduct(No. 15-cv-62617-BLOOM/Valle, 2019 WL 1054125 (S.D. Fla. Mar. 6, 2019)
- United States ex rel. Anderson v. Curo Health Servs. Holdings, 3:13-cv-00672 (Lead) (M.D. Tenn. Mar. 21, 2022)