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ALERT

False Claims Act ▪ Private Equity

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DOJ Complaint Names Private Equity Firm as Defendant in False Claims Act Case Targeting Health Care Portfolio Company

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The U.S. Department of Justice's recent decision to name a private equity firm as a defendant in a False Claims Act complaint against one of the firm's portfolio companies, while uncommon, shines a spotlight on potential risk areas for private equity firms whose portfolio companies operate in industries with significant False Claims Act exposure like health care. In its complaint in intervention in *United States ex rel. Medrano v. Diabetic Care Rx, LLC d/b/a Patient Care America et al.* (S.D. Fla. No. 15-62617-civ), filed on February 16, 2018, DOJ alleges that compounding pharmacy Patient Care America ("PCA") paid illegal kickbacks to several marketing firms in exchange for referrals for certain compound drugs that were reimbursed by Tricare, a federal health care program that provides health insurance for current military personnel, military retirees, and their dependents. The complaint further alleges that the pharmacy's controlling stakeholder, private equity firm Riordan, Lewis & Haden, Inc. ("RLH"), managed and controlled PCA and participated in the charged misconduct. The government's intervention to target both PCA and its private equity shareholder reflects a potential sea change in its approach to such cases.

The Scheme Alleged in the Complaint in Intervention and RLH's Involvement

The DOJ's complaint against PCA arises from an alleged marketing scheme involving compound topical pain creams. PCA, a compounding pharmacy previously focused on providing intravenous nutrition to patients with end-stage kidney disease, changed course in early 2014 and entered the compound pain cream business. Allegedly, Tricare reimbursement rates for pain cream products were known to be unusually high at the time.

In service of PCA's compounding pain cream initiative, the complaint alleges, PCA entered into independent contractor agreements with three marketing companies, under which each company would target and refer patients—specifically Tricare beneficiaries—to PCA for compounded drug prescriptions. PCA compensated the marketing companies exclusively via commissions: the marketers received 50% of PCA's profits from each referred prescription. Over time, referrals from the marketing companies accounted for the vast majority of PCA's total compounding revenue. And because these referrals were generally concentrated among Tricare beneficiaries, reimbursements from Tricare for the pain creams also came to make up a substantial proportion of PCA's profits.

The complaint alleges that PCA's commission payments to the marketing firms were illegal kickbacks under the Federal Anti-Kickback Statute ("AKS"), and that the claims resulting from these kickbacks were presented to Tricare for payment by PCA in violation of the FCA. Specifically, the complaint alleges that the marketers provided services and were paid commissions by PCA as independent contractors, which did not qualify for employment safe harbor protection under the AKS. The complaint also alleges additional misconduct, including that marketers paid kickbacks to patients by covering copayments regardless of financial need, in order to secure and fill additional prescriptions. Finally, the complaint alleges that the marketers also paid telemedicine physicians to write prescriptions without patient consent and without establishing legitimate physician-patient relationships. The complaint alleges that, as a result of the marketing scheme and related misconduct, PCA ultimately received more than $68 million in reimbursement for compound pain and other topical creams.

The complaint alleges that private equity firm RLH was not only deeply involved in the strategy and management of PCA, but also that it exerted considerable influence over a number of the bad acts described in the complaint. The allegations focus on two RLH partners, Michel Glouchevitch and Kenneth Hubbs, who also served as officers of the co-defendant pharmacy.

Per the complaint, RLH invested in PCA in July 2012, and planned to increase the company's value so that PCA could be sold at a profit after five years. Shortly after RLH's initial investment, however, Medicare reimbursement rates for PCA's core business at the time dropped considerably, and PCA's revenue fell accordingly. The complaint alleges that RLH, led by Glouchevitch and Hubbs, initiated and championed PCA's entry into the pain cream business in order to make use of "the extraordinarily high profitability of this therapy" and generate a "quick and dramatic payback" on its investment. The complaint quotes RLH documents that recognized that overcharging for products in the pain management business risked "cross[ing] the line from an ethics standpoint." In service of the pain cream venture, RLH is alleged to have played a significant role in the staffing and oversight of PCA. For example, after initiating PCA's entry into the pain cream market, Glouchevitch then recommended that PCA hire Patrick Smith as CEO against the advice of RLH's own consultant.

With respect to the specific violations alleged, the complaint makes both general and specific claims of knowledge on the part of RLH. It alleges that RLH, based on its extensive experience investing in the health care industry, was well-versed in the Anti-Kickback Statute and related laws and regulations, including the obligation of PCA to make a good faith attempt to determine patients' financial condition before waiving copayments. The complaint goes further, however, alleging that at a relatively early point, RLH and PCA were specifically advised by outside counsel that PCA should not be submitting claims to Tricare for prescriptions referred by marketers because of potential anti-kickback concerns.

Finally, the complaint alleges that RLH participated in the scheme by periodically funding the commission payments to the marketing firms when those payments were due before PCA had received the corresponding Tricare reimbursements. The complaint alleges that RLH was aware that this money was used to pay marketing commissions.

Medrano is pending in the District Court for the Southern District of Florida.

Considerations for Private Equity Firms in the Health Care Industry

While much remains to be seen regarding how this case will play out in litigation, and it may prove to be an outlier on its facts, *Medrano* potentially signals a new frontier for DOJ in pursuing FCA cases and provides some clues as to the type of conduct that DOJ may consider in deciding issues of authority and control when assessing FCA liability. Accordingly, private equity firms should consider the following when investing in and operating portfolio companies in the Health Care industry:

- <u>Level of Involvement</u>: It is common for private equity firms to have representatives serving on the boards of directors of portfolio companies. Where a private equity firm is the majority or sole stakeholder in a portfolio company, it is important to take into account the extent to which the firm is involved in shaping operations and decisions at the portfolio company level. The DOJ's approach in the *Medrano* case suggests that a private equity firm's risk of an allegation of False Claims Act liability may increase with the degree of involvement in the portfolio company's day-to-day operations. Accordingly, private equity firms may wish to consider drawing clear lines of demarcation in corporate policies and agreements relating to actions taken by individuals in their capacities as directors, officers, and stockholder representatives of portfolio companies. Also, to the extent that private equity firms provide services to portfolio companies, they may wish to consider providing such services through separate organizations that are distinct from the firm's investment funds.

- Monitoring and Compliance of Portfolio Company Activity: Particularly in industries where False Claims Act liability is significant, private equity firms should consider development of robust monitoring and compliance programs at the portfolio company level. This type of initiative establishes the "tone from the top" and evidences the intent of the investors and board leadership to ensure that the portfolio company has appropriate internal legal support and compliance staffing, including training for the portfolio managers with primary responsibility for overseeing and supporting the company's operations.
- Board and Committee Participation: Specific to board-level oversight, firms should consider forming a compliance-focused subcommittee on a portfolio company's board of directors. The subcommittee can be tasked with ensuring compliance with internal policies and implementation of the compliance program consistent with industry guidance and standards.
- Advice of Counsel and Advisors: *Medrano* underscores the importance of obtaining and following the advice of counsel and consultants on matters involving potential False Claims Act liability. A robust portfolio company compliance program with the type of committee reporting structure described above would provide a forum for consideration of advice from counsel and other advisors on risks material to the business.

If you have any questions or would like more information about the False Claims Act, click here to go to our False Claims Act practice web page, or please contact an attorney in our False Claims Act practice.