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Diabetic Care RX Case Is A Warning Sign For Private Equity

By **Christopher Hewitt and Jayne Juvan** (May 7, 2018, 1:44 PM EDT)

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The United States government recently sent shock waves through the private equity industry by charging a private equity firm for its portfolio company's alleged health care fraud. The case, United States ex rel. Medrano v. Diabetic Care RX LLC d/b/a Patient Care America, involves alleged illegal conduct involved with pharmacy compounding, or the practice of creating customized medicines for individual patients, by the portfolio company. In a startling twist, the government also sued the private equity sponsor that owned a controlling interest in the portfolio company.

While the government's allegations are egregious, private equity firms that invest in health care companies should take note of the government's interest in pursuing not only enrolled health care providers, but also their owners, for perceived misconduct. Even though the litigation is in the early stages, private equity firms can glean several lessons from the complaint.

Health Care Fraud Allegations

According to the complaint, when the private equity firm acquired the portfolio company, it acted as a compounding pharmacy for intravenous nutritional therapy for patients receiving dialysis for end-stage renal disease. When Medicare reimbursement rates dropped dramatically for this particular therapy, the company shifted its business focus to providing compounded topical creams with far higher reimbursement rates and healthy gross profit margins.

In pursuing this highly lucrative line of business, the government alleges that the portfolio company violated multiple health care fraud and abuse laws, including by:

- Paying marketing firms 50 percent of the profit earned from prescriptions filled from their referrals, thus violating the Federal Anti-Kickback Statute, which makes it illegal to knowingly and willfully offer or pay any remuneration in exchange for referrals payable in whole or in part by federal health care programs;

- Targeting beneficiaries of Tricare — a government health care program that provides benefits to uniformed service members, retirees and their families — to sell them customized pain creams, scar creams and vitamins they didn't need;

- Submitting claims to Tricare that were "tainted by kickbacks to marketers and patients and did not arise from a valid prescriber-patient relationship," thus violating the Federal False Claims Act, which prohibits a party from knowingly presenting, or causing to be presented, false claims for compounded drugs to governmental health care programs; and

- Making copayments on behalf of the beneficiaries through a charity jointly funded with the marketers in an effort to disguise what was in reality a waiver of the copayment, a practice prohibited under federal law.

While the health care portfolio company, a separate legal entity from the private equity firm, was likely the provider enrolled in the Tricare programs and contractually entitled to submit claims and accept reimbursement, to make its case against the private equity firm, the government emphasized the firm's alleged dominion and control over its portfolio company, including:

- Approving of the plan to use paid marketing companies to generate referrals;

- Advancing funds to cover payments owed to the marketers until the Tricare payments were received;

- Appointing two of the private equity firm's partners as directors and officers of the portfolio company, who knew that Tricare revenue aggressively grew to over 98 percent of the portfolio company's revenue and that 90 percent of the revenue was derived from referrals from the marketing firms;

- Requiring the portfolio company's chief executive officer to consult with the private equity firm on important decisions and before entering into contracts for payments over certain thresholds; and

- Pressuring employees, through its partners who were directors and officers of the portfolio company, to select ingredients for the creams that yielded the highest reimbursement.

Lessons for Private Equity

The following four measures can help private equity firms mitigate their risk so they avoid the same fate.

1. Conduct Preclosing Due Diligence on Reimbursement Rate Risk

Historically, some private equity firms have been reluctant to invest in the health care industry for at least two main reasons — reimbursement rate risk, and the complicated and draconian regulatory scheme applicable to most health care companies. Based upon the government's complaint, both of these issues appear to be present in Patient Care America.

Not long after the private equity firm acquired the health care portfolio company, Medicare cut reimbursement rates dramatically for intravenous nutritional therapy for patients receiving dialysis for end-stage renal disease, the company's main product line. According to the complaint, the health care portfolio company shifted its focus to topical creams because reimbursement rates were far higher. It is possible that the executives may have felt under pressure to pivot quickly, especially because many private equity firms desire to exit from their investments in approximately five years.

In addition to the typical legal and financial due diligence buyers conduct before making an investment, private equity firms should devote resources to conducting thorough due diligence on the future of reimbursement rates applicable to the target company's core business before an acquisition is completed. That way, the firm is able to assess preclosing whether the target company's main revenue streams are likely to be at risk from potential legislative and regulatory changes.

2. Hire Executives With Industry Expertise Committed to Ethical Practices

Many private equity firms have become more comfortable with the complex regulatory scheme applicable to health care companies by hiring industry veterans and even former regulators to help them navigate it. Sophisticated firms have also hired transactional counsel with health care regulatory expertise. Especially in light of Patient Care America, firms may be at heightened risk if they invest in this space and exert control over their portfolio companies without understanding the regulatory landscape.

Given the complexity and the steep penalties for noncompliance, vetting executives for deep industry expertise and for commitment to ethical conduct is critical. According to the Patient Care America complaint, the private equity firm recruited a new CEO to launch the new topical cream business line. While the CEO ultimately selected did have prior industry expertise, the complaint alleges that the recruiting firm indicated that he would "require more careful management than [the private equity firm] may wish to provide." If true, the board of directors (which is responsible for selecting the CEO) should have asked additional questions to ensure that the CEO ultimately chosen was committed to setting an ethical tone at the top of the organization. If the board had any reservations whatsoever, the board should have passed on the candidate and continued its search.

3. Adopt and Implement a Corporate Compliance Program

While the government alleges in the complaint that both the portfolio company and the private equity firm knew or should have known about the laws and regulations that prohibit heath care fraud and abuse, it is unclear from the complaint whether the portfolio company had adopted a full corporate compliance program. The complaint notes that the portfolio company did have policies and procedures in place, though these policies and procedures likely either were deficient or not fully implemented if there is merit to the allegations.

Directors of almost all corporations owe the duties of care and loyalty to their shareholders. The duty of care requires directors act in an informed manner and with the care of an ordinarily prudent person under similar circumstances. The duty of loyalty requires directors to act in good faith and in a manner they reasonably believe to be in the corporation's best interests. Though boards benefit from "business judgment rule" protection, meaning that a court will presume that the board acted in the best interest of the corporation, this presumption may be overcome if a plaintiff establishes that a director breached the duty of care or duty of loyalty. While a breach of the duty of care is exculpable and indemnifiable, a breach of the duty of loyalty is not, and Delaware courts have determined that the duty of loyalty includes, as a component, a duty of oversight.

The Office of Inspector General at the U.S. Department of Health and Human Services has informed boards of the importance of adopting corporate compliance programs in fulfilling their fiduciary duties. A thoughtfully developed and well-implemented compliance program can help to demonstrate the organization's commitment to honest and ethical conduct, can help ensure legally compliant behavior, and can help to protect both revenue and the organization's reputation. The program should follow the U.S. Sentencing Commission's standards for an effective compliance program as well as guidance released by the OIG. In doing so, the program should establish standards to prevent and detect criminal conduct, ensure a knowledgeable governing authority exercises oversight, make sure care is taken so that excluded persons are not hired, require training at regular intervals, include a proactive monitoring and auditing program, set forth steps for promoting the program systemwide, and ensure allegations of illegal conduct are responded to appropriately.

Perhaps most importantly, it is not enough to simply adopt a program — over time, the program needs to become part of the fabric of the company's culture. Everyone in the organization — including the individuals at the top — must be held accountable for adherence to the program.

The board of directors should adopt the corporate compliance program by passing a formal resolution. A compliance officer should oversee the program, a compliance committee should be in place to carry out the functions of the program, and the compliance officer should periodically report to the board. To ensure proper checks and balances, the compliance officer should not solely report to the chief executive officer. The compliance officer should regularly ask questions and engage in healthy skepticism. The organization should also have an anonymous reporting hotline so that individuals associated with the organization are able to report potential misconduct anonymously and without fear of retaliation. The board of directors may also form a risk committee responsible for overseeing the implementation of the program.

4. Maintain Corporate Separateness

Given this case, private equity firms should also be mindful of the level of dominion and control they exert over their health care portfolio companies. Care should be taken to ensure lines are not blurred and that policies and procedures are adopted that clearly delineate the capacity in which individuals are serving based upon their different roles. Corporate formalities should be closely followed to ensure as great a separation as possible between the private equity firm and its portfolio companies so that the assets of the private equity firm do not become subject to the liabilities of the portfolio companies.

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[1] United States ex rel. Medrano v. Diabetic Care RX LLC d/b/a Patient Care America (S.D. Fla No. 15-62617-CIV-BLOOM Feb. 16, 2018)