<u>Private Equity and Health Care Fraud – A New Frontier?</u>

The US Department of Justice (DOJ) recently joined a federal *qui tam* lawsuit¹ brought against a private equity firm that specializes in health care pharmacies. Notably, the case also charges individual partners of the private equity firm, Riordan, Lewis & Haden, Inc. (RLH) based in Los Angeles.² They are charged with violations of the federal Anti-Kickback Statute (AKS) and the federal False Claims Act (FCA) in connection with their management of Diabetic Care Rx/Patient Care America (PCA), a compounding pharmacy. The case involves reimbursements from TRICARE, the health care program for the military and their families.

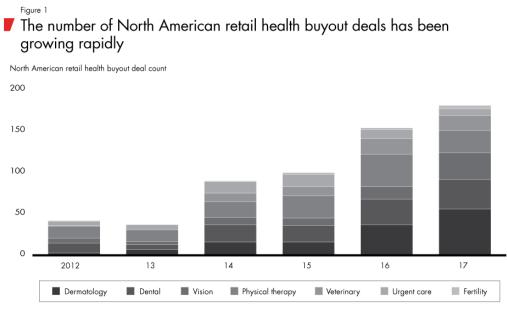
The complaint alleges that the firm and its partners violated the False Claims Act by seeking payment for prescriptions that were written by doctors who had not seen the patient and for whom there was no legitimate medical need.³ The government also accuses them of paying kickbacks in the form of commissions for unnecessary compound prescriptions, including pain and scar creams. The Anti-Kickback Statute prohibits the knowing and willful, offer, solicitation, payment, or receipt of any remuneration, to induce or in return for referring an individual for health care for which payment may be made under a federal health care program. Penalties in these cases can be steep: Violations of the FCA bring possible civil penalties of \$10,957 to \$21,916 per claim,⁴ plus treble damages, and reimbursement of attorney fees and costs. AKS civil monetary penalties can be as high as \$50,000 per claim plus treble damages. Several recent pharmaceutical cases were settled for over a billion dollars.⁵

The government in *Medrano* finds it significant that the private equity partners sought to increase the value of PCA and exit the investment in five years. Health care investors typically have a goal of increasing the value of the company and then selling it at a profit. But in this case, the government alleges that the way they went

about it violated the law. It claims that two partners, PCA board members, led an initiative to increase revenues by entering the pain management market, looking for a quick payback, but crossing the line from an ethical point of view. The government alleges that they entered into aggressive marketing contracts, with high commissions, that generated possibly fraudulent claims for a new product; and that this was done to make up for lost revenues from lower than expected government pricing for other products. The case was originally filed in 2015 and the government intervened in February of this year.

Follow the Money

The government's approach to health care fraud has always been to "follow the money", and while private equity has not previously been on the radar, this is changing. Bain & Company recently reported a "surge" in retail healthcare deals.⁶ From 2012 to 2017, the number of deals has "soared, increasing at a compound annual rate of 34% in North America."⁷



Source: Bain retail health deal database

Investors see health retail health care as a fragmented, high margin sector, with opportunity for consolidation, performance improvement and growth. The fact is that Medicare, Medicaid and other federal (like TRICARE) and commercial health coverage programs are a reliable and prompt revenue source. Often consumers are paying little or nothing for the goods or services. New technologies in health care and an aging baby boomer population also indicate innovation and growth in the health care sector.

The Office of Inspector General for Health and Human Services (HHS-OIG) has begun to identify dentists in "chain" practices, often funded by private equity, as having a propensity for performing unnecessary dental procedures on children in the Medicaid program. And several fraud settlements have been reported in these cases.⁸ Franchise type operations in urgent care and physical therapy also appear to be areas of interest to the government.

<u>The Yates Memo – Individual Accountability</u>

One of the most interesting and concerning aspects of *Medrano* is the fact that individual partners and executives of the company were also charged. Former U.S. Deputy Attorney General, Sally Yates, issued a memo in 2015 on individual accountability for corporate wrongdoing. It stated: "One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing." The memo goes on describe six elements of this policy which are currently reflected in the US Attorney's Manual (USAM) at 9-28.210-28.500.

The guidance requires prosecutors in civil and criminal case to strengthen their pursuit of individual corporate wrongdoing by taking the following six steps. 1) To qualify for a cooperation credit, the corporation must provide all relevant facts about the individuals responsible for the misconduct. 2) Prosecutors should focus on individuals from the start of the investigation. 3) DOJ criminal and civil attorneys should work together. 4) Absent extraordinary circumstances, individuals should not be released from liability when settling with the corporation. 5) DOJ attorneys must have a clear plan to resolve related individual cases. 6) Civil attorneys should consistently focus on responsible individuals and bring charges without regard to their ability to pay. 10

The Risk to Private Equity Firms and Partners

Every private equity firm and partner knows that health care is an industry subject to intense, multi-layered regulations, especially when it comes to government payments. The AKS and its multiple safe harbors can be especially tricky to navigate.

What are the risks that private equity firms and their partners face in the healthcare sector?

There are essentially three areas of risk. Acquired risk, the risk that a serious compliance or false claims matter comes with the investment. For example, the company being acquired is already the subject of a sealed *qui tam* case, that neither the buyer nor the seller knows about. Acquired risk can be known or unknown. Transactional risk, risk arising under the Anti-Kickback Statute in relation to the investment itself, that is, if the government finds that part of the transaction included some form of remuneration for referrals to federal programs. For example, the purchase of a dialysis facility that employs a physician seller under a contract that

exceeds market value could be construed as an AKS violation. Finally, post transaction risk is the risk in the *Medrano* case, this is risk created by the investor in its management of the company, or in its failure to exercise due care in the compliance area after the acquisition.

Dealing with The Risk

As with all risk, it is important to identify and quantify the risk, and then decide if you want to accept the risk, eliminate the risk, or mitigate and manage the risk. The following are a few suggestions for private equity firms and their principles to consider.

Have an effective compliance and ethics program of your own in place. Most PE firms have some type of compliance program related to investments and financing, but if you venture in the health care sector, you should also have a compliance plan specific to those investments. Look at the revenue sources for your investments to start: Are they primarily Medicaid, as in the dental sector? Pay attention to Medicare Advantage, private plans that provide Medicare services and pay contracting providers, they currently cover a third of Medicare beneficiaries and are expected to reach half by 2025. By assessing the revenue streams for your investments, you can develop compliance plans that address those specific risks. The existence of an effective compliance program is a factor in the government's decision whether to prosecute and entitles a company to reduced penalties and fees if a violation occurs.

Up your due diligence game. In the current market, there can be a rush to take advantage of opportunities that curtails a complete compliance due diligence. Consider using an outside compliance specialist to conduct a specific compliance review where time or expertise is lacking. It should be performed in collaboration with any other due diligence work. Investment firms typically focus their due

diligence on the financial aspects of the transactions, and too often rely on the seller and its warranties when it comes to government audits, investigations and compliance. Pay attention to issues with accrediting agencies, such as JCAHO. These accreditations are more than a certificate on the wall, any findings of immediate jeopardy could close down a facility within hours. Accreditation findings are also indicative of other possible compliance problems. Verify the information provided by the seller, check government websites and other open sources to confirm, and consider Freedom of Information (FOIA) requests to government agencies related to the company and its filings. Check the company's compliance program, review hotlines and exit interview complaints about compliance to identify possible problems. Review all audits and investigations, by public or private payors, for the past five years. Interview those employees responsible for billing and claims for compliance. Do not rely on the seller's information and warranties alone.

Get an AKS review of the transaction. Prudent health care investors often have the transaction reviewed by financial and legal experts in the Anti-Kickback Statute to value the purchase for FMV purposes and to analyze the transaction for any AKS issues. This is always a good practice.

Manage Performance in Balance with Compliance. As anyone who has been through a government investigation, lawsuit or serious audit knows it can be very, very expensive. Excellent performance can still be achieved in conjunction with effective and robust compliance. The peace of mind alone is well worth the effort. When making changes and improvements to existing policies, processes, staffing and operations, check it to make certain that it is not creating a compliance problem or violation of law. Knowing the requirements is an essential first step and the compliance program does that for you. Pay attention to employee complaints and hotline calls or reports or concerns about compliance. Too often these are ignored as

takeover "growing pains" and that employee becomes a whistleblower, as in *Medrano*. If the company has a robust compliance program, maintain it, support it and use it. If not, invest in one. The government pays special attention to any new processes or operations that have as their sole purpose increasing claims or revenues without a counterbalancing purpose of maintaining compliance with payment rules. Anti-kickback issues can be nuanced, when is a commission not a commission but rather a kick-back? What is excessive compensation to a former owner? Private equity mangers should carefully consult with compliance experts and legal counsel before adopting these arrangements to protect themselves and their firm.

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¹ The lawsuit was originally brought by two former employees under the *qui tam* or whistleblower provisions of the federal False Claims Act which permits private parties to sue for false claims on behalf of the government and to receive a percentage of any recoveries.

² See, Dep't of Justice, Office of Public Affairs, *United States Files False Claims Act Complaint Against Compounding Pharmacy, Private Equity Firm, and Two Pharmacy Executives Alleging Payment of Kickbacks*, Feb. 23, 2018. Available at https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-compounding-pharmacy-private-equity. (Accessed on June 6, 2018).

³ Complaint in Intervention, United States ex rel. Medrano v. Diabetic Care RX, LLC, No. 15 Civ. 62617 (S.D. Fla. Feb. 16, 2018), D.E. 36.

⁴ Effective on February 3, 2017. See 82 FR 9131, Feb. 3, 2017.

⁵ Department of Justice. Fact Sheet, Significant False Claims Act Settlements and Judgments. Available at: https://www.justice.gov/opa/press-release/file/918366/download (Accessed May 16, 2018).

⁶ Bain & Company, *What's Behind the Surge in Retail Health Deals?* Available at http://www.bain.com/publications/articles/whats-behind-the-surge-in-retail-healthcare-deals.aspx (Accessed June 6, 2018).

⁷ *Id.*

⁸ See, Office of the Inspector General, Questionable Billing for Medicaid Pediatric Dental Services in California. OEI-02-14-00480. May 2015. See also, OIG, OIG Excludes Pediatric Dental Management Chain From Participation in Federal Health Care Programs. April 2014. Available at https://oig.hhs.gov/newsroom/news-releases/2014/cshm.asp. (Accessed June 6, 2018).

⁹ Dept. of Justice, Sally Yates, Deputy Attorney General, *Individual Accountability for Corporate Wrongdoing*, September 15, 2015. Available at https://www.justice.gov/archives/dag/file/769036/download. (Accessed June 6, 2018). ¹⁰ *Id*.