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Healthcare provider investments: key points for regulatory due diligence

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Private equity investments in healthcare providers have grown exponentially in recent years as investors see the high potential for profitability in the industry. Nonetheless, it is important for investors to keep in mind that healthcare entities are subject to numerous laws and regulations, including, without limitation, fraud and abuse laws. Apart from the expense of defending against allegations of fraud and abuse, the sanctions and penalties authorised by the fraud and abuse laws may prove devastating to a healthcare entity and its investors.

An investor seeking to make an acquisition of part of, or all of, a healthcare entity, should carefully conduct healthcare regulatory due diligence of the target and prudently structure the transaction in compliance with applicable laws before closing on the deal.

Due diligence and structure

The laws applicable to healthcare providers are too numerous for one article, but there are a few that most often arise. Anti-kickback laws generally prohibit persons from knowingly and wilfully offering or receiving remuneration in return

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for a referral or recommendation of a healthcare business. There may, however, be exceptions or safe harbour regulations that protect against liability under such laws depending upon the structure of the applicable financial arrangements. Self-referral laws generally prohibit a physician from making referrals for certain healthcare services to entities with which the physician (or an immediate family member) has a financial interest. False claims laws generally prohibit persons from knowingly presenting or causing to be presented a false or fraudulent claim for government payment or approval. It is also important to note that while these laws may not apply to the ownership structure of the target provider, there may be other types of relationships that are governed by the laws which may have an impact on the provider. The corporate practice of medicine doctrine ('CPOM') essentially bans unlicensed individuals and entities from engaging in the practice of medicine by restricting them from employing licensed physicians. Many jurisdictions with CPOM laws permit professional service entities to practice medicine, but only if owned by physicians licensed in that jurisdiction. Arrangements whereby non-licensees have financial stakes in professional service entities, whether through direct ownership or through management arrangements, must be carefully structured.

Investors in healthcare providers should understand how these laws are implicated by the specific facts and circumstances. They should also carefully examine all physician ancillary relationships outside of the basic ownership structure as those may have implications for the provider. The appropriate vetting should include ensuring that any service for which a physician is paid is fully needed by the provider and that the compensation paid by, or to, the physician, is fair market value.

Additionally, agreements with government payors should receive careful attention as a significant change in ownership of the provider may trigger the assignment provisions of the agreements or change of ownership regulations. Pre-closing consents may be required for the transaction and the notice periods to obtain such consents may be lengthy.

Moreover, transfers of facility licences and certificates of need ('CONs') are subject to various statutes and regulations. A significant change in ownership of the provider, even less than 50 percent, may trigger the transfer regulations. Depending on the structure of a transaction, transfers of licences and CONs can require notice or approval by the relevant agency. Proper diligence should be conducted in connection with any transaction to determine what the relevant agencies will require.

Regulatory counsel can determine the types of government notifications and/or consents that are required in connection with the transaction as part of its due diligence review. An investor should pay close attention to this portion of the transaction due diligence as government notification requirements could impact the way in which an investor should consider structuring the transaction, notifications could have an impact on the provider's ability to operate or bill payors for its services for some time after closing and the notifications could impact the timing of the closing date. In some instances, there could be a short-term depletion of the provider's revenue stream.

Further, to guard against the risk of government investigations, repayments or fraud suits, every healthcare company and organisation should have a well-defined corporate compliance program. These programs should be designed to guard against the risk of overbilling, McCARTER & ENGLISH ATTORNEYS AT LAW

miscoding or otherwise violating federal and state healthcare regulatory requirements. When considering an investment in an existing healthcare provider, an investor should comb through the provider's compliance program, if one exists. It is also important to check that the provider's compliance team is actively reviewing audit results and implementing effective corrective action plans.

Penalties and other reasons for scrutiny

Violations of anti-kickback and self-referral laws may lead to imprisonment, exclusion from government programs, criminal fines, civil liability and recoupment of payments made as a result of the violations. This risk is now present more than ever because of the increased interest of applicable laws. As such, an investor should determine if it wants a provider to resolve any actual violations prior to closing, either by making a repayment for monies owed or by voluntarily disclosing a violation to the government and reaching a settlement agreement. This should reduce the risk that a new owner will carry this type of liability going forward.

An investor must also consider what impact these violations might have on the provider's future revenue stream. It might be that a provider has been so successful in generating business in the past because it has been offering inducements that violate anti-kickback laws. Even if the investor is able to account for past liabilities, it should be aware that the provider will have to change its practices immediately and should evaluate whether the provider will be able to generate sufficient revenue after closing. If not, the investment might no longer be attractive, or worse, the buyer might not be in a position to service its debt payments.

In addition, CPOM violations can invite the close scrutiny of payors. The case law is rife with examples of payors going after providers who were improperly structured under the CPOM and seeking to recoup all payments by the plaintiff payors to the providers.

Finally, an investor should consider what effect, if any, these liabilities and changes in future practices have on the price it wants to pay to invest in the business. While a dramatic impact to the cash flows may affect whether an investor wants to proceed with a transaction, an adjustment to the purchase price may still cause the investment to be attractive to the investor.

Conclusion

Healthcare providers have become attractive investments for private equity in light of the industry's growth and the potential for robust profits. However, healthcare is also an area of strict regulation and the laws can reach even the most minor investors. It is imperative that investors considering a purchase of any portion of a healthcare provider do significant regulatory due diligence of the provider and work with competent counsel to educate themselves on the ins and outs of healthcare law. An investment, properly structured, can pay significant dividends. ■