

Believing in Conceiving: Private Equity's Rebirth in the Fertility Sector

Following the launch of several platforms in recent years, it seems that private equity's interest in the fertility space is trending up again. Investment in this sector brings some unique issues that potential investors should consider. In addition to the issues to consider in any [physician practice transaction](#), below we discuss **10 diligence issues unique to investments in the fertility sector**.

1. Don't assume that government pay is off the table or that anti-kickback laws do not apply.

For purposes of the federal Anti-Kickback Statute (AKS), TRICARE, which covers military personnel, counts as a federal healthcare program. TRICARE covers some services that could lead to conception. If government programs are involved, the federal AKS applies and will subject the transaction to AKS analysis. In addition, some states have all payor anti-kickback statutes that subject a transaction to the same requirements as the AKS but for all payors, including self-pay patients.

2. What is the structure of lab ownership?

A fertility practice necessitates coordination with an embryology lab. Whether the lab needs to be owned by the group practice will largely depend on state law requirements. Thus, a private equity investor may or may not be able to have direct ownership in the lab. This also could affect the structure of the physician ownership at the holding company level. In addition, some fertility joint ventures are currently being structured as lab-only joint ventures. If you are looking to pursue this model, it will be important to understand what revenues and costs are allocated between the practice and the lab.

3. Consider partnerships with referral sources.

We have seen investors consider separate practice partnerships in the fertility sector with referral source physicians such as OB/GYNs. Many states have physician self-referral laws that prohibit a physician from referring to an entity in which he or she has an ownership interest unless certain exceptions are met, the most common one being the group practice exception. This may require that the reproductive endocrinologist be housed in the OB/GYN practice itself or that a separate management company be established to manage the reproductive endocrinologist practice.

<p>4. If the practice reports SART data, do a deep dive.</p>	<p>Many reproductive endocrinologists report their statistics regarding the number of cycles and outcomes to the Society for Assisted Reproductive Technology (SART). It is important to know where your target falls as compared to industry norms as the fertility sector is highly consumer driven and patients often choose providers based on reported outcomes.</p>
<p>5. Ask about specimen storage.</p>	<p>Many practices provide for egg banking and specimen storage. An audit of the storage facility's records and any potential incidents, including equipment failure, is key to understanding historical exposure and the efficacy of existing operations.</p>
<p>6. How are patient consents managed?</p>	<p>Each state has separate requirements for patient consents specific to fertility, including those related to specimen storage. Ensuring that the practice complies with the requirements of each state in which it operates and from which it draws patients is an important part of diligence.</p>
<p>7. Beware of patient referral programs.</p>	<p>Although the practice may not receive government payments, as previously stated, many states have an all-payor AKS, which includes commercial insurance and self-pay patients. "Refer a Friend" and "Free Cycle Programs" could potentially be viewed by regulators as an inducement to patients under these statutes.</p>
<p>8. How are patient discounts managed?</p>	<p>Does the practice provide self-pay discounts or waive the patient co-pay? Doing so may present issues under both commercial contracts and state insurance laws, including potential payor audits. If the practice has a prompt pay discount, it is important to understand not only the amount of the discount but whether the discount is consistently applied across the patient population.</p>
<p>9. Where are procedures performed?</p>	<p>Understanding the mix of surgical procedures and whether they are performed in-office or in an ASC or hospital setting is important. Do the physicians have ownership in an ASC? If so, is it owned through or separate from the practice? Does the ASC restrict where procedures can be performed? If the physicians perform procedures in-office and in a separate ASC, it is important to understand where procedures will be performed post-closing, especially if you will not have ownership in either the practice or the ASC.</p>

10. What are the practice's relationships around pharmacy?

Fertility treatments involve the management of certain outpatient prescription drugs. What are the practice's existing relationships with pharmaceutical manufacturers? Does the practice or do the individual physicians have ownership in a fertility pharmacy? Although many states permit such ownership, there may be limits and restrictions. But, if the practice does not have its own pharmacy, this also may be an opportunity to add an ancillary revenue stream post-closing.

About the Bass, Berry & Sims Healthcare Private Equity Team

Although there are issues to consider when investing in any physician practice, an investment in certain specialties such as fertility present unique regulatory risks. Bass, Berry & Sims regularly counsels private equity firms in creative and current management service organization (MSO) structures across all specialties, including women's care and fertility. We are also experienced at structuring creative compensation and retention arrangements. With over 200 attorneys in its nationally recognized healthcare industry practice, we represent clients in more than 30 healthcare industry sectors. We regularly assist private equity firms and healthcare portfolio companies in finding creative and pragmatic, business-oriented solutions while navigating the unique healthcare regulatory, M&A and business environment.

To learn more about our team, industry experience and value-add, [click here](#).

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