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Healthcare Alert

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Key operational issues for reproductive healthcare companies

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What operational issues and unanticipated circumstances are reproductive and sexual healthcare companies facing as the field grows?

What's the Impact?

- Reproductive healthcare companies must balance business needs with unique legal and medical-ethical issues.
- Compliance with various state and federal laws related to patient care, services, and business practices requires careful attention to operational processes and objectives.

Companies operating in the reproductive healthcare and sexual health space provide an array of services and products and do so in a number of ways, including through the following:

- Digital platforms that provide information and resources for subscribers;
- Telehealth companies that connect patients with providers for treatment;
- Brick-and-mortar clinics and facilities that provide medical treatment and surgery services, in vitro fertilization (IVF), laboratory screening and testing, cryobanking, and other assisted

reproductive technologies (ART); and

- Companies that provide digital health technologies or complementary services that provide additional support to patients and consumers seeking reproductive and sexual care.

Given the innovation and accelerated progress in this area from a medical and technological standpoint, operational issues frequently arise that intersect with legal and medical-ethical matters and, as a result, often involve sensitive issues or must be resolved on an urgent basis.

Below, we have summarized the key operational issues that companies operating in the reproductive healthcare space address as the reproductive and sexual health field grows and faces unanticipated circumstances. This includes:

- Informed consent
- Embryo and gamete retention and disposition
- Anonymity of donors
- Screening and testing requirements
- Release of laboratory test results
- Marketing
- New services and business structures

Informed consent

Issues of informed consent surface in the context of reproductive healthcare services, primarily due to the fact that the first companies providing fertility care services only started doing so relatively recently—the first child born from IVF was in 1978—and technologies continue to rapidly evolve. Further, the laws governing these issues do not keep up with the medical advances being made. Thus, the interactions, relationships, and arrangements among fertility companies, on the one hand, and patients, donors, intended parents, donor-conceived persons, and other individuals receiving fertility services, on the other hand, result in unique issues that were not anticipated when IVF was first utilized, some of which are related to the "informed consent" process utilized. Ultimately, requirements for informed consents vary based on state law and subject matter, which should be tracked, followed, and properly documented in the patient's medical record.

For example, donors, as well as patients that utilize donated reproductive tissue, must provide clear consent with respect to the screening/testing of donated material and potential risks related to such. Additionally, there may be ambiguities related to the patient's intent with respect to the ultimate disposition, destruction, and/or transfer of the tissue.

Telehealth and digital health companies must build in appropriate consents to their patient workflows and should be cognizant of state laws in building out these processes. For example, state law may require a patient's consent to receive patient treatment via telehealth. Relatedly, there may be state regulatory requirements for patients to consent to each refill of a prescription by a mail-order pharmacy or "enrollment" by the patient in an auto-refill program for the medication. Depending on the state's requirements, certain "opt-in/opt-out" language may not

be permitted or must be tailored in a specific way to ensure the patient's agreement is deemed to be affirmative approval. Companies that are required to obtain patient consents should ensure that the workflows that operationalize these consents do so in a compliant manner.

Embryo and gamete retention and disposition

Fertility providers and tissue banks face unique situations regarding the disposition of reproductive tissue and field inquiries regarding the transfer, disposition, or destruction of tissue. These issues often arise when the donor of the reproductive tissue is no longer alive (or otherwise cannot confirm their intent) or if there are multiple parties involved that have a claim to the reproductive material (e.g., a couple that created and preserved an embryo).

From a legal perspective, proper inventorying of reproductive tissue is critical to avoid potential liability related to loss of tissue and improper transfers or dispositions. In addition, fertility providers must adhere to any agreements, patient authorizations, and consents that were completed prior to the patient's storing of reproductive tissue. Requirements for informed consent regarding reproductive tissue disposition are dictated by state law and, generally, should clearly address any time limitation on the storage of reproductive tissues (and fees for such) and the available choices for disposition of the tissue in the event of the death, divorce/separation, abandonment, or failure to pay storage fees.

However, cryopreservation agreements and informed consents may only address "typical" scenarios and may not provide clear direction regarding particular or nuanced issues that arise. For example, the posthumous collection of reproductive tissue may require a written directive for retrieval (based on state law requirements), which may not be available. In addition, parties may introduce "outside" facts in an attempt to show that a patient's prior consent does not reflect the person's subsequent wishes. Generally, disposition of reproductive tissue is governed by documentation evidencing the patient's intent at the time of the procedure/collection (e.g., cryopreservation agreement, disposition instructions). Addressing situations where a party seeks disposition that is contrary to the patient's documented intent or not clearly addressed within the patient's documentation is both interpersonally and legally sensitive and may require a court order to enable the fertility company to proceed.

In addition, following the *Dobbs* case, questions may arise with respect to the disposition or destruction of embryos depending on the parameters of new state laws that attempt to restrict abortion services. Providers and tissue banks may enter into arrangements to transfer embryos out of state in order to address potential issues in this regard.

Anonymity of donors

As described in our alert on the regulation of reproductive tissue banks, there is a recent trend to expand oversight of reproductive tissue banks and provide access to donor health information and identity.

Although there is industry support and advocacy for the release of non-identifying donor information for genetic and medical reasons, releasing identifying information about a donor

(and/or mandating this) still appears controversial and is handled in various ways by fertility centers, banks, and donor programs that operate in the US. That said, given the technological advances and data gathering/sharing capabilities of genetic sequencing companies, there is a possibility of a donor's loss of anonymity. As a result, fertility providers should have clear policies in place that delineate these scenarios and the provider's policy for responding to questions from donors, intended parents/relatives, and donor-conceived persons. In addition, reproductive healthcare companies should ensure that informed consent procedures and forms identify the potential disclosure/contact obligations of the company with respect to third-party donors in order to alert the donor of the potential for disclosure if and when required by law.

Screening and testing requirements

Federal and state laws govern the requirements for screening and testing of reproductive tissue. At the federal level, the Food and Drug Administration (FDA) implements a robust framework for tissue banks and imposes requirements regarding screening and testing of infectious diseases, genetic variants, and medical conditions. At the state level, there may be specific screening and testing requirements, which may vary based on the donor's relationship to the recipient and the donated material. However, these laws vary, and, as a result, questions come up with respect to testing of a particular infectious disease or genetic condition that is not mandated by federal or state law and liability associated with a lack of testing for non-mandated diseases and conditions.

Relatedly, companies are now identifying ways through new technologies to aggregate data and genetic markers in order to test for a broader range of conditions, including de novo genetic variants (i.e., non-hereditary). This would allow providers to identify potential non-normalities and select or discard embryos based on such results, which may raise ethical considerations.

Release of laboratory test results

Reproductive healthcare companies work hand-in-hand with laboratories to provide testing and screening services to patients and donors of reproductive tissue. Laboratory test results are frequently ordered for a patient in connection with a plan of care and may be interpreted by a physician or other allied health practitioner to provide the patient with information about what the test results mean and potential treatment options based on those results. In the reproductive and sexual health context, testing may occur for the purposes of genetic screening, diagnosing sexually transmitted diseases, and for additional purposes to evaluate fertility or health conditions that may impact fertility (e.g., sperm mobility, hormone levels, and otherwise). In these contexts, a physician may request authorization from the patient to provide the test results to a genetic counselor or other person assisting with the patient's treatment plan. More and more patients are requesting direct access to their laboratory test results, particularly as virtual care companies are coordinating physician and laboratory services as part of a single patient-facing offering and seek to make these results available to patients through their digital platforms. As companies facilitate access to test results, questions arise regarding a laboratory's ability to release this information to patients.

A number of states attempt to restrict a laboratory's release of test result information directly to patients (which varies in a number of ways, such as requiring the ordering provider's consent). However, the HIPAA Privacy Rule sought to remove barriers to an individual's direct access to his or her own test reports from covered entities, including laboratories, and preempts these state laws if the patient makes an affirmative request to the laboratory for release of this information to the patient. Further, the Privacy Rule and its commentary describe that an individual may not be denied access to his or her health information based on the information's sensitive nature or potential for causing distress to the individual, with a limited exception where a provider has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person, and the individual is provided a right to have this denial reviewed by a third-party provider. Furthermore, the information blocking provisions in the federal 21st Century Cures Act place additional requirements on laboratories with respect to test results which must be carefully considered.

Marketing

Reproductive healthcare companies that are utilizing social media strategies and online marketing tools to grow and expand must pay close attention to state and federal parameters around marketing through social media platforms to remain in compliance as regulations evolve, particularly with respect to payments made to marketers (including influencers, celebrities, or other patients that are paid to advertise services), promotion of off-label uses, and use of "free" products or provision of promo codes to potential consumers and patients to incentivize orders of services.

From a content ownership and control perspective, building in approval rights over content and messaging while balancing truth-in-advertising considerations is also critical.

New services and business structures

Historically, reproductive and sexual healthcare services have not been reimbursed by commercial and government payors, and these services are paid in cash by patients.

This cash pay reimbursement market has resulted in business structuring and innovative care delivery models that otherwise may pose additional risks under a commercial and government payor framework. This includes the utilization of digital tools to assist consumers and patients in navigating reproductive care, such as integrating electronic health records (EHR) systems, telemedicine, cloud-based storage, artificial intelligence (AI), and machine learning (ML) capabilities into existing, traditional services and processes to improve care. For example, a number of fertility providers have internal processes to automatize certain steps in an embryologist's workflow, and other AI-based solutions have similar mechanisms to harness existing data for embryo selection. Other companies utilize patient communication portals or other resources to drive patient satisfaction and understanding in an effort to bridge the gap between the clinical services and personalized patient needs.

As these services become more accepted, there has been a push for reimbursement by commercial and government payors, which should be considered by companies operating in this

space (particularly if the goal of the particular service or product is to obtain reimbursement from these payor types).

In addition, as a result of the cash-pay market, certain services and products have been cost-prohibitive for individuals. Increasingly, however, individuals are expecting that these types of services be included as part of their employer-sponsored benefits, which has resulted in a demand for direct-to-employer contracting between employers and organizations that can arrange for fertility benefits for employees. Fertility providers and reproductive healthcare companies may enter into arrangements with employers in order to satisfy this demand and should be aware of potential implications or additional obligations imposed.

What's next?

Reproductive and sexual healthcare companies must carefully balance the opportunities created by new technologies against the risks intrinsic to a rapidly shifting legal landscape. Nixon Peabody's Healthcare team understands the unique needs of businesses navigating this space and how to address these operational complexities.

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