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Healthcare Alert

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Reproductive healthcare trends: Navigating telehealth

By Alexandra Busto and Jill H. Gordon

We examine trends at the intersection of reproductive healthcare and telehealth and offer guidance for companies operating in this space.

What's the Impact?

- Telehealth companies and providers should continue to monitor evolving state regulatory requirements to ensure compliance as reproductive healthcare and sexual health services are delivered and advertised across states through virtual care systems

Telehealth services have traditionally included a wide range of reproductive healthcare and sexual health services, including contraception, medication abortion, erectile dysfunction treatment, fertility testing, and sexually transmitted infection care. During the public health emergency (PHE), telehealth companies expanded and invested in reproductive healthcare and sexual health, and the decision of the U.S. Supreme Court in *Dobbs v. Jackson Women's Health* spurred additional growth in this arena, resulting in the development of innovative virtual care ecosystems. The PHE's expiration on May 11, 2023, will coincide with continued state and federal reactions to the *Dobbs* decision, and consequently, telehealth providers delivering reproductive health services will be forced to confront state regulatory realities.

Below are the trends arising at the intersection of reproductive healthcare and telehealth that we are watching as 2023 progresses.

- **Multi-state practice**: State laws on licensing and the corporate practice of medicine continue to drive and significantly impact how reproductive healthcare services may be delivered on a state-by-state basis
- **Increase in state regulation of the provision of care**: Greater scrutiny of telehealth companies has resulted in an increase of state oversight over the provision of clinical care, including over transactions and investment in the healthcare space
  - At the same time, the recent flurry of actions and investigations at the federal level may spill over and create an enforcement frenzy by state regulators
  - This will likely lead to increased state interest in telehealth providers, including those traditionally operating in non-governmental payor settings, such as reproductive health and sexual health investors and providers
- **Rise and development of a consumer-centric virtual care ecosystem**: During the pandemic, healthcare companies focused their efforts on the delivery of care through a seamless consumer experience, which cultivated a higher level of integration among laboratory, prescribing providers, and pharmacy services
  - As companies react to *Dobbs* and find their regulatory footing in the post-pandemic world, companies will continue to identify the white space for delivering reproductive and sexual health services through innovative care models, which must be done in compliance with state laws
- **Direct-to-consumer advertising**: As consumers become increasingly comfortable and more vocal about seeking out reproductive and sexual health services, providers have harnessed social media to target and appeal to potential patients
  - Companies operating in this space should be clear about whether their service is regulated as a healthcare service, and if it is, pay close attention to state and federal parameters around marketing through social media platforms to remain in compliance as regulations evolve

Multi-state practice

State regulations continue to have a significant impact on the way reproductive and sexual care services are delivered across state lines. As a result, telehealth providers that provide cross-border reproductive healthcare services must pay close attention to state licensing and regulatory requirements for delivering care and prescribing medication on a multi-state basis. Importantly, although there have been efforts at the federal level to expand access to reproductive healthcare services following *Dobbs*, state laws ultimately drive the delivery of these services by telehealth companies and pharmacies. Thus, while federal regulators have signaled that there may be an easing of restrictions in order to enable access to these services, telehealth companies are still subject to state law restrictions based on the state where a patient is located and must operate in compliance with those laws.

From a federal perspective, there have been relaxations of traditional barriers to receiving abortion care services via telehealth. In January 2023, the U.S. Food and Drug Administration (FDA) issued regulations on medication abortion aimed at providing greater accessibility to these services. Specifically, the FDA's regulations (1) formalize the agency's earlier comments by permanently removing the requirement that a patient must have an in-person visit with a provider to obtain medication abortion and (2) expand the ability of retail pharmacies to dispense mifepristone—one of the drugs used in medication abortion—for patients with a prescription, where previously only certified prescribers were permitted to dispense mifepristone directly to the patient during an in-person visit.

Post *Dobbs*, a number of states have enacted abortion bans or restrictions and made it illegal or very difficult for pharmacies and telehealth providers to provide medication abortion. Critically, legal and regulatory requirements for prescribing and dispensing medication abortion are dictated by state requirements and vary on a state-by-state basis. As a result, state regulations are critical drivers of the way reproductive and sexual care services are delivered across state lines. As telehealth companies expand into new states and offer medication abortion and reproductive healthcare services to patients, companies should ensure state law compliance in each state of operation—meaning, states in which patients are located, as there may be a brighter light shone on care provision and prescribing practices as state and federal regulators continue to react to *Dobbs*.

Increase in state regulation over the provision of care

State legislatures and regulators have begun to closely evaluate private equity and commercial investment in healthcare, particularly in light of the proliferation of investment and the rise of telehealth during the pandemic. As a result, there has been an increase in state laws limiting or restricting merger and acquisition activity with the goal of addressing healthcare competition and accessibility issues, with states often tying the analysis to transactional activity. A number of states—California, Connecticut, Delaware, Massachusetts, Nevada, New Jersey, New York, Oregon, Rhode Island, and Washington—have established new, independent commissions or have otherwise expanded the authority of an existing regulatory body to monitor and limit growth in health spending. At the same time, *Dobbs* is shining a bright light on what historically has been a "fudging" of legal compliance with state licensure and corporate practice of medicine rules.

Moreover, at the federal level, in response to the rise of telehealth "unicorns" during the pandemic, the U.S. Department of Justice and Department of Health and Human Services Office of Inspector General have issued enforcement actions against telehealth companies for fraud and abuse violations, and the U.S. Drug Enforcement Agency is scrutinizing the prescribing practices of telehealth companies and online pharmacies.

Although traditionally, there has been less scrutiny in the arena of reproductive health because these services are paid in cash rather than reimbursed by government payors, a number of aspects of reproductive care and sexual health services are (or will be) potentially covered by government payors. Further, there may be a carry-over effect in enforcement activity as state governments begin to scrutinize telehealth models and take a closer look at transactions involving these companies. The increased state oversight undoubtedly adds regulatory pressures that impact telehealth companies and activity in this space.

Rise and development of a consumer-centric care ecosystem

The pandemic and the *Dobbs* decision created a confluence of events that prompted efforts to deliver reproductive healthcare services through virtual models and alternative care settings. At the outset of the pandemic, companies launched virtual care delivery systems to offer a seamless, consumer-facing experience, often with a suite of services offered to patients as a "one-stop shop." These models resulted in telehealth ecosystems requiring sophisticated integration among various provider types, spanning from laboratory services, clinical providers, and pharmacies. As part of this, companies have engaged in horizontal and vertical expansion to create infrastructure that houses virtual operating systems that are integrated with supply chain providers.

Companies that are expanding in this way or partnering with other providers and digital health companies must continue to comply with state laws in the states where patients are located, which governs how each of these services is provided and licensed at all levels.

Direct-to-consumer advertising

Over the past decade, the rise of social media has significantly expanded consumer access to information about health conditions, fostered patient demand for transparency in the provision of care, and created connectivity among similarly situated individuals and communities. This has been particularly evident in the arena of reproductive healthcare and sexual health services, which historically have been areas that have carried stigma or created feelings of embarrassment for patients.

As consumers have become more comfortable and vocal about these topics, there has been a corresponding increase in the level of comfort and collaboration between social media and healthcare providers in this space. In response to this, companies have sought out ways to expand reproductive healthcare services and invest in sexual health beyond the more well-known categories of contraception and pregnancy, and new digital products and services have been created.

As a result, there has been a blurring of lines between convenience and clinical care. On the one end of the spectrum, companies that provide healthcare services must comply with federal and state regulatory frameworks that govern the provision of healthcare services, including with respect to advertising and marketing of those services. On the other end, companies may offer a product or service that does not constitute the provision of healthcare and, thus, are primarily responsible for compliance with fair business practices (e.g., truth-in-advertising rules) like regular businesses.

The gradations across this spectrum are complex, and companies should carefully vet whether their product or service may be deemed within the scope of healthcare and, thus, a regulated activity. Healthcare and companies operating in this space (or on its fringes) that utilize social media to promote products and services should pay close attention to (1) whether the advertisement is for a product or service that falls within the definition of healthcare—i.e., is a regulated activity—and (2) what parameters state and federal regulators have established around promotion and use of social media and influencers, including with respect to off-label uses. Recent enforcement actions at the federal level have used social media advertisements as their hook, ultimately questioning treatment and prescribing practices (particularly where controlled substances are involved) of companies that are involved in suspect marketing schemes.

Looking ahead

Telehealth companies and providers should continue to monitor the evolving regulatory and legislative landscape, particularly at the state level, to ensure compliance as reproductive healthcare and sexual health services are delivered across state lines through virtual care systems.

Our Healthcare team will continue to monitor the trends in reproductive healthcare that will have an impact on the industry. For more information on the content of this alert, please contact your Nixon Peabody attorney or:

Alexandra Busto
213.629.6146
abusto@nixonpeabody.com

Jill H. Gordon
213.629.6175
jgordon@nixonpeabody.com