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HEALTHCARE LAWYERS

Client Alert: Abortion – Five Issues to Watch in 2023

Priority Update:
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It has been over half a year since the Dobbs v. Jackson Women's Health case was ruled upon by the Supreme Court, effectively overturning *Roe v. Wade* and granting extensive power to individual states to regulate, restrict, or ban abortion. The *Dobbs* decision has had ripple effects in the realm of healthcare delivery and health privacy, resulting in disruptions in shared national standards for women's healthcare, disparities in medical education and training due to geographic location, increasing misconceptions about abortion access among the public and healthcare professionals, a growing reliance on telehealth services and medication abortion, and an erosion of medical privacy protections. Here are the top five issues we are monitoring in 2023.

1. The End of Homogenous Standards of Care? The *Dobbs* decision altered abortion access nationwide, reinstating previously invalidated restrictions and triggering new prohibitions in many states. Multiple states with limited existing legislation have filled policy gaps previously occupied by federal law. Some passed regulations restricting access while others bolstered abortion protections. The result is that we now live in country with a complex patchwork of different laws governing reproductive care. As of January 2023, 25 states broadly permit access to clinical and telehealth medication abortions, while 13 states have banned abortion at every stage of pregnancy without exceptions in cases of rape or incest. The remaining states have varying gestational limits (i.e. six weeks in Georgia, 15 weeks in Arizona and Florida, 22 weeks in South Carolina, etc.). Meanwhile, roughly half require in-person clinical visits with a physician (or requirements for ultrasound) that curtail or effectively eliminate telehealth/medication abortion options. In this variegated legal landscape, patients are compelled to weigh different risks dependent on their state of residence or when considering travel to more restrictive jurisdictions. A woman with a high-risk pregnancy in Kansas City, *Kansas* knows she can terminate her pregnancy up to 22 weeks, whereas in Kansas City, *Missouri*, she would only be able to do so in a medical emergency. While a victim of rape in California can procure an abortion locally, no such option exists for residents of Texas or Louisiana, who might be required to travel hundreds of miles to a state permitting an elective abortion.

For providers in states where abortion is heavily restricted or criminalized, there are significant concerns about compromised diagnostic and treatment standards. Women may be reluctant to disclose vital medical history involving reproductive health. Correspondingly, healthcare providers may be reluctant to ask standard medical questions related to any history of miscarriage or abortion. There have been recent reports of obstetricians delaying treating pregnancy complications until patients' lives are in danger for fear of civil lawsuits and other legal consequences. As the legal landscape continues to shift, it remains to be seen how providers and patients will navigate diverging standards and expectations impacting reproductive care.

2. Divergent Med-School Standards Over 40% ob-gyn residents are educated in states that make non-emergency abortions unlawful. Residency programs for obstetricians and gynecologists face a precarious situation as they try to balance state abortion bans with national accreditation requirements. In September, the Accreditation Council for Graduate Medical Education (ACGME) reaffirmed its standards for ob-gyn trainees:

"Programs must provide clinical experience or access to clinical experience in the provision of abortions as part of the planned curriculum. If a program is in a jurisdiction where resident access to this clinical experience is unlawful, the program must provide access to this clinical experience in a different jurisdiction where it is lawful."

Among many challenges, there are multiple dilemmas for medical schools. If they wish to keep their accreditation, they will need to overcome the logistic challenges involved in arranging out-of-state training, and circumvent state attorneys general and legislatures who may advocate that abortion related training is professionally unnecessary. On the other hand, should they comply with state demands to remove abortion training from their programs, they risk loss of accreditation, which will make the schools less attractive to applicants, and will likely diminish the reputation of graduates who will be thought less-qualified than graduates from medical programs in permissive

states. There are larger long-term concerns involving sufficient accessibility to clinicians working in women's health. In many hospitals and other medical facilities, residents are often relied upon as a cost-effective source of labor. Should medical students interested in reproductive health decide en masse to pursue their education or clinical training in permissive states, one concern is that fewer available ob/gyn residents may lead to inferior level of medical expertise available to women living in prohibitive states.

3. Misconceptions about Abortion Access It is important to recognize that binary categorizations of permissive or prohibitive states can be misleading. It is easy to put California in one box and Texas in another, but there are many states that occupy a middle ground. Georgia, for example, is considered very restrictive with a ban after only six weeks of gestation. Similarly, states that require abortions to take place in a hospital setting can greatly diminish access, while in-person requirements eliminate tele-abortion options. In addition, ongoing legal challenges and court injunctions that can quickly halt or reverse state policy contribute to public confusion as well.

Consistent policy within a single state requires cooperation and agreement between the executive, legislative, and judicial branches of government. In Wisconsin, a pre-Roe ban went into effect immediately after the *Dobbs* decision. But the response by Wisconsin's Attorney General, Josh Kaul, was to offer clemency to anyone prosecuted for violating the statue, followed by announcement that that his office would be challenging the ban in court. Despite such assurances, abortion clinics vacated the state of Wisconsin. Multiple states have permissive laws, but attorney generals in power who are threatening abortion providers. These conflicting forces create a twilight zone that can puzzle doctors and patients.

Media coverage can also obscure the underlying legal reality. Last year, voters in both Kansas and Kentucky *rejected* ballot initiatives that would determine that no guarantee to a right to abortion existed under the constitution of the state. These results were widely lauded by pro-choice advocates. The aggressive media coverage obscured the fact that neither result altered the status quo, such that Kentucky's bans remained in effect, while Kansas' statuary bans remained inactive per the State Supreme Court's ruling.

Similarly, active litigation contributes to a sense of limbo and uncertainty as to what services providers can offer or render. For example, a court in Wyoming ruled that an abortion ban with exceptions for medical emergencies was unconstitutionally vague, as it did not provide adequate guidance for patients and clinicians as to what was unlawful. Meanwhile, in September, Indiana passed an abortion ban that was quickly blocked pending a looming decision from the State Supreme Court. The dependability of future-oriented medical guidance, particularly in cases of high-risk pregnancies or potential fetal abnormalities, relies on a stable and predictable legal environment, which is currently absent in multiple states.

Finally, there is an alarming level of confusion about telehealth/medication abortion availability. According to recent KFF Health Tracking Poll, approximately half of adults report they are "unsure" as to whether medication abortion is legal in their state, including 41% of women ages 18 to 49. Similarly, troubling, 10% of women residing in states where abortion is currently banned incorrectly believe that medication abortion is legal in their state.

4. Telemedicine Medication Abortions The COVID-19 pandemic played a significant role in the growth of telehealth abortion in the United States. In response to the pandemic, the U.S. Food and Drug Administration (FDA) relaxed some of its rules around mifepristone, allowing it to be prescribed through mail-order pharmacies. On January 3, the FDA went a step further and approved a protocol allowing pharmacies certified by the manufacturers to dispense mifepristone directly to patients with a prescription. Unless prevented by state law, the new policy would allow a patient to pick-up a prescription at a local certified pharmacy and avoid the airmail delay. Such changes are conducive to growing demand on telemedicine abortions. Additionally, in states where abortion is unavailable, patients who might have sought an in-person abortion are now turning to out-of-state telehealth instead. Inevitably, this will end up in court. At some point, restrictive states may pursue out-of-state entities, such as Aid Access or carafem, who provide their residents with mail-order prescriptions of medication abortion. Such litigation may pressure cross-state licensing norms for physicians, nurse practitioners and pharmacists.

One of most aggressive lawsuits currently receiving attention is *Alliance for Hippocratic Medicine v. FDA*. Plaintiffs comprise a group of anti-abortion medical organizations and doctors. They are suing the FDA and Biden Administration, seeking to vacate the approval of mifepristone and demanding that it be immediately removed from the market. The plaintiffs claim that the FDA used a regulatory approval pathway that is only available for treating life-threatening illnesses, inappropriately disregarded contrary scientific evidence, and ignored the Comstock Act (which prohibits sending lewd materials in the mail). The FDA countered that the plaintiffs lacked standing to sue, that their claims were untimely, and asserted that the agency properly exercised its authority to approve mifepristone based on its scientific expertise. The litigants are currently awaiting a ruling by the trial judge, which threatens an unprecedented removal of approval status for a medication in the United States, with confusing implications for practitioners. If a preliminary injunction currently under consideration is granted, the focus will turn

to whether the Fifth Circuit Court of Appeal or the U.S. Supreme Court will do anything to prevent a massive disruption to access to mifepristone.

Meanwhile, in Washington v. FDA, Washington Attorney General Bob Ferguson is leading a lawsuit against the FDA, joined by eleven other states, seeking to ease restrictions on mifepristone that are exceptional and restrict access to mifepristone needlessly complicated. The FDA's mifepristone risk mitigation program (REMS) requires prescribers and pharmacies to be specifically certified, and dispensation to comply with certain requirements such as ensuring that disclosures and acknowledgments are reviewed and signed by the patient. Arguing that mifepristone sends fewer people to the emergency room than Tylenol or Viagra, Ferguson asserts that the FDA regimen is unduly burdensome, causing many pharmacies and physicians to refrain from dispensing abortion medication. The outcomes of these cases may have significant implications for the future of telemedicine and medication abortions in the US.

In other cases, pro-choice advocates are currently pursuing several major lawsuits. In late January 2023, plaintiffs filed separate cases in North Carolina and West Virginia federal district courts, arguing that state restrictions on medication abortion are preempted by the Federal Food, Drug, and Cosmetic Act (FD&C Act). In accordance with preemption doctrine, a federal law can supersede state law if complying with both is impossible, or if state law obstructs Congress's objectives. In Bryant v. Stein, a North Carolina physician is suing the state's Attorney General, claiming that the state's medication abortion controls – including an in-person dispensing requirement and a 72-hour waiting period – are preempted by federal law. In GenBioPro v. Sorsaia, a pharmaceutical vendor of generic mifepristone is suing officials in West Virginia, challenging state laws restricting mifepristone access. The complaint relies on preemption doctrine, arguing that the state's requirements unlawfully conflict with the FDA's authority to determine prescription drug risks and medication dispensing standards nationwide. These cases highlight the way that *Dobbs* has reshaped and accelerated the use of litigation around reproductive health rights.

5. Data Privacy Concerns in a Post-*Dobbs* World The *Dobbs* decision raises important questions about health privacy and the need for new laws to protect the confidentiality of personal health information. Following the Supreme Court decision in *Dobbs*, several states with restrictive abortion laws announced their intention to investigate and prosecute individuals who facilitate out-of-state abortions in abortion-permissive states, including patients, providers, and third parties such as employer health plans. This has brought attention to the limitations and gaps of the Health Insurance Portability and Accountability Act (HIPAA) as a source of legal protection for provider-patient confidentiality, personal medical information, and data privacy. Despite a guidance statement from the Department of Health and Human Services in June 2022, HIPAA applies only narrowly to healthcare providers who submit electronic claims to third party payers and their contractors and does not address other entities.

In shining a light on the limits of HIPAA to protect heath privacy, the Federal Trade Commission (FTC) has emerged as a force, utilizing its powers to address consumer health privacy beyond HIPAA. It is no accident that the FTC's first consumer health privacy decision focused on Flo Health, a period tracking app accused of misleading consumers about their health data protection. The FTC's growing role cracking down on consumer health privacy violations can only be understood as a response to the privacy concerns awakened by the *Dobbs* decision. Beyond the FTC, the need is apparent for additional protections in the form of state-specific health privacy laws and comprehensive consumer data privacy laws to secure health privacy and prevent unauthorized access to personal medical information.

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