# NELSON HARDIMAN

# **Client Alert: How Telemedicine Changes the Abortion Conversation**

## Legal Update: How Telemedicine Changes the Abortion Conversation

Since the <u>May 2022 leaking</u> of a prospective Supreme Court decision to <u>reverse Roe v. Wade</u>, public attention has focused on a groundswell of abortion-related legislation. By the end of the year, some estimate that <u>26 states</u> will try to reduce or eliminate legal abortion access within their jurisdictions, with a smaller number of states trying to strengthen or expand legal abortion access.

Meanwhile, much less attention is being paid to the ways in which the abortion procedure itself has changed in recent decades. Both medicine and technology have advanced in significant ways since the 1973 Supreme Court decision establishing legal protections for women electing to terminate a pregnancy.

Half a century ago, obtaining a safe abortion required a procedure performed in a medical clinic or hospital. Today, more than half of all abortions occur in privacy as the result of a medication that can be taken in privacy. Increasingly, the prescribing of the medication takes place virtually, in digital exchanges over a computer or smartphone, and the medication can be mailed, affording even further privacy. The implications for this transformation are profound and are likely to confound efforts to prevent access.

In 2000, the FDA approved <u>medication abortion</u>. That decision enabled clinicians (not only physicians, but also physician assistants (PAs) and nurse practitioners (NPs) to prescribe mifepristone and misoprostol for patients seeking to end a pregnancy in its first 70 days. As the two-drug regimen can be safely taken at home, practically, there was no longer a need for patients to physically visit a medical facility. Nevertheless, pre-pandemic, the FDA required that a patient physically visit the dispensing site as a condition to obtaining the drug regimen. In the name of "safety," several states also mandated multiple in-person clinician visits, an additional requirement perceived by many as a step to slow and dissuade some women from following through with the procedure. Multiple studies in recent years have shown the medications to be safe and effective, raising arguments that access should be further extended with over-the-counter (OTC) availability without a prescription requirement.

The COVID-19 pandemic imposed a paradigm shift regarding the relative value of in-person contact when weighed against the risk of an infectious viral transmission. Near the beginning of pandemic, the <u>FDA waived</u> in-person dispensing requirements for nearly all medications, with the glaring exception of mifepristone. After lawsuits and some back and forth court rulings throughout 2021, by spring 2021, the FDA <u>announced</u> it would no longer enforce rules requiring in-person visits, permitting mailing of the medication. As of <u>December 2021</u>, the rule was formalized permitting certified prescribers or pharmacies to dispatch mifepristone *by mail*. Similarly, President Biden reversed a late Trump-administration policy requiring the in-person clinician visit.

For most of the country, these changes make it possible for clinicians and patients to connect remotely via the Internet, then conduct the necessary encounter and exchange of information required for medical abortion in private locations. Similarly, medication can now be lawfully dispensed by mail directly to the patient. The impact of these changes is profound. Already, a majority of abortions no longer occur in person at a fixed, identifiable, locations susceptible to protests or police activity. In the future, as a telemedicine modality of abortion predominates, it will be difficult (if not practically impossible) for state authorities to monitor, much less interfere or prevent medication abortions. States that try will likely be in opposition to a majority of their voters. Public opinion strongly favors privacy rights and tends to reflect support for first trimester access to abortion. (Mifepristone is approved for up to ten weeks, well within the first trimester.)

Nevertheless, the adoption of restrictive laws, which try to "close the door" on telemedicine as an avenue of abortion, will limit the number of clinicians who can furnish abortion access. The practice of medicine and pharmacy are licensed at the state level. Thus, doctors and pharmacies licensed in restrictive states have no desire to violate laws that risk their licensing or other enforcement actions. On a parallel track, parties practicing medicine or pharmacy may also risk potential *criminal* action for allegations related to unlicensed practice.

At the same time, there is a practical limit to what regulators or law enforcement can hope to achieve in the face of modern technology. For example, nothing prevents a patient residing in a prohibitive state from establishing or



claiming a sufficient relationship with a permissive state, allowing for a doctor licensed in the permissive state to prescribe and dispense the medication. Restrictive states will find it difficult if not impossible to enforce their restrictions on out-of-state licensed physicians and pharmacies. Practically speaking, one state has no power to influence another state's regulatory authority. To the extent that legislative efforts reflect the "battle lines", it is already apparent that permissive states will deny enforcement of any orders from restrictive states. All of these differences are likely to afford "out-of-state" doctors a greater degree of protection in the process.

Yet another dimension of the conversation goes beyond the question of what doctors and pharmacies may or may not do. Already, there are advocacy organizations, some based outside the United States (such as <u>AidAccess</u>) willing to prescribe and mail abortion pills from abroad. While these activities may not comport with federal law (*i.e.* the Food, Drug and Cosmetic Act, which restricts importation of sources of non-FDA approved versions of drugs), there is no practical way to prevent this form of access. The flood of fentanyl mailed into the United States from abroad without interdiction should provide a preview of the near impossibility of intercepting small quantities of pills sent through the mail.

Even as the public policy debate continues to rage over implications of the anticipated demise of *Roe v. Wade*, the rise of telemedical abortion highlights the extent to which technology reshapes the conversation and the practical contours of the question of abortion access. Medication abortion itself brings the conversation around abortion into a consumer-directed era of healthcare, in which regulators have less ability to track, let alone manage, patient behavior and clinical options that occur digitally or over the phone. Ultimately, abortion represents yet another part of the healthcare universe transformed by telemedicine.

**Note:** Nelson Hardiman is launching a series of webinars delving deeper into the regulatory questions at the intersection of telemedicine and abortion, beginning **June 29th**. For additional information, please visit our <u>website</u>. In the interim, please feel free to email us at <u>info@nelsonhardiman.com</u>.

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