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Assuring Access to Abortion

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SUMMARY. Over the spring of 2020, numerous states announced measures suspending abortions in response to COVID-19. Banning abortion during the pandemic proved counterproductive. Not only did bans fail to preserve health care resources, prohibiting access to abortion care exacerbates the strain on the health care system. People who lack access to abortions will travel to neighboring states, induce their own abortions, or carry pregnancies to term. More importantly, the people hit hardest by suspending abortion care are those for whom the pandemic already has had devastating effects. Lifting legal restrictions on medication abortion, and expanding telehealth abortion services specifically, can conserve health care resources and reduce unnecessary provider-patient contact. To these ends, in July 2020, a federal district court enjoined a U.S. Food & Drug Administration restriction, for the duration of the pandemic, that requires in-person collection of the first drug (mifepristone) of the medication abortion regimen at a health care facility. However, the Supreme Court stayed the injunction pending the appeals process. In addition, eight states carve out exceptions for abortion in their telemedicine policies, and 19 states require in-person administration of abortion services, thereby prohibiting remote care indirectly. The result is a country divided by legal permission for teleabortion: around half of states permit remote care and the other half prohibit it. Policymakers and executive officials can eliminate barriers to safe abortion services now and in the future. Although not without limitations, telehealth for medication abortion can ease the burdens on pregnant people, health care workers, and health systems in light of the unprecedented challenges presented by COVID-19.

Introduction

Abortion law and policy has been in flux since the beginning of the pandemic. In March 2020, 12 states suspended abortion care, for differing lengths of time, in response to COVID-19 (Sobel et al., 2020). State officials argued that the policies classifying abortion as a nonessential surgery reduced patient-physician contact as well as preserved medical supplies, hospital space, health care capacity. All but two appellate courts were unpersuaded by these arguments. Federal district courts in six states issued injunctions of the orders after holding that the bans violated patients' constitutional right to an abortion, ignored medical evidence of the short-term and long-term consequences of delayed abortion care, and exacerbated the public health emergency by ultimately increasing pregnant people's use of health care systems.

Around the same time, telemedicine for medication abortion care expanded over the summer and fall of 2020. Medication abortions make up almost 40% of the nation's total abortions (Jones et al., 2019). In a medication abortion, which occurs during the first 10 weeks of pregnancy (or 11 weeks for off-label but accepted use), patients ingest two pills: the first drug, mifepristone, is followed by a second drug, misoprostol, taken 24 to 48 hours later. Extensive research demonstrates that medication abortion, like many other health care procedures, can be safely and effectively administered online or over the telephone. In July 2020, a federal district court held that the FDA's requirement that mifepristone, the first drug

administered in a medication abortion, must be collected at a hospital, medical office, or clinic was unconstitutional while the pandemic lasts. As a result of the district court's decision, patients living in states that do not require in-person collection could receive counseling online and medication abortion by mail. The expansion of remote care for abortion, however, slowed when the Supreme Court stayed the district court's injunction in January 2021.

Given the challenges still presented by COVID-19, state and federal policy should permit teleabortion to the extent it is feasible, and suspend medically unnecessary requirements, such as in-person counseling, that increase clinic-patient contact. Enabling remote access to abortion would ease the already heavy burdens that fall disproportionately on low-income people and people of color, and thwart state attempts to further eviscerate abortion rights. To that end, the Biden administration should suspend the FDA's in-person requirement, removing the unnecessary impediments to progress erected by the Supreme Court. In the same vein, states should encourage the expansion of telehealth, which includes medication abortion.

State Abortion Care Suspensions

In March and April of 2020, 12 states issued executive orders and public health directives that either implicitly or explicitly suspended most (and in one state, all) abortion services during the COVID-19 emergency. In all but two states, these policies were

enjoined by courts, lifted after settlements with state officials, or expired when executive orders expired. (For more information on state abortion bans, see Chapter 15 in *Assessing Legal Responses to COVID-19: Volume I*).

The executive orders of five states (Alabama, Ohio, Oklahoma, Tennessee, Texas), issued by the governor or the state's public health department, were enjoined by federal district courts, which held that either the suspension of non-essential services did not apply to abortion or the bans contravened the constitutional right to abortion before viability. Texas is distinct among these five states because its legal path was particularly twisting; a federal appellate court ultimately enjoined the ban in part.

The Texas attorney general applied the Governor's order mandating all licensed health care professionals postpone surgeries and procedures not immediately medically necessary to all abortion care — surgical and medication — unless there was a threat to the life of the pregnant person. In late March 2020, the U.S. District Court for the Western District of Texas granted a temporary restraining order, which the Court of Appeals for the Fifth Circuit reversed. The Fifth Circuit held that Texas's abortion ban was a reasonable way to conserve medical supplies and hospital capacity, even though medication abortion requires no gown, mask, eyewear, shoe covers, or gloves; is not administered in a hospital or physician's office but in standalone clinics; and rarely results in a complication that would require a hospital bed (Upadhyay & Grossman, 2019). The Fifth Circuit, on the other hand, determined that delivering medication abortion requires personal protective equipment because of the pre-termination ultrasound and in-person consultation required of all abortions by Texas law. The district court granted a second temporary restraining order, permitting medication abortion and abortion for patients nearing the state's gestational legal limit. After another round of opinions, the Fifth Circuit reversed again, which resulted in the resumption of the abortion suspension with one exception. The revived suspension was short-lived; two days later, the governor's office issued a statement that abortion was excluded from a new order's terms.

Seven states (Alaska, Arkansas, Iowa, Kentucky, Louisiana, Mississippi, West Virginia) issued orders that expired or were replaced. The Arkansas order lasted longer than the others. From April 10, 2020, until June 1, 2020, the Arkansas Department of Health banned surgical abortions except if necessary to protect the life or health of the patient. The U.S. District Court for the Eastern District of Arkansas granted a temporary restraining order, but the Court of Appeals for the Eighth Circuit reversed it. The Eighth Circuit held that suspending abortion was a reasonable means to conserve hospital space and PPE, adopting the Fifth Circuit's reasoning. The state issued a modified order allowing access to abortion services if patients had at least one negative COVID-19 test within 48 hours (then, as modified, 72 hours) prior to the procedure. The testing requirement was lifted on June 12, 2020, when the order expired.

During the weeks of fluctuating legal status across these states, patients had their appointments cancelled with a moment's notice

and were turned away from clinics (Alexandria, 2020). Clinics that reopened had lengthy waiting lists for appointments. The resulting hardships of state abortion suspensions, affirm that, for patients with delayed or denied care, abortion is an essential health care service.

Strain on the Healthcare System and Deepened Disparities

What state suspensions made clear was that abortion restrictions do not conserve scarce medical resources and do not impede COVID-19's spread. To emphasize what may be obvious, during the pandemic, people who travel for abortion care cannot limit social contact and take risks that could be avoided but for their state's animus for abortion rights. Many people who lack access to abortion will travel to other jurisdictions to end their pregnancies, consuming the same medical resources but requiring providers in neighboring states — without the assistance of additional staff or capacity — to manage an influx of new patients (Bearak et al., 2020). As a consequence, wait times and crowding increased at clinics in states neighboring those with abortion suspensions. Increased delay results in more expensive and invasive procedures later in pregnancy or timing out of a legal abortion altogether. In Texas, for instance, according to a recent study, the abortion rate declined by 38% during April 2020 (White et al., 2021).

People who did not or could not travel might terminate pregnancies by ordering online one or both of the pills taken in a medication abortion and taking them without physician supervision. Self-managed abortion can be effective and safe. However, it can also increase costs for the health care system if patients lack accurate information and adverse health consequences occur.

Finally, and perhaps most significantly, continuing a pregnancy requires prenatal care that includes multiple interactions, each necessitating PPE, with health care professionals — far more PPE, hospital space, and health care professionals' time than any type of abortion. Furthermore, childbirth has steep costs and health risks, particularly for low-income people and people of color. The United States has the worst maternal mortality rate in comparison to countries similarly situated; Black women are four times as likely to die in childbirth than white women (Foster, 2020).

As the pandemic has raged, health disparities have become only more pronounced. Abortion suspensions fall disproportionately on people who have shouldered the hardships imposed by COVID-19 — people who are unemployed or essential workers, and those who do not have access to health care or face other logistical challenges. Expanding access to medication abortion, particularly through telemedicine, is one means to help slow COVID-19's spread and close resource gaps. The case, *American College of Obstetricians & Gynecologists (ACOG) v. FDA*, addressed just that issue by lifting a nationwide requirement that patients collect medication abortion at a healthcare facility — progress now thwarted by the Supreme Court's order staying the injunction. And as the next section makes plain, longstanding state and federal regulation, which contradicts medical evidence and clinical practice, continues to make delivering medication abortion needlessly difficult.

The Battle over Remote Abortion Care

Abortion has been more closely regulated than comparable (and riskier) outpatient procedures long before COVID-19 (Jones et al., 2018). Specifically, state legislation has targeted medication abortion to undermine abortion rights rather than ensure patient safety, during the pandemic or before it. On the contrary, medication abortion could require no contact with health care providers for most patients, except that law requires it.

Legal Restrictions on Telemedicine for Abortion

Despite the ease with which medication abortion can be administered, and its proven effectiveness, nearly half of the states and the federal government obstruct efforts to provide remote solutions for its delivery. The FDA restricts mifepristone under a drug safety program – a Risk Evaluation and Mitigation Strategy, or REMS. When FDA concludes that REMS requirements are insufficient to protect patient safety, it can also issue an Elements to Assure Safe Use (ETASU), which can circumscribe distribution and limit who can prescribe a drug and under what conditions. The FDA mandates, among other requirements, collection of mifepristone at a clinic, physician's office, medical center, or hospital. The dominant interpretation of the ETASU is that certified providers may not dispense mifepristone through the mail or retail pharmacy.

Several states' laws impose additional restrictions in accord with or beyond FDA restrictions. Nineteen states mandate that the prescribing physician be physically present (LawAtlas State Abortion Laws, 2019). Eight states ban telehealth through legislation that exempts abortion from any permitted telemedicine. In addition, 33 states prohibit non-physicians from administering medication abortion despite evidence that advanced practice clinicians can safely and effectively counsel patients. These restrictions layer on top of additional legal requirements, such as mandatory pre-termination ultrasounds and in-person counseling.

So, while the clear trend is to extend telemedicine generally through state orders and legislation, abortion continues to receive exceptional treatment. The same is true on the federal level. In 2020, the federal government expanded telehealth for non-abortion medical services. The coronavirus relief legislation issued guidelines for Medicaid and Medicare coverage of telehealth and included grants to develop telehealth practices for federally qualified health centers, rural health clinics, and hospices. Yet last year, Congress considered the Teleabortion Prevention Act, which would require that physicians be present during terminations.

Support for Telemedicine for Abortion

A study launched by Gynuity Health Projects (with FDA permission through an Investigational New Drug Approval) assesses the efficacy of providing medication abortion care by videoconference and mail. Providers counsel patients through videoconferencing, and patients confirm gestational age with blood tests and ultrasounds at a location of their choosing. During the pandemic, patients who are not at risk for medical complications, are less than eight weeks pregnant, and have regular menstrual cycles

may not need blood tests or ultrasounds. Results of the study indicate that "direct-to-patient telemedicine abortion service was safe, effective, efficient, and satisfactory" (Raymond et al., 2019). Embracing this evidence, several states have protected access to abortion through executive orders, encouraging an increasing number of health centers to adopt teleabortion methods (Baker, 2020).

The case suspending the ETASU for collecting medication abortion – *ACOG v. FDA* – is presently before federal courts. On July 13, 2020, the U.S. District Court of the District of Maryland issued a nationwide injunction of in-person requirement for the duration of COVID-19 national emergency. The court noted that the FDA's restriction contradicts substantial evidence of the drug's safety and singles out mifepristone without any corresponding health benefit. Of the thousands of drugs regulated by the FDA, and the 17 subject to the same ETASU, mifepristone is the only one that patients must retrieve at a medical center but may self-administer without supervision. The FDA further permits mailing the same compound, when not prescribed for abortion or miscarriage, to patients' homes in higher doses and larger quantities.

The decision also details the cumulative effects of abortion restrictions based on expert testimony and public health research. The court cited evidence of how the in-person requirement exacerbates the burdens already shouldered by those who work essential jobs or are unemployed, have lost health insurance, live in multi-generational homes, and lack transportation. The opinion highlighted that low-income patients and people of color suffer disproportionately; they are more likely to become ill, to have inadequate resources to respond to illness, and will have worse health outcomes as a result deep health inequalities.

The FDA appealed the district court's decision to the U.S. Court of Appeals for the Fourth Circuit, and petitioned the Supreme Court for a stay of the injunction in October and again in December 2020. Again before the district court, the briefs filed by the solicitor general and ten states strain credibility, contesting that in-person collection imposes heightened risks for patients. States like Arkansas, which suspended abortion under the guise of protecting people from COVID-19, claimed that the pandemic poses only a minimal threat for people seeking abortion care. The government argued that mask mandates, increased testing, and better treatment have recently "mitigated or resolved any burdens" on travel, finances, or childcare, as well as eliminated risks of contraction (Solicitor General Brief to U.S. District Court of the District of Maryland, Case 8:20-cv-01320-TDC, Nov. 11, 2020).

The government's position was that remote medication abortion is a health risk, but COVID-19 contraction is not. ACOG replied with the obvious rejoinder: "the day Defendants filed their motion, approximately 100,000 people in the United States were diagnosed with COVID-19 – a new global record – and nearly 1,000 people died from it" (Plaintiff Brief in Opposition to Defendants' Renewed Motion to Stay the Preliminary Injunction, at 1, No. 20-1320-Tdc, Nov. 13, 2020). Not only has COVID-19 remained deadly, but the FDA had produced no evidence or expert to prove that the injunction had caused harm to any patient.

The district court refused to lift or narrow the injunction in December 2020, relying on extensive evidence and public health expertise. The Supreme Court, however, was not persuaded by the same factual record. In January 2021, the Court stayed the district court's injunction pending appeal. Justice Sotomayor wrote a strong dissent, which relied heavily on the district court's findings, calling the FDA's exceptional treatment of medication abortion "unnecessary, unjustifiable, irrational" and "callous" (*Food & Drug Administration v. American College of Obstetricians & Gynecologists*, 2021). The case is now before the U.S. Court of Appeals for the Fourth Circuit.

Although the outcome of the ACOG litigation is far from settled, the Biden administration could reverse course immediately and waive the enforcement of the in-person ETASU for the life of the pandemic and for the foreseeable future, just as the FDA has done for other drugs. Over the long term, a new FDA commissioner should begin the process of repealing the REMS applied to mifepristone.

Removing federal restrictions on medication abortion would foster the expansion of virtual clinics. Due to the district court's ruling this summer as well as the Gynuity investigational study, providers in 15 states and Washington, D.C., currently administer

abortion via telemedicine (Baker, 2020). Virtual clinics and online pharmacies, many established in the last year, offer care that costs less, protects privacy, increases convenience, and reduces delay without compromising the efficacy or quality of care. Patients in places like Minnesota, where the state's handful of abortion clinics cluster in major cities, no longer have to drive hundreds of miles to pick up a safe and effective drug before driving back home to take it.

To be clear, measures like remote abortion have clear limitations; they depend on people having internet service or phones, for one. For another, they cannot serve people with high risk pregnancies — a population in which people of color are disproportionately represented (Harrison & Megibow, 2020). Finally, medication abortion cannot assist patients seeking terminations after 11 weeks of pregnancy.

That said, by lifting the nationwide FDA restriction, the new administration would encourage the growth of remote abortion services for the significant numbers of patient seeking to end early, uncomplicated pregnancies in the half the country that allows teleabortion. 🦠

Recommendations for Action

Federal government:

- The FDA should repeal or stop enforcing the REMS for medication abortion.
- Specifically, the FDA should issue guidance confirming the results of studies demonstrating medication abortion's safety and efficacy, allowing mifepristone to be ordered through mail-order prescription services and retrieved at retail pharmacies.
- The Biden administration should stop defending the lawsuit that seeks to lift a federal district court's injunction of the FDA in-person requirement.
- Congress should enact legislation that advances teleabortion by recognizing that medical abortion can be a health service appropriately included in plans for telemedicine's expansion.
- Congress should repeal the Hyde Amendment, which prohibits federal funding for almost all abortions.

State governments:

- Legislators should repeal an array of abortion regulations, such as waiting periods and in-person counseling, so that patients can avoid unnecessary visits to clinics and decrease the risk of COVID-19 exposure.
- Law enforcement and prosecutors abstain from applying criminal laws to punish self-managed abortion.
- Legislators should repeal restrictions on telemedicine as applied to abortion, such as in-person and physician-only administration of medication abortion.
- The legislature and state agencies, including state medical and licensure boards, should include medication abortion among the healthcare services subject to state efforts to expand telemedicine or to relax restrictions on telemedicine.
- State agencies should lift restrictions on telehealth modes (include audio-only communications), locations (use at home), delivery (health care providers operating across jurisdictions), and provider licensure (interstate licensure compacts).

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