

Medicaid Coverage of Medication Abortion Delivered via Telehealth

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Introduction

The COVID-19 public health emergency has shown the need to increase access to health services through telehealth, including for Medicaid beneficiaries. A year into the pandemic, millions of people have accessed services via telehealth.¹ The need and desire for telehealth will persist after the pandemic ends, particularly for individuals seeking time-sensitive reproductive and sexual health care including abortions. The American College of Obstetricians and Gynecologists (ACOG) encourages all providers to strategize how they could integrate telehealth into their services since the use of telehealth can increase abortion access.²

How does medication abortion work?

Medication abortions are safe, effective, and non-invasive. The National Academies of Science, Engineering, and Medicine—a non-partisan panel of scientific experts—confirmed in 2018 that medication abortions are safe and low-risk interventions.³ According to the Guttmacher Institute, medication abortions accounted for approximately thirty-nine percent of abortions in the United States in 2017.⁴

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¹ See Ctr. for Disease Control & Prevention, Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic —United States, January—March 2020 (Oct. 30, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6943a3.htm.

² See Am. C. of Obstetricians & Gynecologists, *COVID-19 FAQs for Obstetrician—Gynecologists*, GYNECOLOGY, https://www.acog.org/clinical-information/physician-faqs/covid19-faqs-for-ob-gyns-gynecology; Clinical Guidance Practice Bulletin, Medication Abortion Up to 70 Days of Gestation, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation">https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation (last visited Feb. 17, 2021).

³ See Nat. Acad. Sci., Engineering & Med., *The Safety and Quality of Abortion Care in the United States*, https://www.nap.edu/read/24950/chapter/4 (last visited Feb. 17, 2021).

⁴ See Guttmacher Inst., Medication Abortion, https://www.guttmacher.org/evidence-you-can-use/medication-abortion (last visited Feb. 17, 2021).

Medication abortion involves taking two medications: mifepristone and misoprostol.⁵ Mifepristone blocks progesterone, a hormone needed for a pregnancy to continue development, and misoprostol, which causes the uterus to empty. The U.S. Food and Drug Administration (FDA) allows patients to take mifepristone and misoprostol at home with the choice of self-assessment or clinical follow-up to determine success of the abortion.⁶

What restrictions does the FDA impose on medication abortion?

For more than twenty years, the FDA has imposed significant restrictions on dispensing and distributing mifepristone. It classified the restrictions as a Risk Evaluation and Mitigation Strategy (REMS), a designation that allows imposing restrictions on a limited amount of drugs. The three main REMS requirements are:

- mifepristone must be dispensed in a clinic, hospital, or under the direct supervision of a certified medical provider;
- the prescribing provider must be certified in the mifepristone REMS Program by submitting a Prescriber Agreement Form to the drug distributor; and
- the patient must sign and the provider must obtain the FDA-approved Patient Agreement Form.⁷

In 2016, the FDA approved a new evidence-based regimen and drug label to allow use of mifepristone for up to ten weeks of gestation and permit home administration.⁸ Of more than 20,000 FDA-regulated drug products, mifepristone is the only one that the FDA requires to be picked up in person even though it can be safely self-administered at home. People who seek abortion—half of whom have low incomes and many of whom are people of color—are more likely to work in essential jobs, have less access to health care, face greater health risks, and have limited means of transportation. As such, these requirements impose a heavy burden on burden on patients, their families, as well as providers.

On July 13, 2020, a judge for the U.S. District Court for the District of Maryland granted a preliminary injunction against the FDA's enforcement of the REMS in-person requirements, ruling that the REMS' in-person dispensing requirements place an undue burden on patients' constitutional rights to abortion care and severely jeopardize the health and economic stability

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⁵ See Am. C. Obstetricians & Gynecologists, Clinical Guidance Practice Bulletin, Medication Abortion Up to 70 Days of Gestation, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation (last visited Feb. 17, 2021).

⁶ See Am. C. Obstetricians & Gynecologists, Clinical Guidance Practice Bulletin, Medication Abortion Up to 70 Days of Gestation, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation (last visited Feb. 17, 2021).

⁷ See Food & Drug Admin., Approved Risk Evaluation and Mitigation Strategies (REMS), https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390 (last visited Feb. 12, 2021).

⁸ See Food & Drug Admin., Mifeprex (mifepristone) Information, https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information (last visited on Feb. 18, 2021).

of patients, their families, and clinic staff during the COVID-19 pandemic.⁹ The preliminary injunction remained in effect until January 12, 2021, when the U.S. Supreme Court stayed the injunction at the Trump administration's request pending a decision by the U.S. Court of Appeals for the Fourth Circuit.¹⁰

How does telehealth delivery of medication abortion work?

The telehealth delivery of medication abortion is rapidly evolving in the midst of the COVID-19 pandemic. One study looked at the ways in which COVID-19 changed abortion delivery among independent abortion clinics since May until the end of 2020. Eighty-seven percent of clinics reported shifts in protocols due to COVID-19, many of which related to telehealth:

- 71 percent of clinics reported moving to phone or video for follow-up appointments;
- 41percent reported starting or increasing telehealth for patient consultations and screenings;
- 20 percent reported allowing patients to quickly pick up medication abortion pills; and
- 4 percent began mailing medications to patients after telehealth appointments.

Before the COVID-19 public health emergency, another multistate study assessed the outcomes of medication abortion provided through telehealth and compared them with inperson clinician meetings. ¹² The researchers reviewed the health records of 5,952 patients who had medication abortions: 738 patients received abortion via telehealth and 5,214 received abortions in person. Telehealth patients took mifepristone in view of the clinician on a secure video-conferencing platform while the other patients took mifepristone before a clinician in-person. In both groups, misoprostol was either dispensed at the health center or prescribed. The researchers found that telehealth medication abortions are comparable to inperson medication abortions. In fact, in-person medication abortion patients had a higher likelihood of follow-up. When comparing all patients who completed follow-up, telehealth patients were less likely to experience ongoing pregnancies and referrals for aspiration

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⁹ Am. C. of Obstetricians & Gynecologists et al. v. U.S. Food & Drug Admin., No. 90 (D. Md. Jul. 13, 2020) (order granting preliminary injunction), https://www.aclu.org/legal-document/preliminary-injunction-granted.

¹⁰ Food & Drug Admin. v. College of Obstetricians & Gynecologists et al., No. 20A34 (592 U.S. Jan. 12, 2021) (order granting application for stay),

 $[\]frac{\text{https://www.supremecourt.gov/opinions/20pdf/20a34_3f14.pdf\&sa=D\&source=editors\&ust=16136629}{47868000\&usg=AOvVaw0hk-Rgipb1LtBuYirQCrrB}.$

¹¹ See Ushma D. Upadhyay et al., Adoption of No-Test and Telehealth Medication Abortion Care Among Independent Abortion Providers in Response to COVID-19, X CONTRACEPTION 2 (2020), https://www.sciencedirect.com/science/article/pii/S2590151620300320.

¹² See Julia Kohn et al., Medication Abortion Provided Through Telemedicine in Four U.S. States, 134 Obstetrics & Gynecology 2,

https://journals.lww.com/greenjournal/Fulltext/2019/08000/Medication Abortion Provided Through Telemedicine.19.aspx (last visited Feb. 17, 2021).

abortions. Across both groups, fewer than one percent of patients reported significant adverse events and none reported deaths.

How does Medicaid cover medication abortion?

The Medicaid Act requires states to cover abortion services for which federal funding is available. Since 1976, an annual appropriations bill rider known as the Hyde Amendment has restricted federal funding for abortion services in Medicaid. In its current version, the Hyde Amendment only requires coverage in the narrow circumstances of rape, incest, or life endangerment.¹³ However, states may use their own funding to pay for abortions past these circumstances and sixteen states have opted to do so.¹⁴

The Medicaid program does not differentiate between the different types of abortion interventions (e.g. medication, aspiration, surgical). According to Medicaid law, states that have opted to cover prescription drugs (all states) must cover all outpatient drugs from any manufacturer participating in the Medicaid Drug Rebate Program. Mifepristone has been approved by the FDA and its manufacturer, Danco Laboratories, has a Medicaid rebate agreement in place with the U.S. Department of Health and Human Services. Therefore, all states through their Medicaid programs must cover mifepristone under the circumstances of rape, incest, and life endangerment.

How does Medicaid cover telehealth services?

During the COVID-19 public health emergency, the Centers for Medicare and Medicaid Services (CMS) published substantive telehealth guidance on Medicaid. For instance, CMS released guidelines to facilitate widespread adoption of telehealth services in state Medicaid programs.¹⁷ It noted that states have a great deal of flexibility with respect to covering

¹³ U.S. Dep' t of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Pub. L. No. 115-245, 132 Stat. 2981, 3118, §§ 506-07 (2018).

¹⁴ See Guttmacher Inst., State Funding of Abortion Under Medicaid, https://www.guttmacher.org/state-policy/explore/state-funding-abortion-under-medicaid (last visited Feb.18, 2021).

¹⁵ Generally, states must cover outpatient prescription drugs made by a manufacturer with a rebate agreement in place as long as the drugs are used for a medically accepted indication. 42 U.S.C. § 1396r-8.

¹⁶ See, also, HCFA, Dear State Medicaid Director Letter (Mar. 30, 2001), https://www.medicaid.gov/Federal-Policy-Guidance/downloads/smd033001.pdf (informing states that the manufacturer of Mifeprex has entered into a rebate agreement with the federal government, and as a result, states must cover the drug). Misoprostol is also an FDA-approved prescription; however, as explained below, mifepristone is subject to special requirements.

¹⁷ See CMS, State Medicaid & CHIP Telehealth Toolkit: Policy Considerations for States Expanding Use of Telehealth (COVID-19 Version), https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf (last visited Feb. 18, 2021).

Medicaid services delivered via telehealth by confirming that states possess full authority on telehealth delivery and Medicaid coverage. 18 States define:

- what constitutes telehealth;
- what types of providers can deliver services via telehealth;
- what services can be reimbursed for telehealth; and
- What reimbursement structures are available for telehealth services.

CMS also recommended that states amend Medicaid managed care contracts to extend the same telehealth flexibilities authorized under Medicaid fee-for-service.¹⁹

Even before the COVID-19 public health crisis, all fifty states and Washington, D.C. covered some form of live video telehealth in Medicaid fee-for-service.²⁰ Eighteen states reimbursed for store-and-forward modalities and twenty-one reimbursed for remote patient monitoring modalities.²¹ During the pandemic, many states also began reimbursing audio-only telephone services, though some have indicated that they might eliminate or reduce this flexibility when the public health emergency ends.²²

Medicaid flexibility is important for access to telehealth services for pregnant patients, whether or not they seek abortions.²³ The American College of Obstetricians and Gynecologists, the Centers for Disease Control and Prevention, and the Office of Population Affairs have encouraged OB-GYNs and other reproductive health providers to strategize how to integrate

¹⁸ *Id.*

¹⁹ See CMS, Medicaid State Plan Fee-for-Service Payments for Services Delivered Via Telehealth, https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-telehealth-services.pdf (last visited Feb. 18, 2021).

²⁰ See Ctr. for Connected Health Pol'y, State Telehealth Laws & Reimbursement Policies (Fall 2020), https://www.cchpca.org/sites/default/files/2020-10/CCHP%2050%20STATE%20REPORT%20FALL%202020%20FINAL.pdf.

²¹ *Id.* Store-and-forward communications, which are asynchronous or do not occur in real-time, involve the electronic transmission of medical information (like digital images, documents, and pre-recorded videos) in order to aid in diagnoses and medical consults. Remote patient monitoring involves the use of telehealth technologies to collect medical data, like vital signs and blood pressure, from patients in one location in order to electronically transmit that information to health care providers in a different location.

²² *Id. See, also,* Fabiola Carrión, Nat'l Health Law Prog., *Medicaid Principles on Telehealth* (May 11, 2020), https://healthlaw.org/resource/medicaid-principles-on-telehealth/.

²³ See CMS, STATE MEDICAID MANUAL § 4432(B) (Identifying the services that must be available to pregnant individuals "regardless of whether [they were] seeking an abortion," including: (1) Pregnancy tests which would have been performed whether or not the individual was seeking an abortion; (2) Tests to identify sexually transmitted infections [such as chlamydia, gonorrhea, and syphilis]; (3) Laboratory tests routinely performed on a pregnant patient, such as pregnancy tests, pap smears, and urinalysis; (4) Family planning)), https://www.cms.gov/Regulations-and-Guidance/Manuals/Paper-Based-Manuals-Items/CMS021927.

telehealth into their services.²⁴ In addition, some states have moved to explicitly authorize Medicaid reimbursement of reproductive health services delivered via telehealth.²⁵

How do states restrict access to telehealth delivery of medication abortions?

According to the Guttmacher Institute, at least seventeen states in 2019 required the physical presence of the prescribing clinician when dispensing medication abortion, essentially banning telehealth delivery of abortions. ²⁶ Other states are on their way to do the same, like Ohio, which passed a telehealth abortion ban in December 2020. ²⁷

How can we improve access to medication abortions via telehealth for Medicaid enrollees?

Several policy changes are needed to fulfill telehealth's promise to secure abortion access. First, the National Health Law Program urges Congress to end the Hyde Amendment and pass the Equal Access to Abortion Coverage in Health Insurance Act, which would restore insurance coverage of abortions in health programs and plans such as Medicaid. Second, the Biden administration should take immediate action to not only lift the REMS' dangerous restrictions on an essential health care service during the Public Health Emergency, but also to end the REMS on mifepristone for good. Finally, states should reverse bans on telehealth delivery of abortion and issue guidance on Medicaid coverage of reproductive and sexual health services delivered via telehealth.

²⁴ See Am. C. Obstetricians & Gynecologists, COVID-19 FAQs for Obstetrician—Gynecologists, https://www.acog.org/clinical-information/physician-faqs/covid19-faqs-for-ob-gyns-gynecology; Ctr. for Disease Control & Prevention, Ensuring access to family planning services during COVID-19: a summary of CDC's family planning recommendations for healthcare providers, https://www.cdc.gov/reproductivehealth/contraception/covid-19-family-planning-services.html; Office of Population Affairs, Family Planning Nat'l Training Ctr., What Family Planning Providers Can Do to Meet Client Needs During COVID-19, https://www.fpntc.org/resources/what-family-planning-providers-can-do-meet-client-needs-during-covid-19 (last updated July 16, 2020).

²⁵ See, e.g., NC Medicaid Division of Health Benefits, Special Bulletin COVID-19 #86: Telehealth and Virtual Patient Communications Clinical Policy Modifications -Family Planning Services for MAFDN Beneficiaries (May 11, 2020), https://medicaid.ncdhhs.gov/blog/2020/05/11/special-bulletin-covid-19-86-telehealth-and-virtual-patient-communications-clinical; Texas Health & Human Servs., COVID-19:Updates for Healthy Texas Women and Family Planning Program, https://www.healthytexaswomen.org/sites/htw/files/documents/htw-fpp-covid-updates.pdf.

²⁶ See Megan K. Donovan, Guttmacher Inst., *Improving Access to Abortion via Telehealth* (May 16, 2019), https://www.guttmacher.org/gpr/2019/05/improving-access-abortion-telehealth#.

²⁷ See Kat Jercich, *Ohio legislature passes ban on abortion via telehealth*, HEALTHCAREITNEWS, (Dec. 21, 2020), https://www.healthcareitnews.com/news/ohio-legislature-passes-ban-abortion-telehealth.

²⁸ Equal Access to Abortion Coverage in Health Insurance Act, H.R. 1692, 116th Cong. (2019), https://www.congress.gov/bill/116th-congress/house-bill/1692.

This is the third and final factsheet from the National Health Law Program about Medicaid coverage of reproductive health services delivered via telehealth. The first fact sheet in the series is <u>Medicaid Coverage of Family Planning Services Delivered via Telehealth</u>. The second fact sheet in the series is <u>Medicaid Coverage of Pregnancy Care Delivered via Telehealth</u>.

For additional recommendations on how Medicaid should cover services provided via telehealth, please see NHeLP's Medicaid Principles on Telehealth.