Second Edition

ACCESS, *DELIVERED*

A TOOLKIT FOR PROVIDERS OFFERING MEDICATION ABORTION

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PLAN C

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INTRODUCTION

Across the country, healthcare providers are demonstrating new models of access to medication abortion. The COVID-19 pandemic has spurred innovation in online care as patients and providers alike seek safe and effective alternatives to in-person clinic visits. In addition, some of the regulatory barriers to providing medication abortion via telehealth have been loosened by the U.S. Food & Drug Administration. Most importantly, the medical community, drawing on cutting-edge research and long proven international models, has widely endorsed new "no test" protocols for medication abortion which allow most patients to safely and effectively terminate an early pregnancy without requiring an in-person provider visit for most patients.

The UW Medicine Access, Delivered Research Team, in partnership with Plan C, has worked with primary care clinicians and abortion providers around the country to document these new models of medication abortion services. *Access, Delivered: A Toolkit for Providers Offering Medication Abortion* consolidates the on-the-ground lessons from over 100 providers offering and working to offer medication abortion services without a clinic visit during these unprecedented times. This toolkit is not comprehensive or complete; nonetheless, it has valuable information for any provider and/or administrator interested in offering telehealth medication abortion.

This Provider Toolkit includes:

- Step-by-step guidance about how to add the service to your practice, including links to medication abortion clinician training, "no test" protocols for care delivery, information on how to obtain the mifepristone from the approved distributors; suggestions for storing, labeling, and shipping medications; and guidance on how to ensure appropriate professional liability coverage;
- Sources of state-specific information about abortion and telemedicine regulations that may impact how and where online models of abortion care can be provided;
- An opportunity to participate in research to evaluate and monitor new models of care, with the goal of helping more clinicians participate as abortion providers; and
- Resources for clinicians and patients

The Provider Toolkit is part of a broader Access, Delivered initiative. Our research team will continue to document and evaluate novel medication abortion service models using implementation science techniques and update the Provider Toolkit through an iterative, process improvement approach. Given this broader endeavor, we want to hear from you! If you are using the Toolkit or innovating in your own practice, please reach out. During this extraordinary time of continued recommendations for social distancing, primary care and other clinicians have a unique opportunity to shape the future of abortion access in the United States (U.S.). We hope you will join us in modernizing access to this essential health care technology.

WHAT PROVIDERS ARE SAYING

"As a physician who had never done abortion care previously, it has been so meaningful and rewarding to make medication abortions a part of my practice. No-touch, self-managed abortions are easy to integrate into my day-to-day work and provide a much-needed service to people in my state who want to use this option. They all have different reasons, whether it's privacy, cost, convenience, safety, etc., and they have been so appreciative of the way they get to take control of their bodies and this very personal event in their lives. I have been gratified to learn how safe it is – we really need to get this technology more directly into the hands of women who need it. It should be a regular part of primary care practice, and ideally something we can just prescribe at a pharmacy."
– Primary Care Provider, WA

"Over the last 10 years I have watched with anger and concern the increasing restrictions to abortion being placed on women in many states. The nationwide shut down from Coronavirus and the call out for people to assist motivated me to action. While I have been providing abortion care for over 20 years, the leap to doing no-touch medication abortions and mailing pills was a total shift. It has been amazing and forced me to acknowledge that most women can self-manage their abortions without as much handholding as I was used to providing. It also opens up access for so many women in need who would have struggled to find a provider."
-Primary Care Provider, NY State

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BACKGROUND

Abortion is common. One in four women in the U.S. have had at least one abortion by the time they reach age 45 years.[1] Abortion pills, which include mifepristone and misoprostol, are a modern health technology. They are recognized by the World Health Organization as essential medicines and are used by millions worldwide every year for safe access to early abortion care.[2–4]

In the U.S., the mifepristone/misoprostol regimen was approved for use in 2000 to safely mange early pregnancy abortion.[5] Although proven to be a safe medication, mifepristone was given a Risk Evaluation and Mitigation Strategy (REMS) designation by the U.S. Food and Drug Administration (FDA), which is assigned to certain medications with safety concerns to help ensure the benefits of the medication outweigh risks.[6,7] The U.S. FDA Mifepristone REMS program requires healthcare providers to register with the product distributor in the U.S. by signing the Provider Agreement, and for their facility to store and dispense their own supply of mifepristone to patients. This requirement makes it impossible for a clinician to write a prescription for mifepristone that can be dispensed from a pharmacy. However, on April 12th, 2021, in response to the COVID-19 public health emergency, the FDA stated that mifepristone need not be dispensed in-person, allowing for mail and other delivery of mifepristone from registered providers to patients during the U.S. Public Health Emergency due to COVID-19.[8,9]

Mifepristone pills must be ordered by the registered provider from one of two product distributors (GenBioPro, Danco), stored, and dispensed directly to the patient from the provider or through a mail-order pharmacy under the supervision of the registered provider. Regardless of how they receive mifepristone and misoprostol, patients will take the medications and end their pregnancies outside the clinical setting. The requirement to obtain medication from a provider has led to misperceptions about the complexity and safety of medication abortion provision and barriers to care.[10] More information about the Mifepristone REMS requirements and ways to meet them while providing care can be found in the following sections: Restrictions on mifepristone, Establishing a provider agreement with a distributor, Patient consent and distributor patient agreement form, Dispensing and distributing the medications, and Record keeping and reporting.

Around the world, medication abortion is increasingly being offered using updated evidence-based protocols that do not require an in-person visit or clinical testing. In the U.S., laws in many states allow patients to receive services via telemedicine with abortion medications mailed by clinicians or contracted pharmacies directly to patients. This service delivery approach reduces risks of COVID-19 to both patients and providers and sets the stage for new approaches to abortion care even after the threat of COVID has been contained. More information about medication abortion and associated patient care can be found in the following sections: What is medication abortion?, No-test protocols, and Providing patient care.

MEDICATION ABORTION: The basics

Key Points

- One in every four women in the U.S. received abortion service.[1]
- Medication abortion with mifepristone and misoprostol or misoprostol alone has been proven to be safe and effective over decades of use. These medications can also be used to effectively treat miscarriage.[11–16]
- Medication abortion remains underutilized in the U.S., largely due to medically-unnecessary and outdated FDA restrictions on how mifepristone can be provided (it is not yet available through retail pharmacies).[6,10,17]
- Medication abortion is within the scope of family medicine and other primary care provider settings.[18,19]
- New evidence-based protocols that do not require an in-person visit or clinical testing are the new standard of care for medication abortion, allowing for entirely remote early abortion care for most patients.[20–24]

Relevant Definitions

- **Clinician-supervised medication abortion** - using misoprostol only or mifepristone/misoprostol to terminate a pregnancy under the supervision of a trained healthcare professional.
- **Self-managed abortion** - the practice of ending a pregnancy without the involvement of a healthcare professional. This practice is increasingly safe and common with the advent of medications that can safely induce an abortion.[25]
- **Unsafe abortion** - defined by the World Health Organization (WHO) as a procedure for terminating an unintended pregnancy carried out either by persons lacking the necessary skills or in an environment that does not conform to minimal medical standards, or both.[26]

What is medication abortion?

Medication abortion (also called the abortion pill or abortion with pills) has been provided by clinicians in the U.S. for more than two decades.[6] Abortion pill medications can be used for both induced abortion as well as treatment for early miscarriage.[27,28] Still, medication abortion currently accounts for only about 40% of induced abortions done in the U.S., while rates in some European countries are as high as 80-95%.[29,30] This difference indicates a potential unmet patient interest in medication as a method for terminating an early pregnancy. Moreover, only about 5% of abortions are performed outside of specialty clinics, even as abortion care is well within the scope of primary care medicine.[31] Research suggests that when safe, legal abortion services are available for patients who choose this option, their lives are better than those denied access to abortion.[32] Many patients surveyed about their attitude towards abortion would prefer to receive abortion care from their primary care physician.[33,34] We encourage primary care clinicians to be part of the solution to offer full spectrum care throughout the reproductive life span in order to meet the needs of patients.

There are currently two safe and effective regimens for medication abortion.

1) Mifepristone plus Misoprostol Combination - The most common type of medication abortion in the U.S. is the combination of mifepristone followed by misoprostol. This is the most effective method of abortion with pills (95-98% of abortions are successful) and has the fewest side effects.[35] The FDA-approved regimen includes oral mifepristone followed 24 to 48 hours by misoprostol to end a pregnancy through 70 days from last menstrual period (LMP).[36] Though not summarized in this document, many evidence-based regimens are commonly used in practice.[14,20,24,37,38] The National Abortion Federation supports use of mifepristone/misoprostol up to 77 day and the World Health Organization up to 91 days after LMP.[24,39–42] A growing body of research supports the use mifepristone/misoprostol without a clinic visit to an upper GA limit of 77 days from LMP.[20,21,24]See the Evidence-based no-test protocols for more information.

2) Misoprostol Alone – Misoprostol used alone is also a safe and effective form of medication abortion, though this method is less effective than when used in combination with mifepristone (about 85 percent of early abortions are successful when only misoprostol is used) and may have more side effects.[13–16] The World Health Organization has endorsed the use of misoprostol alone for early abortion when mifepristone is not available with regimens for pregnancies up to 24 weeks.[15] A recent systemic review concluded that the misoprostol alone regimen is a safe and effective option, with higher success rates among regimens that start with a high enough initial dose and continued doses as needed over time.[15,43] Unlike mifepristone, misoprostol does not have a U.S. FDA REMS requirement. It can be dispensed from a pharmacy with a licensed clinician prescription.

Both of these options can be used to treat miscarriage as well as to induce abortion.

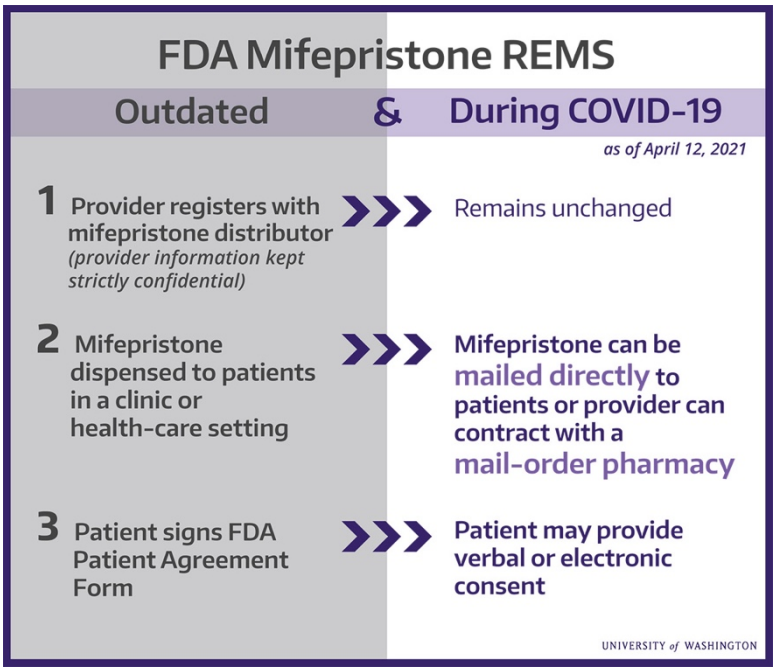
Learn More

The following additional training resources on medication abortion care provision are available free of charge:

- How to Use Abortion Pill: Medical Student Course - A course designed for medical students consisting of 7 video lectures averaging ten minutes long.[44]
- TEACH - Training in Early Abortion for Comprehensive Healthcare An all-inclusive interactive curriculum with extensive tools to train new reproductive health providers to competence.[45]
- Overview of Medication Abortion An hour-long course tailored to primary care providers which includes example videos of patient interactions, activities to practice what is learned, and links to additional resources.
- Kaiser Family Foundation – The Availability and Use of Medication Abortion A one-page overview of medication abortion use and access in the U.S.[46]

Restrictions on mifepristone

In 2000, the U.S. FDA approved mifepristone for use in medication abortion with a special requirement now known as the Risk Evaluation and Mitigation Strategy (REMS) program, which has limited access to medication abortion in the U.S.[6,7,10,17] FDA Mifepristone REMS program requires that mifepristone only be dispensed to patients by providers who have registered with one of the two mifepristone distributors in the U.S. (GenBioPro, Danco) (see Establishing a provider agreement with a distributor). Providers must have all patients sign the Patient Agreement and maintain a copy in the patient record (see Patient consent and distributor patient agreement form). Providers must also document the serial number and expiration date of the distributed mifepristone in the patient record (see Record keeping and reporting).



The REMS also require that registered providers order their own supply of mifepristone and dispense to patients in the clinical setting. The REMS restrictions have largely been interpreted to imply that mifepristone cannot be dispense through commercial pharmacies or my mail. However, during COVID-19, it became apparent that the REMS were creating undue burdens on patients trying to access abortion care and putting both patients and providers at risk by requiring an in-person clinical visit to obtain mifepristone. On April 12th, 2021, the FDA issued a letter stating that mifepristone need not be dispensed in-person when used to induce abortion or for miscarriage management, allowing for mail and other delivery of mifepristone from registered providers to patients during the U.S. Public Health Emergency due to COVID-19.[8,9]

During the U.S. Public Health Emergency, providers are able to dispense and deliver mifepristone via mail or other methods from their clinic, and can also contract with mail order pharmacies to dispense the medication to their patients.[8,9] Providers must still register with the distributor, have the patient sign the Patient Agreement Form, and document the mifepristone serial number and expiration date in the patient record. For more information on dispensing and distributing, see sections Dispensing and distributing the medications

Evidence-based no-test protocols

In response to the challenges of providing medical care during the COVID pandemic, the global medical community swiftly adapted to using new evidence-based, "no test" protocols that do not require an in-person visit or clinical testing, thereby allowing for provision of medication abortion via telehealth. These new protocols have now been widely adopted in the U.S. in response to the COVID-19 pandemic.[47] These protocols build from examples where provision of medication abortion clinical testing and/or an in-person visit has already been practiced safely and with good outcomes.[48–50] Specifically, research has shown that:

- Medical abortion can be prescribed safely without a physical exam or ultrasound by using the patient report of last menstrual period (LMP) to estimate gestational age (One study found that 90.5-99.1% of woman knew their LMP, 70.8-90.5% with certainty).[23,51–53]
- Other research suggests that a medication abortion for an early pregnancy has minimal risk for Rh sensitization, and, therefore, Rh typing and administration of anti-D antibodies in Rh-negative women is unnecessary.[54]
- Additionally, it has been shown that telehealth follow-up after medical abortion based on patient symptoms is comparable to an in-office visit.[55]

The new evidence-based protocols were developed by leading experts at the American College of Obstetricians and Gynecologists, National Abortion Federation, Planned Parenthood Federation of America, Reproductive Health Access Project, and Society for Family Planning.[20,21,23,24,56] Internationally, similar protocols are endorsed by the Royal College of Obstetricians and Gynecologists and consistent with the World Health Organization's guidelines for use of medication abortion pills.[15,22] The range of recommended practices in different protocols is presented in Table 1.

Table 1. Mifepristone, Misoprostol Abortion Medication Abortion Protocols

	The American College of Obstetricians and Gynecologists[23]	Reproductive Health Access Project[20]	National Abortion Federation (NAF)[24] (Though the protocol is not publicly available this video is based on NAF guidelines)	Raymond et al 2020 Proposed No-Test Medication Abortion Protocol[21]	The Royal College of Obstetricians and Gynecologists[22]
Consultation	Telephone or video conferencing.	Telephone or video conferencing. Provide written information electronically or by fax.	Counsel and educate patient according to standard of care.		Telephone or video conferencing. Provide related written info. via email or link.
Assessing GA	Assess remotely for patients with regular periods, establish via LMP.	Confirm patient has done a home pregnancy test and assess via LMP.	Confirm patient has done a home pregnancy test and assess via LMP.	Confirm patient has done a home pregnancy test and assess via LMP. Alternatively perform serum pregnancy test for confirmation.	Assess remotely for patients with regular periods, establish via LMP.
Ultrasound Requirements		Required if LMP indicates GA >77 days, patient has irregular periods, or if patient has known risk factors for ectopic pregnancy. US performed at clinician discretion if GA is between 70-77 days.	Required if LMP >77days, patient is uncertain of LMP within 1 week, or if pregnancy has not been confirmed with in-home test.	Required if LMP >77 days, patient is uncertain of LMP within 1 week, or patient has known risk factors for ectopic pregnancy.	Required if patient is unable to provide LMP of reasonable certainty within thresholds of eligibility, or if at high risk of ectopic pregnancy.
Rh typing	Not required	Perform if GA >56 days.	Perform if GA >70 days.	Perform if GA >70 days.	Not required
Providing Mifepristone/Misoprostol		Mifepristone and Misoprostol are mailed to or picked up by the patient.			Mifepristone and Misoprostol are mailed to or picked up by the patient.
Additional Meds			Analgesics, antiemetics.	Analgesics, antiemetics.	Analgesics, antiemetics
Additional Items		Instructions for pain treatment, pregnancy test, medication guides, copy of consent, information to reach on-call clinician.	Instructions for each medication provided.	Instruction sheet, health facility emergency contact information, two high-sensitivity pregnancy tests.	Low-sensitivity pregnancy test, written instructions
Follow up Timing and Method	Telephone or video conferencing to review signs of successful pregnancy expulsion.	The clinician should call the patient to ensure bleeding happened within 24 hours of misoprostol administration. Review plans for contraception.	Telephone follow up to confirm success of MA is appropriate.	Follow up within one week after dispensing treatment.	Telephone or video conferencing including discussion of contraception options. Patient can also self-assess for completion.
Confirmation of Completion	The patient can take a urine pregnancy test at home 4 weeks after the abortion.	The patient takes a urine pregnancy test in 3-4 weeks.	Confirmation can be established by US, hCG testing (preferred) or physical exam by office visit, telephone, or electronic communication.	The patient takes a high-sensitivity pregnancy test four weeks after the MA. If positive, repeat in one week.	The patient uses low-sensitivity pregnancy test.
Indications for follow up ultrasound		Bleeding does not occur within 24 hours of misoprostol administration, or if follow up pregnancy test is positive.	Completion of MA is unable to be confirmed.	Symptoms of continuing pregnancy persist after MA, or if repeat pregnancy test is positive.	

PREPARE & LAUNCH: Setting up early abortion care

Key Points

- Mifepristone is not available through pharmacies; providers must register with a distributor, purchase pills, and dispense them to patients or make special arrangements with a mail-order pharmacy.[6]
- Address liability insurance. Most providers find that adding medication abortion to professional liability coverage causes no or a low premium increase.
- Review abortion, telemedicine, dispensing, telepharmacy, and reimbursement laws in your state as they may limit the ability to implement "no test" early abortion services in some locations. See our section on Regulatory compliance for sources of information.

Establishing a provider agreement with a distributor

Because the FDA's Mifepristone REMS require that the medication be dispensed directly to patients under the supervision of a registered provider, providers must register, purchase, store, and dispense the medication to patients.[6] Mifepristone is not stocked or available in pharmacies. The provider must register directly with one of the two U.S. distributors: GenBioPro and Danco. In most circumstances, a single registered provider is sufficient for all the clinicians who provide medication abortion in their clinic or healthcare system in order to avoid multiple accounts between the distributor and the healthcare system.[57] To set up an account and place an order with either, a provider must:

- have a current prescribing license through the U.S. Drug Enforcement Administration (DEA) (which requires a health care provider to meet state licensing requirements)
- have a commercial shipping address (one that can receive a FedEx package; it does not need to be a medical clinic)
- sign a prescriber agreement (GenBioPro, Danco)
- provide billing information.

To register with either distributor, visit the distributor website and complete the Prescriber Agreement. Provider personal information is kept strictly confidential.[57] It is stored by the distributor and not shared with the FDA or any other entity. The distributor will follow up to complete the registration process and share information about how to order the pills though their system. They also provide Patient Agreement Forms (see section Patient consent and distributor patient agreement form) and informational materials upon request. Though detailed financial forms are included in the process, they are designed for large volume clinic agreements and may not be applicable to all provider settings. The company agents are available to work with providers in various contexts to ensure that the basic information is gathered, and all forms are completed appropriately.

Distributor	GenBioPro	Danco
Website	https://genbiopro.com/	https://www.earlyoptionpill.com/
Prescriber Agreement	GenBioPro Prescriber Agreement	Danco Prescriber Agreement
Product(s) Available	Generic mifepristone (200 mg, one tablet) Generic misoproqstol (200 mcg, packaged as 4 tablets)	Mifeprex (mifepristone; 200 mg, one tablet) Generic misoprostol (200 mcg, packaged as 100 or 60 tablets)
Mifepristone Pricing	$50 (1 tablet)	$50 (1 tablet)
Misoprostol Pricing	$5.40 (4 tablets per bottle)	$59.56 (100 tablets per bottle) $57.96 (60 tablets per bottle)
Minimum order	None (though shipping charges may be waived with a minimum purchase)	None (though shipping charges may be waived with a minimum purchase)
Primary Contact for Questions	Evan Masingill President GenBioPro, Inc. 855-MIFE-INFO info@genbiopro.com	Abby Long, MPH Director of Marketing and Public Affairs Danco Laboratories, LLC (788) 432-7596 along@earlyoptionpill.com

Professional Liability Insurance

In the past, high premiums for adding abortion care to professional liability coverage was a key barrier for primary care and other physicians to offer this service.[58] Many providers implementing medication abortion services during COVID have found that medication abortion care is included in general liability coverage for no additional cost.

Before adding medication abortion to their practice, providers with existing liability coverage should verify that it covers provision of medication for first-trimester abortion. Providers can check their current policy and, if not specified, refer to the original application for coverage to see if abortion services were included. Often policies do not specify what is covered but refer to what was reported in the application. If coverage for medication abortion is not clear, providers should contact their insurers to verify they are covered by their current policy. It can be helpful to highlight that the service includes providing a set of pills with an excellent safety history and taken at the patient's convenience, not provision of procedural abortions or full obstetric care. Additionally, it may be important for a provider or practice to verify that liability coverage includes services provided by telemedicine. Under COVID-19 conditions, many insurers have already expanded coverage for telemedicine, so if a provider has been notified by their insurer about telemedicine coverage, this should apply to all services offered.

What Providers Say About Ensuring Liability Coverage

Primary care physicians who have recently negotiated coverage for medication abortion care with no or low additional premiums offer these tips:

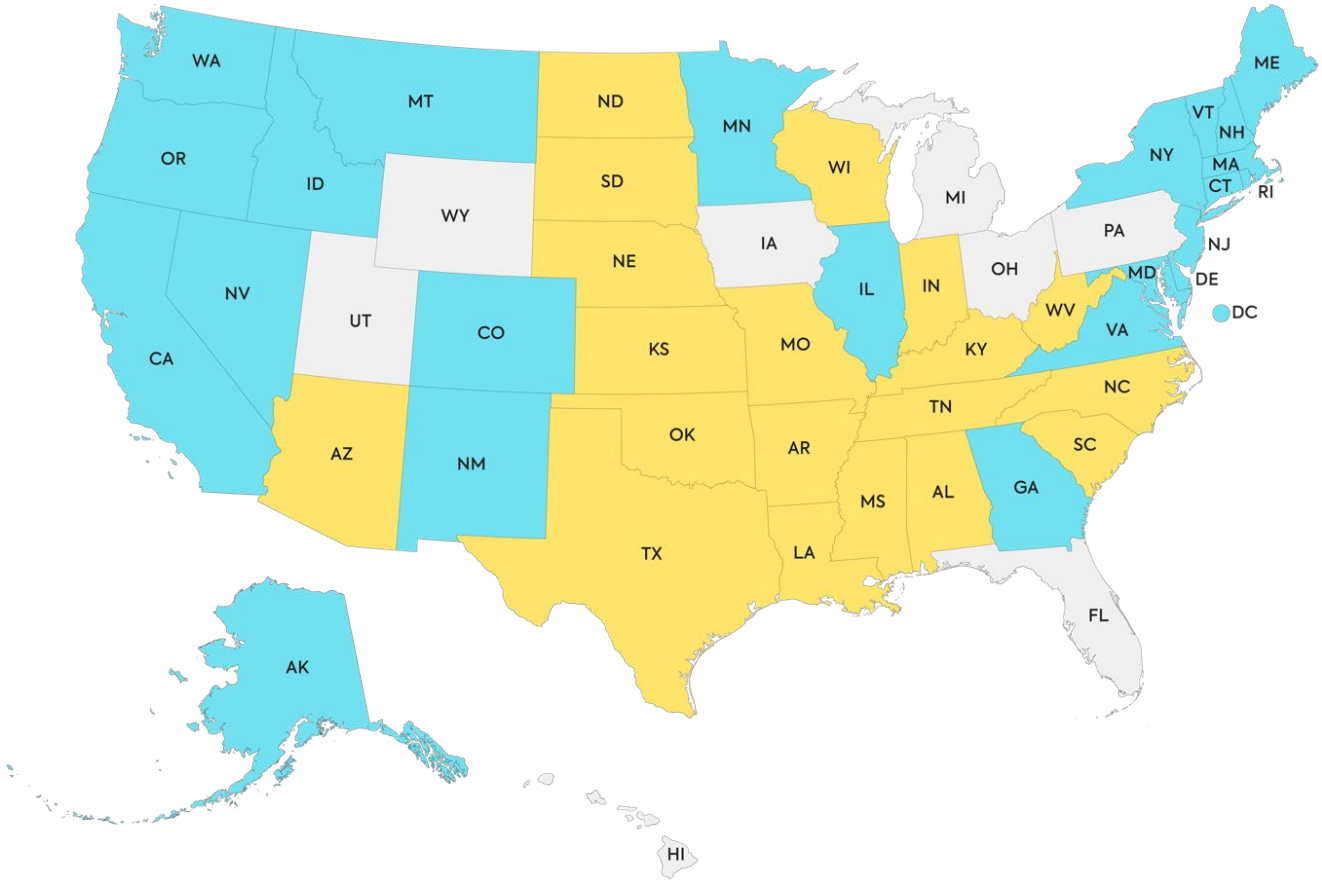
- When contacting your insurance provider, start with the assumption that provision of medication abortion is covered under your current policy and you are contacting them to verify.
- If presented with a higher premium, challenge it. Most insurers are probably ill informed about medication abortion, including that it is just a set of pills and a medication with an excellent safety profile.
- Share that colleagues with other insurance providers have extended coverage at no additional cost. We are happy to connect you with other providers who can share more about their experience.
- Mention you are willing to consider other insurance providers if your provider insists on charging more.

Regulatory Compliance

Providers should consider all state-based regulations regarding provision of abortion care, dispensing and shipping medications, and telemedicine. In particular, state laws may place restrictions on the types of providers who can provide abortion care, the ability to provide abortion care via telemedicine, or may impose other special requirements (mandatory waiting periods, specialized informational materials, clinical testing requirements, special consents for minors, etc.).

Currently, primary care providers, specialty reproductive health clinics, and web-based telemedicine healthcare providers are offering telehealth medication abortion services across the country. An up-to-date list of providers by state can be found at Plan C's Guide to Pills.

As of April 2021, 19 states have passed laws that restrict telehealth abortion provision.[59]



The following resources can be referenced to help providers determine what is allowed in their state:

State Abortion Laws

- Guttmacher Institute An Overview of Abortion Laws is a good starting point for information on state-based abortion laws.[60]
- The State Abortion Laws database provides free information on various state abortion regulations, relevant court cases, and attorney general opinions that directly impact the provision of abortion services in the U.S. These publicly available datasets were created through a collaboration between the Policy Surveillance Program at Temple University's Center for Public Health Law Research, Resources for Abortion Delivery, Guttmacher Institute, American Civil Liberties Union, Center for Reproductive Rights, National Abortion Federation, and Planned Parenthood Federation of America. [61]

State Telemedicine Laws

- The Federation of State Medical Boards Telemedicine Policies: Board by Board Overview has information about state telemedicine laws with links to regulatory information for each state. [62]
- Center for Connected Health Policy Telehealth Policy Current State Laws & Reimbursement Policies has information on state telemedicine and reimbursement laws and regulations.[63]
- Direct Primary Care resource website 'DPC Frontier', curated by Philip Eskew, DO, JD, MBA, offers extensive information about the relevant laws and regulations related to setting up a direct primary care practice, including medication dispensing and malpractice. [64] Power to Decide has a guide to State Level Telehealth Policies, include Medicaid and private payer reimbursement policies.[65]

Considerations for incorporating abortion care into clinical practices:

The Reproductive Health Access Project has developed guidance for providers interested in initiating abortion services in their practices: Toolkit for Integrating Abortion into Primary Care[66] This resource includes key considerations for all interested providers regardless of the size of their practice institution.

From Reproductive Health Access Project:

"Integrating abortion requires sensitivity and determination to overcome obstacles and barriers. Barriers depend on the existing culture of the practice, the level of knowledge and skill, as well as the attitudes and feelings of the staff. In order to effectively integrate abortion services, these concerns need to be identified and addressed. No single strategy will work for all health centers; cultural, geographic, and political differences call for individualized approaches."

IMPLEMENTATION: Providing abortion care

Key Points

- Telemedicine modalities — including video, telephone, and/or written electronic communications — are sufficient for patient intake, assessment, and counseling for the vast majority of early abortion patients.[67]
- There are many free platforms which allow clinicians to video chat or phone with patients without showing their own contact information.
- Dispensing includes proper product labeling and logging product serial numbers, with distribution to patients by pick up or mail.[5]
- Patients can successfully assess abortion outcome and identify need for any follow up.[19,68]

Telemedicine & service delivery approaches

The new medication abortion protocols can be used for in-person consultations, and for remote care, including using:

- Conventional telemedicine consultations (synchronous video visits)
- Telephone consultations (synchronous non-video visits)
- Asynchronous telemedicine consultations (online patient intake with asynchronous provider review and electronic patient-provider communication)

These options for remote care are not only critical strategies for protecting patient and provider health during the COVID-19 pandemic, but also offer patients a high level of convenience and privacy, which evidence indicates they appreciate.[69]

The types of telemedicine consultations allowable in your state will depend on state telemedicine regulations, including any requirements for establishing a patient-provider relationship and whether asynchronous care is allowed. In many states, regulations allow for a patient-provider relationship to be established remotely (i.e. one can accept a new telemedicine patient without having first seen them in person) and/or guidelines in this regard have been relaxed during COVID-19. In addition, many state telemedicine guidelines/regulations allow services to be provided fully asynchronously (i.e. without a live video interaction with the patient). However, some states may require video interaction; the form of interaction may influence how services are reimbursable by private and public payers. More resources for understanding the state-specific regulatory landscape are included in the Regulatory compliance section.

Although synchronous telemedicine care, including phone calls and video visits, has become routine (especially as a result of COVID-19), providers may be less familiar with fully asynchronous models of telemedicine, also known as E-visits. These models often consist of a

questionnaire filled out online by the patient which is then reviewed by a clinician who responds electronically with a care plan and prescription, if needed. Asynchronous models can offer benefits for both patients and providers in terms of efficiency, COVID-19 safety, convenience, and privacy. In asynchronous models of abortion care, patients typically provide information about last menstrual period (LMP), regularity of periods, and pertinent medical history, sign or indicate agreement with FDA required consent forms (see Record keeping and reporting), have the opportunity to access supplementary information, and specify if they have any additional questions or would like to request a synchronous visit with the provider. The provider then reviews this information, asking via electronic communication for additional information (if needed), and either approves/rejects the treatment or makes arrangements for a synchronous visit (video or telephone) or additional testing, if indicated.

One highly successful asynchronous abortion service is Aid Access, which currently serves tens of thousands of patients in the U.S. each year in collaboration with U.S.-based clinicians. For more information about this model and how to get involved as an Aid Access provider, reach out to Elisa Wells and Francine Coeytaux at Plan C or Dr. Rebecca Gomperts at Aid Access.

Learn More:

Additional information for those new to telehealth can be found in these toolkits:

- Angad Singh, MD, University of Washington, The Telehealth Toolkit[70]
- U.S. Centers for Medicare & Medicaid Services, Dept. Health & Human Services, General Provider Telehealth and Telemedicine Tool Kit [71]
- RHIhub, Rural Health Information Hub supported by the Health Resources and Services Administration of HHS, Rural Telehealth Toolkit [72]

Patient consent and distributor patient agreement form

The FDA Mifepristone REMS require that providers have patients sign the unaltered mifepristone-specific Patient Agreement Form in addition to standard consent forms.[73] The provider must then maintain a copy of the patient's signed Agreement Form in the patient medical record. While many telemedicine platforms have a mechanism for capturing electronic signatures, providers may obtain either verbal consent (by telephone or video call) or written consent (by email) while the COVID-19 public health emergency is in effect and document the Patient Agreement in the patient medical record.[8] As with in-person services, to give consent, the patient must first understand the risks and benefits of the treatment and voluntarily agree to them.

Dispensing and distributing the medications

As described in Restrictions on mifepristone, the FDA Mifepristone REMS require that a certified healthcare provider registered with the mifepristone distributors dispenses the medication to patients.[6] The relevant language from the FDA Mifepristone REMS is: *Mifeprex may only be dispensed in clinics, medical offices, and hospitals by or under the supervision of a certified healthcare provider*.

Dispensing is typically defined as preparing and packaging a prescription drug in a container and labeling the container with information required by state and federal law.[74] The REMS, however, do not specify how mifepristone should be distributed from providers to patients.[6] Specifically, there is no requirement in the REMS that the medications be taken in the presence of the provider and no language prohibiting mailing the pills.

Furthermore, on April 12th, 2021 the FDA stated that it would not be enforcing this dispensing portion of the REMS during the COVID-19 Public Health Emergency, alleviating the need for a patient visit and allowing for the mailing of the pills directly to patients by clinics or contracted mail-order pharmacies under the supervision of registered providers .[8,9] However, state pharmacy dispensing laws may limit shipment of any medication, including mifepristone, within the state where the medication is dispensed or to other states.

To reduce risk during COVID-19 and increase convenience in general, providers are offering alternatives to in-clinic medication pick up, including collaborating with mail-order pharmacies, mailing the pills, using a courier service, or offering curbside pickup.

	Online, Mail Order Pharmacy with Provider Supervision	Provider Shipped Medications from Clinic Stock
Dispensing	Provider contracts with mail-order pharmacies to dispense medication through the mail	Provider dispenses medication from their own clinic stock
Labeling	Pharmacy prepares medication labels based on state and federal regulations	Provider prepares labels based on federal or state regulations, prints using: • label printer • dispensing software
Delivery	Pharmacy mails medication directly to patient	Provider delivers medications directly to patients using: • courier service • mail service • clinic pick-up
Documentation	Pharmacy sends provider the serial number of mifepristone for each patient, to be documented in patient record or medication log	Serial number of mifepristone for each patient must be documented in patient record or medication log

Online, mail-order pharmacy with provider supervision

Due to the FDA statement clarification allowing clinics to deliver mifepristone or contract with mail-order pharmacies to dispense and mail mifepristone directly to patients during the COVID-19 public health emergency, providers are working with pharmacies to store and dispense mifepristone directly to their patients.[9,75]

1. *Setting up with a mail-order pharmacy*

There are currently two mail-order pharmacies contracting with registered providers to store mifepristone and dispense under their supervision.

- Honeybee Health, an online, mail-order pharmacy serving 44 states and territories, contracts with providers and dispenses mifepristone and other medications in the U.S. To set up a contract dispensing account with Honeybee Health, providers can contact Honeybee Health Director of Patient Services, Sarah Mayo, prescribers@honeybeehealth.com, (310) 559-5903.
- American Mail Order Pharmacy, also known as AMOP, is an online, mail-order pharmacy that contracts with providers and dispenses mifepristone and other medications. AMOP accepts 99% of all insurance plans, specializing in Medicare Part D, and also has competitive cash prices for those without insurance. They also allow for one payment to the provider for the consultation, mifepristone, and other medications which the provider then passes along to AMOP upon fulfillment of the medication order. Providers can contact AMOP at info@amoprx.com, (888) 772-3811

A provider registered with a mifepristone distributor must still purchase the mifepristone but can enter an agreement with a mail-order pharmacy and then have the mifepristone shipped directly to the partner pharmacy instead of their office. The pharmacy then stores and dispenses the mifepristone directly to patients under the supervision of the provider. The steps to set up such an arrangement are as follows:

- Register as a certified prescriber with a mifepristone distributor (see Establishing a provider agreement with a distributor).
- Indicate the collaborating mail-order pharmacy as a secondary shipping address.
- Set up an account with the mail-order pharmacy and sign a contract agreeing to the terms of service. Confirm this agreement with the mifepristone distributor.
- Order and pay for mifepristone through the distributor for delivery to the pharmacy.

2. *Labelling & dispensing medications*

The contracted mail-order pharmacy takes on the labeling of the medications based on federal and state regulations and delivers the medications directly to the patient on behalf of the supervising provider. Patients complete the consultation with the provider and then are referred to the contracted mail-order pharmacy for fulfillment of the entire prescription.

- When working with Honeybee, patients are charged by the provider for the consultation and the cost of the mifepristone medication and then charged by the pharmacy for the misoprostol plus a dispensing fee for the contracted mifepristone dispensing service.
- When working with American Mail Order Pharmacy (AMOP) the provider charges for all costs and reimburses AMOP for any additional medications and dispensing fees.

At the provider's request, both pharmacies will bundle the provider's mifepristone with misoprostol and ships both medications directly to the patient

3. *Documentation*

To comply with FDA distribution requirements, prescribers need to **keep a log of patient names** and the **serial number of the mifepristone** dispensed to them.[5] The log must include:

- Patient Name
- Date of Birth
- Estimated Gestational Age in Days
- Mifepristone Serial Number
- Mifepristone Expiration Date
- Misoprostol lot Number
- Misoprostol Expiration Date

The pharmacy shares back the serial number of the mifepristone dispensed to a specific patient so the provider can document in the patient record and/or mifepristone medication log.

A sample Medication Log sheet is available here. It is also possible to document in an electronic medical record using existing systems.

What Providers Say About Working with Mail-Order Pharmacies

Primary care physicians who have contracted with mail-order pharmacies to dispense their stores of mifepristone offer these tips:

- Working with a mail-order pharmacy saves the provider time, allowing them to focus on the consultation and follow-up care while the pharmacy takes care of the logistics of storing, labeling and shipping the medications according to federal and state guidelines.
- Honeybee has a separate charge that patients are responsible for, while AMOP allows the patient to pay the provider for all the services and then the provider reimburse AMOP directly for the medications and shipping costs.
- From the patient perspective, having two points of contact – the provider and the pharmacy – can present some confusion. If there are issues with delivery, the patient often contacts the provider who then must contact to the pharmacy for resolution.

Provider shipped medications from clinic stock

When permitted by state pharmacy dispensing regulations, many providers are labeling their own medications and mailing the mifepristone or mifepristone/misoprostol combination directly to patients. The steps include:

- Order and store their own stock of mifepristone, misoprostol, and often other medications such as anti-nausea medications and Ibuprofen.
- Label medications following federal and state pharmacy guidelines.
- Deliver medications to patients via mail, courier, or pick-up.
- Document the dispensing of medications based on federal and state pharmacy regulations.

1. *Ordering and storing medications*

Providers must order and store their own stock of medications to dispense to patients. Because mifepristone must be ordered and dispensed under the supervision of a registered provider, but misoprostol is available in a typical pharmacy, some clinicians choose to dispense the mifepristone to the patient and write a prescription for misoprostol. Other routine prescriptions, such as a non-steroidal anti-inflammatory (NSAID) for treatment of mild to moderate pain as needed, and occasionally anti-nausea or additional analgesic medications can also be prescribed through a commercial pharmacy. Some clinics choose to dispense both mifepristone, misoprostol, as well as NSAIDs and other medications so that the patient receives all medications at once with clear instructions on how and when to take each medication. Either way, providers must order their own supply of mifepristone from either one of the two U.S. distributors that can be found in the section Establishing a provider agreement with a distributor. Other medications can be ordered from medication distributors, including the two mifepristone distributor companies or other drug distribution sources.

All medications should be stored at room temperature (they do not require cold storage), protected from light and following standard medication storage requirements.[76]

2. *Labelling medications when dispensing mifepristone*

Providers who choose to dispense and directly mail pills to patients, instead of working with an online, mail-order pharmacy, should follow all federal dispensing requirements and be familiar with dispensing regulations in the state where they plan to practice. While some states require that dispensing healthcare providers follow all pharmacy dispensing laws, other states do not require providers to comply. The following is an overview of potential labeling requirements, adaptable templates for medication labeling, and resources to better understand state specific requirements.

Typical labelling requirements include:

- Prescriber name
- Prescriber phone number
- Patient name and Date of Birth
- Date filled: MM/DD/YY
- Product description
- Directions for use
- Drug quantity
- Use by date: MM/DD/YY (Note: this is either one year from dispense date or the product expiration date, whichever comes first)

Appropriate labels should be physically attached to the respective medications, taking care to not obscure product information such as serial number and expiration date.

Printing on a Normal Printer - Sample medication labels that can be customized and printed on Avery 5160 label stock are linked above and also available in the Additional Resources section. One note, these labels are sized to fit mifepristone and misoprostol packaging available from GenBioPro.

Example mifepristone label: (Template 1)	Example misoprostol labels: (Template 2; Template 3)
Provider, MD - (000) 000-0000 Init: ___ **Medication #1 – Take this first** Pt. Name _____ DOB: _____ Dispensed Date: _____ Exp: _____ Mifepristone: Swallow 1 tablet	Provider, MD - (000) 000-0000 Init: _____ **Medication #2 (misoprostol). Take this medication 24 hours after Medication #1, mifepristone.** Patient name:_____DOB_____ Date dispensed: _____ Exp: _____ Place all 4 tablets into vagina about 1 finger's length deep. Lie down for 30 minutes. Provider, MD - (000) 000-0000 Init: _____ **Medication #3 (Misoprostol): Take only if no bleeding 24 hours after taking Medication #2** Pt. Name _____ DOB: _____ Dispensed Date: _____ Exp: _____ Place all 4 tablets into vagina about 1 finger's length deep. Lie down for 30 minutes.

Using a Label Printer - Providers are also using common label printing machines such as Brother QL 80 Label Printer and Dymo label printer 450 model with the 2-5/16x 4" labels.

Using Dispensing Software - Alternatively, some providers dispense medication directly from their clinic using dispensing software from their supplier. These companies provide packaged medications, dispensing software, and other resources for getting an on-site dispensing program started. Medications are ordered from the company and come in packaging that is ready to dispense and deliver to the patient. The dispensing software enables providers to quickly maintain inventory, produce pharmacy labels with all the required information, store patient information and re-order medications.

One such dispensing company is HPSRx. Focused on women's health and one of the leading suppliers of MVA supplies, this company offers bottles of 8 misoprostol for $6.40 as well as anti-nausea medications and Ibuprofen. There is no startup cost, but HPSRx charges $0.50 per patient for use of the dispensing software. The HSPRx Dispensing Marketing Representative is Zac Baumbach, zac@hpsrx.com or customerservice@hpsrx.com, 800-850-1657

3. *Delivering medications to patients*

Each patient must receive a copy of the mifepristone distributor's Medication Guide (GenBioPro, Danco). A copy of the medication guide is included in the mifepristone box for both Danco and GenBioPro products.

Providers deliver medications directly to patients using a courier services or the US Postal Service[77] and selecting Priority Mail, a flat rate service that includes a tracking function and arrives in about two days.

Helpful materials for this approach include:

- U.S. Postal Service Priority Mail Flat Rate Envelope (these are free and available at most U.S. Post Offices or can be ordered online with free delivery), the small flat rate boxes which cost $7.90 to mail anywhere in the U.S., or other padded envelope.
- Stamps or other postage available at the post office or online ($7.75 is the current postage for the flat rate Priority Mail envelope)

- Package tracking labels are automatically added to qualifying packages when mailed at U.S. Post Offices or can be obtained through www.usps.com, along with postage.

Some providers also offer the option to pick up the mifepristone or mifepristone/misoprostol at a brick-and-mortar clinic site. Examples include having patients drive to the clinic and pick up mifepristone in the parking lot from a clinic staff member or small outdoor lockers where patients can pick up mifepristone using a special code. For patients who are very close to a clinic site this may be the most expeditious and preferred method of medication delivery.

4. Documentation

As with dispensing through a mail-order pharmacy, the provider must comply with FDA distribution requirements by **keeping a log of patient names** and the **serial number of the mifepristone** dispensed to them.[5] The log must include:

- Patient Name
- Date of Birth
- Estimated Gestational Age in Days
- Mifepristone Serial Number
- Mifepristone Expiration Date
- Misoprostol Serial Number
- Misoprostol Expiration Date

A sample Medication Log sheet is available here. It is also possible to document in an electronic medical record using existing systems.

What Providers Say About Storing and Dispensing Their Own Medications

Primary care physicians who are mailing medications from their own clinic stock offer these tips:

- Using a dispensing software really simplified the process and ensures that I am complying with all dispensing requirements.
- Mailing labels purchased through USPS or PayPal allow you to drop packages off at the post office without waiting for an attendant.

Providing patient care

Patient consultation

As is done when providing in-person care, patients should be given information in advance about what to expect, when to seek follow up care, and how to self-assess that the abortion is complete.[21,45,78] Information about reproductive life planning can be shared and some providers offer additional prescriptions for pain control, nausea, and post-abortion contraception. Various examples of sample instructions and patient resources that can be adapted to your practice setting are included in the Additional Resources section.

Patients should be encouraged to call their provider if they experience any problems or have questions.

Information included in the mifepristone drug label:[76]

Common side effects to mifepristone/misoprostol:	Cause for Concern and Follow-up:
Cramping and vaginal bleeding are expected and can signify that the treatment is working. Most common side effects of mifepristone/ misoprostol treatment are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness.	*Patients should contact their healthcare provider if they experience:* 1. **No Bleeding** Scant bleeding and persistent pregnancy symptoms. May require additional course of misoprostol medication or surgical aspiration. 2. **Heavy Bleeding** Prolonged heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications. Patients should be instructed to contact a health care provider if they experience heavy bleeding. May require surgical aspiration. 3. **Prolonged Abdominal Pain** Abdominal pain or discomfort, including weakness, nausea, vomiting, or diarrhea, with or without fever, more than 24 hours after taking misoprostol. Could be infection or ectopic pregnancy. 4. **Fever** In the days after treatment, a fever of 100.4°F or higher that lasts for more than 4 hours. May be symptoms of a serious infection.

On ectopic pregnancies:
"Mifepristone is contraindicated in patients with a confirmed or suspected ectopic pregnancy because **mifepristone is not effective for terminating ectopic pregnancies**. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of an ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed [mifepristone]." [76] Thus, it is important that providers take a careful history of all patients, regardless of whether they have had a prior ultrasound during this pregnancy.

If patient has bleeding and/or pelvic pain during the current pregnancy, and an ectopic pregnancy is clinically suspected, patients should be referred for diagnostic testing that may include pelvic exam, serial serum hCG levels, transvaginal ultrasound, or diagnostic aspiration.

Patient Follow-up

Research suggests that, with proper information, most patients can tell when the abortion has completed. More than 95% of the time, patients themselves are able to determine when they are no longer pregnant or have continued signs of pregnancy. With high quality counseling from a clinician, patients also know when they need emergency or other follow-up care.[55,79–82]

Providers are making themselves available to patients with questions and sharing resources like the Miscarriage + Abortion Hotline or other 24/7 support lines.
Many providers are sending an asynchronous follow-up evaluation survey 2-4 weeks after care and allowing the patient to determine what follow up, if any, is needed.

Whether via e-visit, telephone, or in-person, follow-up communication can include:[45]

- Patient's experience since taking medications, including timing and extent of bleeding and cramping, and resolution of pregnancy symptoms. Questions include:
    - Do you think you are still pregnant? Why or why not?
    - Can you identify the moment when you expelled the pregnancy?
- Assessment of complete abortion based on clinical history and negative at-home pregnancy test 4-5 weeks after taking the medication.
- Asking patient to contact provider for late-onset heavy bleeding or other concerns warranting evaluation and treatment.

Record keeping and reporting

Record keeping for remote medication abortion services will largely mirror what is done for in-person services, with the patient's medical record completed and stored according to the provider's standard procedures.

However, providers should be aware of a few mifepristone- and abortion-specific reporting requirements:

- **Signed Patient Agreement Forms** – The FDA Mifepristone REMS require that providers maintain a copy of the patient's signed Patient Agreement Form[73] from the mifepristone distributor in the patient medical record or otherwise document their understanding of and consent to the Form. The Patient Agreement can be signed electronically or via verbal consent.[8] More information is provided in the Patient consent and distributor patient agreement form section.
- **Medication dispensing logs** — The FDA Mifepristone REMS require providers to dispense mifepristone directly to patients as well as document the medication serial number and expiration date of medications given to each patient.[6] More information is provided in the Dispensing and distributing the medications section and a sample medication dispensing log can be found here and in Additional Resources.
- **Abortion reporting by state** — Many states require that clinicians who provide abortions report each abortion to the state Office of Vital Statistics. Each state has different requirements for whether and when abortion must be reported (sometimes reporting is only required for later gestation pregnancies). Guttmacher Institute reports on state-by-state Abortion Reporting Requirements.[83]

- **Death reporting to distributors** — By signing a Prescribing Agreement with the distributor, providers agree to report any patient deaths to the distributor, identifying the patient by a non-identifiable patient reference and the serial number from each package of mifepristone.[84]

OPPORTUNITIES: Expanding abortion access

Key points

- Misoprostol-only abortion may be an acceptable alternative when the combined regimen is not readily available.[16]
- Providers can improve access by offering patients misoprostol or misoprostol prescriptions in advance of the need for them.
- Several new services provide opportunities for providers to get involved in expanding abortion care access through online telehealth platforms—Aid Access, Choix, Hey Jane, and Abortion on Demand.

Telehealth abortion services

There are a number of new web-based, online services that offer medication abortion care with online consultations and mailed abortion pills. Many of these services provide opportunities for providers to get involved, either in a volunteer capacity or as a part-time clinician. A few examples include Aid Access, Choix, Hey Jane, and Abortion on Demand.

Misoprostol-only, call in prescriptions

Some providers are offering misoprostol-only medication abortion. Misoprostol-only can be used for treatment of miscarriage as well.[16] As described above, misoprostol-only abortion is less effective than mifepristone plus misoprostol abortion but may be an acceptable alternative when the combined regimen is not readily available. The screening protocol for misoprostol-only abortion is the same as for the combined regimen and can be done entirely remotely for most patients.[78] Counseling should include information about side effects, the possibility that the method could fail, and what to do if the patient has continued signs and symptoms of pregnancy. For patients who meet all criteria, providers can write misoprostol prescriptions for patients to pick up at their local pharmacy or send electronic prescriptions through an online pharmacy, such as Honeybee Health. The cost to the patient varies but can range from $5 to $55 depending on insurance coverage, coupons, and variations in drug pricing and availability.

*Table 2. Outline and Summary of Misoprostol-Only Medical Abortion Protocols**

	World Health Organization[15]	International Women's Health Coalition[85]	Gynuity Guidance for Providers[78]
Consultation	Counseling should be provided on decision-making if the patient desires. Appropriate information about the procedure should be provided: expected protocol, duration, symptoms to expect, associated risks and complications, return to normal activities, and plan for follow up care, if any.	This protocol was written for women self-managing their abortion, in a situation where access to a provider is limited or not possible. If an IUD is present, it should be removed either by the patient or a provider prior to the abortion.	Can be performed remotely. Appropriate information about access and taking the pills, what to expect (onset, duration, side effects & management), when and where to seek support, and follow-up plans. Can discuss logistical arrangements (childcare), contraception.
Assessing GA	Establish via LMP, confirmation by bimanual pelvic exam when appropriate.		Gestational age <12 weeks LMP, people are more likely to overestimate GA based on LMP
Ultrasound Requirements	US is not routinely required for provision but can be used to exclude ectopic pregnancy in at-risk patients.		US is not necessary to establish GA, eligibility, or determine regimen & counseling.
Rh-typing	Not required		Not required
Providing Misoprostol	Medical abortion with misoprostol alone is acceptable in locations where mifepristone is not available. Misoprostol is more widely available and at a lower cost than mifepristone. Home use of Misoprostol is acceptable and safe.	Misoprostol is not restricted by REMS in the U.S., unlike mifepristone, and is more commonly available.	The WHO-recommended misoprostol-alone regimen is three doses of misoprostol sublingually or buccally every three hours. Each dose is 800 mcg (four 200 mcg pills).
Additional Meds	Analgesics	Analgesics, particularly NSAIDs	
Additional Items	Clear, written instructions on self-care following abortion, including how to recognize complications and contraceptive counseling.	Sanitary pads, water, and a support person if desired	
Follow up Timing and Method	Contraceptive counseling is essential with goal to start chosen method immediately after abortion.		Plan a follow-up (i.e. via phone, text) 1-2 weeks after. If follow-up contact not possible, abortion can still be provided.
Confirmation of Completion	Medical follow up within 7-14 days is advised for misoprostol-only protocols to confirm completion. Completion can be confirmed by pelvic examination, pelvic US, or repeat hCG measurement.	The patient can monitor diminishing signs and symptoms of pregnancy in the event of successful completion, as well as pregnancy expulsion. A urine pregnancy test can be taken two weeks after care for further confirmation.	Provider should ask about bleeding, side effects, expulsion, and current symptoms. At four weeks, suggest urine pregnancy test to confirm.
Indications for Follow-up Ultrasound	Symptoms of ongoing pregnancy or incomplete abortion.	The patient should seek medical attention in the event of heavy or prolonged bleeding, severe abdominal pain, or signs of infection.	If concern of continuing pregnancy, ectopic pregnancy, excessive bleeding or retained tissue, management options should be discussed.

DATA COLLECTION & RESEARCH OPPORTUNITY

Understanding this new model of care

Because "no test" medication abortion - with limited or no patient-provider interaction - is a new model of care, it is critical that the service model is documented and evaluated so that innovation and best practices can be disseminated widely. To this end, Dr. Emily Godfrey, MD, MPH and Anna Fiastro, MPH, MEM at the University of Washington is conducting an evaluative research project that seeks to document, assess, and share broadly new models of care. In support of this endeavor, the following are suggested elements of patient information to be collected in addition to a summary of necessary information shared throughout the Toolkit.

Suggested patient history prior to medication abortion provision based on the current standards of care (from TEACH[45])

- Last menstrual period; history indicating pregnancy is ≤ 77 days (11 weeks)
- No current clinical suspicion of ectopic or molar pregnancy
- Not anemic, anticoagulated or with a bleeding disorder
- No severe or unstable chronic condition
- No adrenal insufficiency (or chronic use of oral steroids)
- No porphyria
- No IUD in the uterus (must be removed first)
- No allergy to mifepristone or misoprostol
- Expresses clear desire to have abortion and willing and able to follow up as planned

Necessary information to document for dispensing of mifepristone per FDA Mifepristone REMS requirements (In Medication Log)

- Patient name
- Date of Birth
- Estimated Gestational Age in Days
- Mifepristone Serial Number
- Mifepristone Expiration Date
- Misoprostol Serial Number
- Misoprostol Expiration Date

Optional patient information to collect prior to medication abortion provision for research purposes

- Date of patient consultation, method of communication
- Zip code where patient resides
- Race/ethnicity
- Level of education
- Number of prior pregnancies
- Number of previous abortions
- Number of previous medication abortions
- Patient payment method(s)
- How pregnancy was confirmed before patient first contacted provider

    - Date of earliest pregnancy test
- Rh type (if known, how was it determined)
- Patient satisfaction with the model of care (i.e. e-visit with mailed pills)

Suggested patient information to collect post medication abortion based on current standards of care (from TEACH[45], Gynuity miso-only[78])

- Patient's experience since taking medications, including timing and extent of bleeding and cramping, and resolution of pregnancy symptoms. Questions include:
    - Do you think you are still pregnant?
    - Can you identify the moment when you expelled the pregnancy?
- Assessment of success of abortion based on clinical history and at home pregnancy test four weeks after taking the medication.
- Asking patient to contact provider for late-onset heavy bleeding or other concerns warranting evaluation and treatment.

Optional patient information to collect after medication abortion for research purposes

- Did you have any issues receiving the medications?
- How did you confirm you are still pregnant? Or that your pregnancy ended?
- Did you go to a hospital or see a healthcare professional? What type of care did you receive?
- Overall, were you satisfied with the care you received?
- Would you recommend a "no test" model of care to others in a similar situation?

Please let us know if you read or used our Provider Toolkit!

Dr. Emily Godfrey, MD, MPH, and Anna Fiastro, MPH, MEM, at the University of Washington are conducting an evaluative research project that seeks to document, assess, and share broadly this new model of care, and you can help! If you have read or used our Provider Toolkit, we want to hear from you.

Your input not only helps us improve the Toolkit for others, but we would also like to learn more about how you are implementing the service in your own practice. These new, innovative models of abortion care have the potential to revolutionize access.

Please submit your questions at familymedicine.uw.edu/accessdelivered

ADDITIONAL RESOURCES:

Support materials that can be used or edited and shared with patients:

- GenBioPro Patient Resources
  - Medical Abortion: Is It Right for You?: English Spanish Chinese Vietnamese
  - What to Expect Guide: English Spanish Chinese Vietnamese
- Sample Patient Info. Sheet
- Reproductive Health Access Project
  - Sam's Medication Abortion Zine
  - How to Use Abortion Pills Fact Sheet
  - Abortion Pill info to Read Prior to Phone Visit
- All-Options offers unbiased and judgment-free support for all your experiences with abortion, adoption, pregnancy loss, parenting, infertility, unplanned pregnancy, and more. Call 1-888-493-0092 from anywhere in the U.S. to reach a trained advocate or visit all-options.org for more information.
- M+A Hotline If you need support to self-manage your miscarriage or abortion Call or text the Miscarriage & Abortion Hotline 1-833-246-2632
- Reprocare Healthline Medical information and caring support during miscarriage or an abortion with pills.
- Exhale is the nation's premiere organization addressing the emotional health and well-being of individuals after abortion.

Resources for Providers:

- Reproductive Health Access Project
  - Toolkit for Integrating Abortion into Primary Care
  - Phone Triage Call: Bleeding with Medication or Expectant Management of Miscarriage
- TEACH - Training in Early Abortion for Comprehensive Healthcare
- RHEDI: Mainstreaming Abortion in Family Medicine – Education materials for family medicine providers offering medication abortion.
- Kaiser Family Foundation – The Availability and Use of Medication Abortion
- Doxy.me & Doximity are tools for providers to conduct HIPAA compliant patient interactions (messaging, telephone, video) Recommended by providers already offering services but not reviewed by authors of this toolkit.

Useful Templates for Adaptation:

- Patient, medication dispensing log
- Mifepristone labels template
- Misoprostol label templates (If sending two courses of misoprostol: first bottle, second bottle)
- Patient consent forms (Different from the FDA required Patient Agreement Form[73])
- Sample Patient Info. Sheet

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