

Supplemental materials for

Montag Schafer K, Chaisson N. Streamlining the use of mifepristone for early pregnancy loss across a large health care system sets the stage for rapid expansion of medication abortion access in a post-Roe environment. *Ann Fam Med*. 2023;21:Online.

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Frequently Asked Questions - Mifepristone for Miscarriage Management

Who defines the prescribing rules for mifepristone?

The U.S. Food and Drug Administration established a Risk Evaluation and Mitigation Strategy (REMS) program for mifepristone. Details of the requirements are outlined in this document, the LMS/Workday training, and can also be found [here](#).

Who can prescribe mifepristone?

Mifepristone can be provided by or under the supervision of a healthcare provider who prescribes and meets the following qualifications, as defined by the [Prescriber Agreement Form](#):

- Ability to assess the duration of pregnancy accurately.
- Ability to diagnose ectopic pregnancies.
- Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made plans to provide such care through others, and ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.
- Has read and understood the mifepristone [Prescribing Information](#).

What does the process look like for an advanced practice provider, i.e. can they prescribe under the physician on record?

The healthcare provider must have the authority to prescribe, so this could be any independent licensed healthcare provider (MD, DO, APRN, PA). The healthcare provider must otherwise meet the requirements listed above.

Do I need to complete the *Prescriber Agreement Form*?

No. The *Prescriber Agreement Form* was completed by a M Health Fairview representative for all prescribers within the system.

What requirements need to be completed when prescribing and providing mifepristone?

The official US FDA REMS program requirements for mifepristone include:

- Review the [Patient Agreement Form](#) with the patient and fully explain the risks of the mifepristone treatment regimen. Answer any questions the patient may have prior to receiving mifepristone.
- Sign the *Patient Agreement Form* and obtain the Patient's signature on the form.
- Provide the patient with a copy of the *Patient Agreement Form* and *Medication Guide*.
- Place the signed *Patient Agreement Form* in the patient's medical record.
- Record the serial number from each package of mifepristone in each patient's record.
- Report any deaths to the Sponsor that provided the mifepristone (Danco Laboratories, LLC).

Note: The language outlined on the *Patient Agreement Form* is tailored for use of mifepristone for its labeled use, i.e. medical termination of intrauterine pregnancy. Mifepristone for miscarriage management is considered an "off-label" use of the medication. Regardless, after consultation with the Compliance team, the completion of the *Patient Agreement Form* is a requirement for the use of the medication. Therefore it is recommended to provide patient counseling on the requirement of the form per the FDA. Relevant information from the *Patient Agreement Form* has been highlighted in the Patient After Visit Summary available in the Medication Miscarriage Management SmartSet in Epic.

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Additional resources are available below to help understand how to achieve these requirements in clinic:

- Visio Documents:
 - [Mifepristone clinic process](#)
 - [Mifepristone clinic process with RN support](#)
- Workday and LMS training is available for prescribers and patient care staff:
 - Prescribers: Management of Early Pregnancy Loss with Mifepristone
 - Patient Care Staff (RN, MA, LPN, EMT): Management of Early Pregnancy Loss with Mifepristone - Patient Care Staff

How does my clinic order mifepristone?

Mifepristone is available for ordering through the Fairview Pharmacy Services - Wholesale ordering site (<http://mmgtapp4/wholesale/Orders/New>).

- Orders will be due and delivered per your clinic's usual Wholesale delivery cadence
- Expedited shipping available: 1 business day turnaround, site will be billed for additional costs
- Per clinic policy, NO Friday deliveries
- For further assistance, please email DEPT-PHARM-RET-MOWHOLESALE@fairview.org or call 612-672-5132.

How can I access the required patient materials (*Patient Agreement and Medication Guide*)?

The required patient materials will be delivered with the medication supply through Fairview Pharmacy Services - Wholesale ordering. If additional copies of the forms are required, the *Patient Agreement Form* is available [here](#), the *Medication Guide* is available [here](#), or they both can be accessed and printed through the Medication Miscarriage Management SmartSet in Epic.

Can mifepristone be sent home with the patient?

No, mifepristone must be administered and taken by the patient in the clinic. While this is technically allowed by the REMS rules, our clinics are not equipped to label the medication to meet pharmacy law requirements for outpatient medication dispensing.

Can mifepristone be administered during a nurse-only visit?

No, mifepristone must be dispensed to patients under the supervision of a certified prescriber. Per CMS "supervision" is considered to be physically present in the same building.

What follow-up care is recommended for patients receiving mifepristone?

As outlined in the "Mifepristone clinic process" document, a 1-2 week follow up visit is recommended to be scheduled. Recommended follow up at this visit should include one of the following to document the complete passage of tissue:

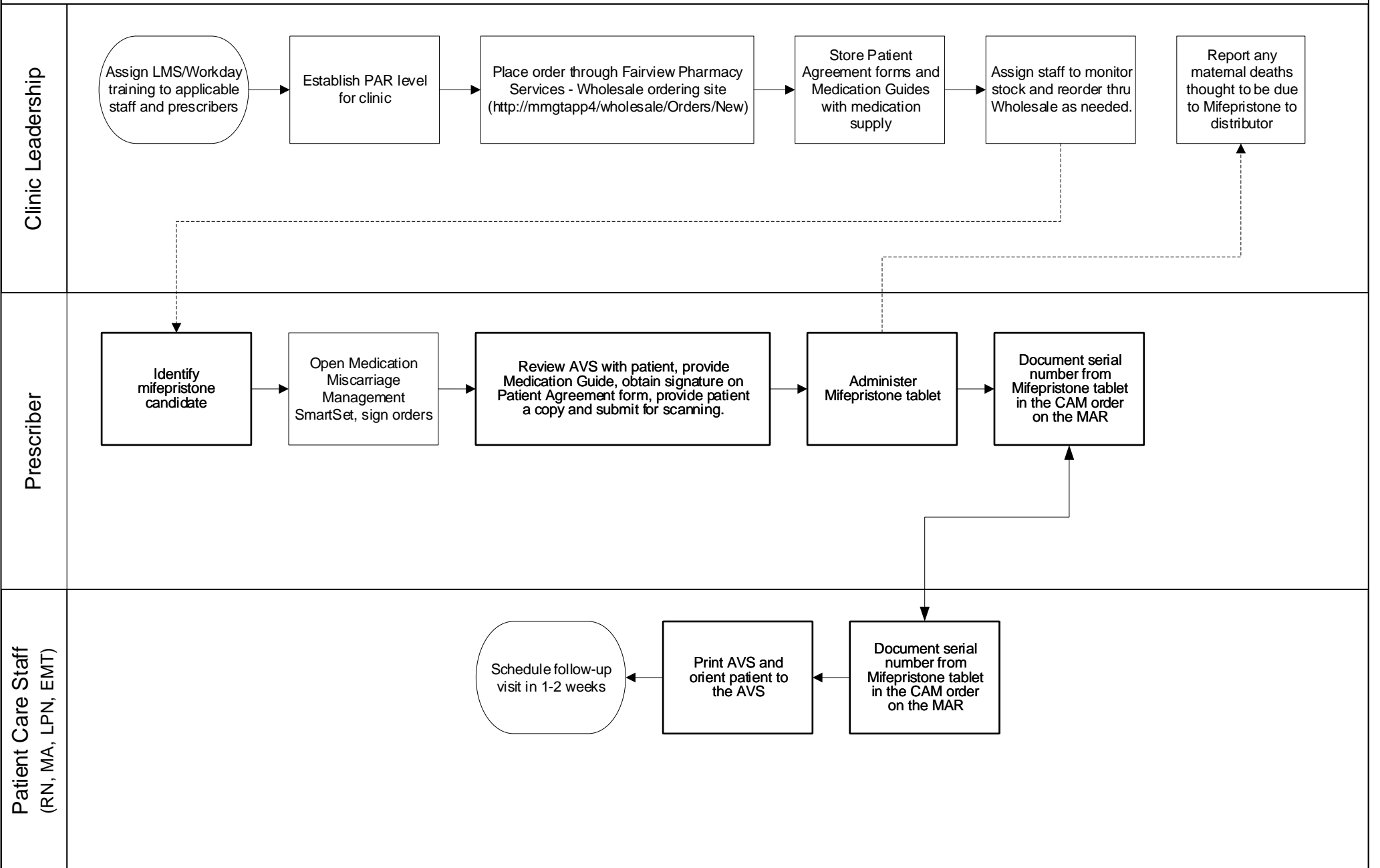
- Ultrasound
- Serial β -hCG measurements, may be used instead in settings where ultrasonography is unavailable
- If the above options are not available, a urine pregnancy test at 4 weeks

Is there a centralized location to find all of these resources?

Yes! These resources are available on the "Mifepristone" Teams page. To join the page:

- Select "Join or create a team"
- Enter code "mrhcagx" into the "Join a team with a code" option

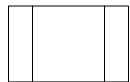
First Trimester Pregnancy Loss Management with Mifepristone – M Health Fairview System (July 2022)



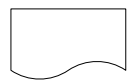
KEY



Process



Related Process



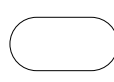
Paper Process



Interface/Auto-print



Decision



Terminator