Access Bridge

TEACH

Expanding ED Access to Mifepristone and Misoprostol:

A Clinician's Guide to the Pharmacy & Therapeutics (P&T) Process

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Providing the best treatment for your patients begins with access to all medication options. This process starts with your hospital's Pharmacy & Therapeutics Committee (P&T) which oversees the hospital approval process for medication access and use. Typically, the committee includes pharmacists, medical staff physicians, nursing representatives, quality improvement managers, and administrators.

Getting a Medication on Formulary 101

From the P&T Committee to Optimizing Medication Options for Your Clinical Practice Setting

1. **Essential Preparation**
    a. **Build allies**. Identify who needs to be on board, potential supporters, and detractors. Consider:
        i. Pharmacist in charge of ED medications
        ii. Pharmacist in charge of OBGYN medications
        iii. Medical director/chair of OBGYN
        iv. Medical director/chair of emergency medicine
        v. Nursing director of ED and/or OBGYN

    b. **Ask for advice** from the leaders listed above and from P&T members. People appreciate being asked for advice about how things work, who the key opinion-holders are, what types of evidence are most compelling, and what questions they would need answered to support the request.

    c. **Meet with opinion-makers.** Identify and address concerns preemptively before the meeting. Anticipate and address common misconceptions in your summary of evidence. Prepare talking points for commonly asked questions. Understand your detractors and their issues; prepare counter-arguments.

    d. **Find other bright spots that can serve as examples** and models.
        i. Do other hospitals in the system or region, local academic medical centers, or other respected hospitals in the state already have mifepristone/misoprostol on formulary?
        ii. If so, collect their monograph[1] and P&T packet—it is faster to edit than to create. Ask pharmacy and OBGYN for advice on how to modify documents to meet your hospital's P&T Committee standards.

    e. **Note regarding Hospital Clinical Guidelines or Policies**: While having an official hospital policy that includes your medication is *not universally mandatory*, it *may* be something your hospital departments or P&T committee request, especially for medications medical staff and pharmacy are less familiar with. If you do need to prepare a clinical guideline or hospital policy, see Appendix 3.

2. **P&T Committee Processes**
    a. Each hospital has a system to add new medications to the formulary so clinicians can order them and nurses can administer them. The system can be managed at the local or regional level (if there is a network of facilities).

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[1] A pharmacy monograph is a detailed, standardized document outlining a drug's pharmacologic details and clinical usages, used for regulatory compliance (FDA), manufacturing standards (USP), and clinical guidance to ensure safety and efficacy.

b. **Find out how P&T works at your hospital.** Ask your pharmacist: Who is on the P&T Committee (chair and members)? When does the committee meet? How can you get your request on the agenda? What needs to be in the P&T packet? Ask for examples from past meetings.

c. **Get on the agenda.** Email the committee chair. If you are having difficulty getting a response, connect with your medical staff administrative office which typically supports committee meetings. You can also request a P&T champion to be assigned to you. Request all the forms you need to submit in advance.

d. **Talk to committee members *before* the meeting.** Secure a "yes" vote by addressing questions and concerns ahead of time to the extent possible.

3. Submit Your Proposal: Elements of a Successful P&T Request

Some hospitals will have a standardized P&T request form, but others may not. Regardless, there are a few main elements that make a P&T request successful:

a. **Clearly Stated Goal**: Add medication to hospital/ED formulary (e.g. mifepristone, misoprostol, contraceptives, and/or emergency contraceptives).

b. **Background Evidence & Information:** Essential Information to include:

i. **Specific medication, dose, and uses**

1. Note: For mifepristone, the dose for early pregnancy loss (EPL) and medication abortion (MAB) is ***not*** the same as used for other indications (e.g. Cushing's). Ensure the hospital knows the correct dose and route you are requesting.

ii. **Evidence** for how it improves patient care. (Effective, standard of care, safe.)

1. See Appendix 2.

iii. **Low financial cost** to the system: costs per medication administered, anticipated doses per month. Note that mifepristone is about $43 per pill, one pill per treatment episode; misoprostol is less than $1 per pill, and each patient requires 8-12 pills; Much cheaper than other commonly used drugs. Neither drug requires refrigeration or cold storage.

iv. **Reasonable pharmacy processes**:

1. For mifepristone: Explain the minimum necessary elements of the Risk Evaluation and Mitigation Strategies (REMS). See Appendix 1 below for details.

2. For emergency contraception (EC): Explain that neither medication option is an abortifacient. You can use the EC one-pager for support.

3. None of the reproductive health medications are controlled substances; none require refrigeration or special storage.

2. **Conflict of Interest** Statement: Make it clear you have no financial gain from the request.

Appendix 1—Mifepristone: REMS 101

Risk Evaluation and Mitigation Strategies (REMS) is a program through the Food & Drug Administration (FDA) that requires specific steps be taken when a patient is given a medication on the REMS list in order to add a layer of protection for patients when receiving medications that have more serious safety concerns than would be considered routine or normal for most medicines.

In the case of Mifepristone, the REMS requirements unfortunately stem from the political nature of abortion care and are *not* based on any evidence-based safety concerns. In fact, mifepristone is *only* on the REMS list for the *lower doses* needed in pregnancy loss care, and is *not* on the list for its *higher doses* used in Cushing's. The American College of Obstetricians & Gynecologists (ACOG) "has long advocated for the removal of the REMS restrictions on the use of mifepristone for reproductive health indications because they do not make the care safer; are not based on medical evidence or need; create barriers to clinician and patient access to medication abortion and medical management of early pregnancy loss; and disproportionately burden communities already facing structural barriers to care, including people of color and those living long distances from a health care professional."[2]

Complying with Mifepristone REMS:

1. Know the updated FDA REMS requirements; note that mifepristone is under litigation, and these REMS requirements may be lifted entirely or may be reversed to earlier FDA requirements.
2. Know which *brand* of mifepristone is carried in your facility: Danco or GenBioPro. Each has separate branded one-page certification forms (for the pharmacy and prescribers) and patient forms (consent and medication guide).
    a. GenBioPro
        i. Prescriber agreement form
        ii. Pharmacy agreement form
        iii. GenBioPro patient agreement
        iv. GenBioPro medication guide
        v. GenBioPro medication guide, see "Need Translated Documents" in med. guide section
    b. Danco
        i. Prescriber agreement form
        ii. Pharmacy agreement form
        iii. Danco patient agreement (see other languages)
        iv. Danco medication guide
        v. Danco medication guide (see other languages)

[2] "Updated Mifepristone REMS Requirements." *American College of Obstetricians and Gynecologists*, Jan. 2023, ACOG. Accessed May 2026. ACOG.org.

3. **Prescriber REMS Certification (Prescriber Agreement Form)**
    a. **Mifepristone must be ordered by a clinician "certified" under the Mifepristone REMS Program.** "Certified" means the clinician signs the *Prescriber Agreement Form* affirming they understand how to clinically use mifepristone and manage any side effects or treatment complications.
        i. Note: ***There is no formal or specific training that must occur*** for a clinician to become "certified." Clinicians can simply educate themselves on mifepristone the way they would any new medication they are adding to their clinical practice.
        ii. The Prescriber Agreement Form is a simple, one-page form that requires the clinician's name, NPI (public information easily found on the Internet), and the address of the *hospital*.
            1. Note: **Prescriber REMS forms *must use the hospital's address!*** If the OBGYN or other clinician uses their *clinic* address, there will be a delay in processing hospital orders for mifepristone.
        iii. Options to meet the certification requirement include:
            1. All ED prescribers complete the *Prescriber Agreement* F*orm*.
            2. One prescriber completes the form which fulfills the REMS requirement on behalf of all ED clinicians (physicians, advanced practice clinicians, +/- residents/trainees). In this case, any clinician in the ED is operating under the "supervision" of the single certified prescriber for the purpose of the REMS program only.
            3. For hospitals that *do* have OBGYN services, either a leader in OBGYN or all of the clinicians on the OBGYN service can complete the REMS form instead of the ED. If *only* OBGYN completes the REMS certification, then any ED clinician who orders/gives mifepristone to their patient is technically doing so *under the supervision* of the REMS-certified OBGYN.
            4. Note: Some hospitals may require option 1, and set an expectation that every emergency clinician must complete the REMS certification form as an opt-out or opt-in process. If this is the case, work with your medical staff office to make completion of the REMS form a *standard part of your EM clinician onboarding and re-credentialing*.
            5. If not all clinicians are certified, and there is no supervising prescriber, create a system so clinicians, nurses, and staff know who can order mifepristone (examples: post on the wall, make information accessible electronically, highlight/asterisk electronic scheduling or tracking systems).
        iv. **Pro-Tip:** Bring blank copies of the Provider Agreement Forms to the committee or other meeting where adding mifepristone will be discussed to allow real-time completion of the form!
    b. Once completed, the **REMS Prescriber Agreement Form is kept on-file in your hospital pharmacy** and **must be sent to the manufacturer** in order to allow mifepristone ordering.

4. **Patient Agreement Form**: Use the manufacturer-specific forms.
    a. Patients must (1) sign and be given a copy of the **Patient Agreement Form**, and (2) be given the **mifepristone medication guide**. Both forms are manufacturer-specific, and are linked above.
    b. The clinician must also sign the Patient Agreement Form, and a signed copy must be entered into the patient's chart.
    c. Note: The Patient Agreement Form is *not designed for miscarriage management* and contains language that may not be clinically relevant.

d. **Tips/Sample language for explaining inconsistencies to patients:**
    i. Federal rules require all patients to sign this form when taking mifepristone, even though the form is not designed for miscarriage. The form mentions "ending a pregnancy." In the case of miscarriage, the pregnancy has already ended but not completely expelled. The medications help your body finish the miscarriage in a shorter period of time.
    ii. Mifepristone and misoprostol used together are the medications proven to work best for miscarriage and are recommended by the country's professional association of OBGYNs, the American College of Obstetricians and Gynecologists.
    iii. Miscarriage is not an FDA-approved indication for mifepristone, but off-label use of medications is common. About 1 in 5 commonly used medications are not FDA-approved, even when they're best for a particular condition – like morphine and aspirin.
    iv. Follow-up is optional. Studies show that follow-up is unnecessary if you feel fine and the medicines work. Here's how to know:
        1. *For missed abortion:* The medications worked if you have 1) bleeding like a heavy period, 2) your pregnancy symptoms go away within a week, and 3) your home pregnancy test is negative in 5 weeks. If all of those are true, you do not need an ultrasound or blood test for follow-up. If you don't have all three of these signs/conditions, you should see a clinician for follow-up.
        2. *If miscarriage and actively bleeding*: The medications worked if: 1) the bleeding slows down, 2) pregnancy symptoms go away within a week, and 3) your home pregnancy test is negative in 5 weeks. If all of those are true, you do not need an ultrasound or blood test for follow-up. If you don't have all three of these signs/conditions, you should see a clinician for follow-up.
    v. See Appendix 4 for sample "cover sheet" language for the REMS patient agreement.

e. You **must document** that the patient received the agreement form and education on mifepristone. EDs manage the documentation requirements in various ways:
    i. An EHR miscarriage template can include the required patient agreement, which is signed electronically by the patient.
    ii. A paper-copy is signed by the patient and scanned into the chart.
    iii. Patients *must* be given a copy of their signed REMS form.
    iv. **Pro-Tip:** Create a template that clinicians can include in their ED note that states the REMS requirements were met.
        1. Sample template language: "REMS Compliance Statement: This patient is being treated for early pregnancy loss in concordance with current Level A scientific evidence, American College of Obstetricians and Gynecologists (ACOG) clinical practice guidelines, and hospital clinical guidelines and policies. As per REMS requirements in this clinical context, the patient was screened for eligibility and does not have any contraindications. The patient was counseled regarding management options, medication side effects, supportive care, anticipatory guidance, and return precautions. The patient signed the manufacturer's Patient Agreement/REMS Form and received the Medication Guide prior to discharge."

Are mifepristone & misoprostol available at outpatient pharmacies? Can I simply write a prescription?

This will vary widely from pharmacy to pharmacy. Most retail pharmacies do *not stock* misoprostol at EPL/MAB doses, nor do they stock mifepristone. Sometimes this is related to misunderstanding on the pharmacy side

about REMS or other legal restrictions. It is a useful exercise to call your local pharmacies and *ask*. You can request they stock the medications, but clarify between pharmacies willing to have the medication "in stock" vs. willing to order it only *after* they receive the prescription, which can lead to a delay of 1-5 days in the patient physically receiving their medication.

List of mifepristone Certified Pharmacies and their locations:

- Danco Certified Pharmacies
- Genbiopro Certified Pharmacies
- An interactive map and more information about pharmacies that supply mifepristone/misoprostol can be found here.

To write a prescription for mifepristone to be filled at a local pharmacy, **the pharmacy must have a copy of your Prescriber Agreement Form on file**.

For **CVS**, the Prescriber Agreement Form only needs to be submitted once for use across *all* participating CVS locations. There are 3 options to submit the form:

- Can be submitted directly to CVS via Genbiopro and/or Danco
- Email to Mifepristone_REMS@CVSHealth.com
- Fax to (513)-297-6503

More information about CVS Mifepristone can be found here

For all other pharmacies, including **Walgreens**, you will need to submit the Prescriber Agreement Form directly to each individual, specific pharmacy location.

While Access Bridge does not have a relationship with nor endorse any specific pharmacy, our champions have reported reluctance and/or refusal to stock mifepristone at many Walgreens pharmacies, particularly in states with abortion restrictions. Also, Costco has publicly declined to carry mifepristone.

Other big chain pharmacies have no public stance and vary by location.

Tips for prescribing mifepristone & misoprostol to outpatient pharmacies:

1. REMS require that mifepristone be dispensed within 4 days of being prescribed. Prescribers can thus include a **"Dispense By" date** in their prescription which is 4 days in the future from the date of prescription.
2. Because misoprostol is often ready to be dispensed before mifepristone, consider adding **"Do not dispense without mifepristone" to your misoprostol Rx** to ensure they are picked up at the same time, allowing them to be taken in the correct order as per the Early Pregnancy Loss & Medication Abortion protocols.
3. If you hold a medical license in multiple states, include your appropriate state licensing information in the notes to the pharmacy to avoid confusion.
4. Be Aware: It is ***not*** required by REMS for the pharmacy to know the gestational age, nor to receive a copy of the *Patient* Agreement Form. However, some Walgreens locations have requested this from prescribers.

Need help?

Both Danco and GenBioPro have great reputations for guiding clinicians through the process. 340B prices may be available.

- *Danco*, $43 per pill
    - Distributor: AmerisourceBergen
    - Contact: Abby Long, Email: along@earlyoptionpill.com
- *GenBioPro,* $42.50 per pill
    - Distributor: RS Northeast
    - Contact: Taylor McDowell, Email: support@genbiopro.com or info@genbiopro.com

***CVS** also has a **Mifepristone Clinical Care Team hotline** to navigate any issues regarding CVS mifepristone: (833) 287-4335. This number is **meant for clinical teams to communicate with CVS**, not the patient/general public.*

Appendix 2 – Resources for P&T Proposal

For Mifepristone

1. Medication Management of EPL Factsheet with citations

2. Access Bridge clinical protocols:
    a. Management of Early Pregnancy Loss (EPL)
    b. Management of EPL (misoprostol only)
    c. Medication Abortion

3. American College of Obstetricians & Gynecologists (ACOG) practice advisories:
    a. Jan 2023 Practice Advisory – Updated Mifepristone REMS Requirements
    b. Nov 2018 Practice Bulletin – Early Pregnancy Loss

For Emergency Contraception (EC)

1. EC One Pager

Sample clinical guidelines and hospital policies in Appendix 3.

Appendix 3 — Clinical Guidelines & Hospital Policies

Hospital Policies are written documents that guide hospital operations and certain aspects of patient care. Policies are formal hospital documents typically managed by a specific department(s), with oversight and approval from the medical staff's Medical Executive Committee (MEC). They must be reviewed on a periodic basis, and any adjustments must be re-approved by pertinent hospital departments, committees, and MEC.

While it is common for leaders or changemakers to *request* a *policy* in order to implement change (ex: begin use of mifepristone and misoprostol to manage early pregnancy loss), most of the time a simpler ***clinical guideline*** is sufficient. **Clinical guidelines** may appear similar to a hospital policy with spelled out instructions, or can look more like our Access Bridge clinical protocols. The goal of a clinical guideline is to facilitate agreement between relevant departments regarding how certain medications should be used for specific patient presentations, and can be used to provide education to clinicians and nursing staff. Updates and edits to clinical guidelines simply require review by the relevant parties actively providing the patient care affected by the guideline.

Whenever possible, champions should advocate for the use of a clinical guideline over a formal hospital policy to help implement new protocols or bring new medications on formulary to improve patient care.

In either scenario, it is a critical step in the process for **champions to attend relevant meetings *in person*** (or live via conferencing platform) to advocate for their proposed change, as well as answer questions and hear feedback from relevant stakeholders.

For examples of real-life versions of these documents that have been successfully used in the field by previous champions, contact us!

Appendix 4 — Sample cover sheet for REMS patient agreement

Language like the following sample can be used to create a cover sheet for the REMS patient agreement to help explain to patients *why* they have to complete the form, and to clarify the language in the form.

Mifepristone in the Treatment of Miscarriage (Early Pregnancy Loss)

You are being treated for a miscarriage, which is when your pregnancy ends for reasons we do not always understand. While you still have pregnancy tissue in your uterus, it will not continue to grow and is no longer a living pregnancy. Your body will need to pass the pregnancy tissue out of your uterus through your vagina, the same way you bleed during your menstrual cycle (a "period").
The medications we are prescribing you (mifepristone and misoprostol) help your body pass this pregnancy tissue so you can complete your miscarriage more efficiently and safely.
You are required to sign a standardized "Patient Agreement Form" to receive one of these medications. This form is used nationwide for all patients receiving these medications. Because it is written for multiple situations, it contains phrases such as "to end my pregnancy."

In your case, these medications are not ending an ongoing or living pregnancy. They are being used to manage a miscarriage that has already occurred, which helps you complete your miscarriage faster and more safely.

As this form is used across the country, we cannot make any changes to the wording on this form. In your case, "ending my pregnancy" means passing the pregnancy tissue out of your body. This is normal treatment for early pregnancy loss ("miscarriage").

Please ask any questions you may have. We are here to support you!

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