CLINIC AND PHARMACY COLLABORATION FOR MEDICATION ABORTION

A resource guide for clinics and mail order pharmacies that would like to collaborate to provide medication abortion care and prescriptions to their patients.

Note: This guidance is current as of August 27, 2021 and reflects the revised distribution of mifepristone permitted during the COVID-19 public health emergency.

WHAT DO PHARMACIES NEED TO KNOW ABOUT THE REMS FOR MIFEPRISTONE?

The US Food and Drug Administration (FDA) can require a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of a drug outweigh its risks.

The goal of the Mifepristone REMS is to mitigate the risk of serious complications by:

- Requiring healthcare providers who prescribe mifepristone to be certified in the Mifepristone REMS
 Program. This is accomplished when the prescriber/supervising prescriber fills out a form to enroll with the
 distributor.
- 2. Ensuring that mifepristone is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber. Retail pharmacies and other pharmacy types are excluded, however the <u>FDA is allowing mail order pharmacies to dispense mifepristone during the COVID-19 public health emergency.</u>
- 3. Informing patients about the risk of serious complications associated with mifepristone. This is accomplished with a <u>Patient Agreement</u> (signed in clinic or electronically/verbally during the COVID-19 public health emergency) and providing the patient with the <u>Medication Guide</u> when dispensing mifepristone.

HOW TO PREPARE FOR PHARMACY DISPENSING OF MIFEPRISTONE?

ORDERING MEDICATIONS

	Mail order pharmacies are able to set up an account with the distributor and then order and purchase mifepristone directly to fill prescriptions from any certified prescribers.
	milephstone directly to fill prescriptions from any certified prescribers.
☐ When the prescriber is completing the <u>Prescriber Agreement</u> , the pharmacy information should be	
	under Shipping Information. Upon receipt of the Prescriber Agreement, the distributor will contact the
	pharmacy to set up an account.

- ☐ Alternatively, the pharmacy can contact the distributor directly to set up an account. The pharmacy should maintain a list of certified prescribers for whom they will be filling prescriptions and this list will be confirmed by the distributor.
- The mifepristone will be sent from the distributor, along with Medication Guides (also available online).

PHAKI	VIACTII	NVENTORY CONSIDERATIONS	
To determine inventory and reordering thresholds for mifepristone and misoprostol, discuss anticipated volume of medication abortion patients per week and whether these visits be days or times.			
	Medica	ations to keep in stock:	
		Mifepristone 200 mg (Danco or GenBioPro) - 1 per patient	
		Misoprostol 200 mcg tablets – 4-8 per patient	
		Note: Standard regimen is 4 tablets taken 24-48 hours after mifepristone. However, some clinicians routinely order a second set of 4 tabs if gestational duration is \geq 63 days or if no bleeding occurs within 12-24 hours after the first dose of misoprostol.	
	Other	medications are routinely in stock:	
		Ibuprofen	
		Ondansetron	
		Others	
	These	medications have no special storage requirements.	
	Since r	DISPENSING & DELIVERY CONSIDERATIONS mifepristone is not a pharmacy benefit and cannot be processed through prescription drug insurance, swhether the cost of mifepristone and/or the dispensing fee and/or the shipping fee will be paid by nic or patient. All other medications can be processed through prescription drug benefits as usual.	
	Consider discrete packaging to protect patient privacy.		
COOR	DINATI	NG CARE	
COORDINATING CARE ☐ If you have an EHR, set up mifepristone and misoprostol for e-prescribing. If you don't have discuss if the prescription can be called in, left on voicemail, and/or faxed.			
	Discuss clinic vs pharmacy hours. Let the clinic know the cut off time for prescriptions to be mailed out same day.		
	Discuss how patients will receive counseling on medications. In general, the clinic provides comprehensi patient counseling, including counseling on medications. The pharmacy must provide the Medication Guide when dispensing mifepristone and will be available to counsel on medications.		
	addres	s the timing for medication delivery, how delivery will be confirmed, and how any delays will be sed. To minimize delays, ensure delivery before gestational duration cut-off used by the prescriber 11 weeks).	
	Contac	ct at the clinic	
	Contac	ct at the pharmacy	
PHAR	MACIST	WILLINGNESS	
		in with pharmacists proactively to verify willingness to dispense medications.	
	will be who is dispen	charmacist(s) at the pharmacy is not willing to dispense, develop a plan to ensure another pharmacist available to dispense medications in a timely manner. Examples include having a second pharmacist willing to dispense available at all times, having overlap with a second pharmacist who is willing to se during particular days/hours, and/or having a manager/pharmacist-in-charge who is willing to se who can come in as needed.	

WHAT DOES THE PHARMACY NEED TO DO FOR EACH PATIENT? ☐ Get patient's preferred mailing address. Document the serial number from the package of mifepristone in the pharmacy system. Provide the patient with a copy of the medication guide and be available to counsel on medications. What Resources Are Available for Pharmacists and Pharmacy Teams? **EDUCATIONAL RESOURCES** ☐ Pharmacists' Roles in Medication Abortion continuing pharmacy education program available at cmecalifornia.com/lms/ucsf. Medication Abortion Pharmacy Counseling Checklist available at <u>birthcontrolpharmacist.com/resources</u>. Medication Abortion Curriculum content available at <u>birthcontrolpharmacist.com/resources</u>. ☐ Medication abortion: Advocating for mifepristone dispensing by pharmacists commentary available at contraceptionjournal.org. MIFEPRISTONE DISTRIBUTOR CONTACT INFORMATION GenBioPro is interested in serving mail order pharmacies. GenBioPro provides both mifepristone and misoprostol. If you have questions about GenBioPro generic mifepristone, or about ordering GenBioPro product, contact GenBioPro at: 1-855-MIFEINFO (1-855-643-3463) or info@genbiopro.com ☐ If you have questions about **Danco brand mifepristone (Mifeprex®)**, or about ordering Danco product, contact Danco at: 1-877-4EARLYOPTION (1-877-432-7596) or info@earlyoptionpill.com

FOR QUESTIONS OR FEEDBACK ON THIS GUIDE, CONTACT MAIL@BIRTHCONTROLPHARMACIST.COM