

PHARMACY AGREEMENT FORM

Mifeprex[®] (Mifepristone)
Tablets, 200 mg

Pharmacies must designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Mifepristone REMS Program on behalf of the pharmacy.

Healthcare settings, such as medical offices, clinics, and hospitals, where mifepristone will be dispensed by or under the supervision of a certified prescriber in the Mifepristone REMS Program do not require pharmacy certification.

BY SIGNING THIS FORM, AS THE AUTHORIZED REPRESENTATIVE I CERTIFY THAT:

- Each location of my pharmacy that will dispense Mifeprex is able to receive *Prescriber Agreement Forms* by email and fax.
- Each location of my pharmacy that will dispense Mifeprex is able to ship Mifeprex using a shipping service that provides tracking information.
- I have read and understood the Prescribing Information for Mifeprex. The Prescribing Information is available by calling 1-877-4 EARLY OPTION (1-877-432-7596 toll-free) or online at www.earlyoptionpill.com; and **each location of my pharmacy that will dispense Mifeprex will put processes and procedures in place to ensure the following requirements are completed.** I also understand that if my pharmacy does not complete these requirements, the distributor may stop accepting Mifeprex orders.
 - Verify that the prescriber is certified in the Mifepristone REMS Program by confirming their completed *Prescriber Agreement Form* was received with the prescription or is on file with your pharmacy.
 - Dispense Mifeprex such that it is delivered to the patient within 4 calendar days of the date the pharmacy receives the prescription, except as provided in the following bullet.
 - Confirm with the prescriber the appropriateness of dispensing Mifeprex for patients who will receive the drug more than 4 calendar days after the date the pharmacy receives the prescription and document the prescriber's decision.
 - Record in the patient's record the NDC and lot number from each package of Mifeprex dispensed.
 - Track and verify receipt of each shipment of Mifeprex.
 - Dispense mifepristone in its package as supplied by Danco Laboratories, LLC.
 - Report any patient deaths to the prescriber, including the NDC and lot number from the package of Mifeprex dispensed to the patient, and remind the prescriber of their obligation to report the deaths to Danco Laboratories, LLC. Notify Danco that your pharmacy submitted a report of death to the prescriber, including the name and contact information for the prescriber and the NDC and lot number of the dispensed product.
 - Not distribute, transfer, loan or sell mifepristone except to certified prescribers or other locations of the pharmacy.

- Maintain records of *Prescriber Agreement Forms*, dispensing and shipping, and all processes and procedures including compliance with those processes and procedures.
- Maintain the identity of Mifeprex patients and prescribers as confidential and protected from disclosure except to the extent necessary for dispensing under this REMS or as necessary for payment and/or insurance.
- Train all relevant staff on the Mifepristone REMS Program requirements.
- Comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed.

Any new authorized representative must complete and submit the Pharmacy Agreement Form.

Authorized Representative Name: _____ Title: _____

Signature: _____ Date: _____

Email: _____ Phone: _____ Preferred email phone

Pharmacy Name: _____

Pharmacy Address: _____

Return completed form to Mifeprex@dancodistributor.com or fax to 1-866-227-3343.



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**THE ORIGINAL
EARLY OPTION PILL**



Danco Laboratories, LLC • P.O. Box 4816 • New York, NY 10185
1-877-4 Early Option (1-877-432-7596) • www.earlyoptionpill.com

*MIFEPREX is a registered trademark of Danco Laboratories, LLC.