



*Becoming a Provider of Mifeprex[®] :
What Providers Need to Know About the Prescriber's Agreement*

To order Mifeprex[®], physicians will need to sign Danco's Prescriber's Agreement/Account Setup Form. Mifeprex[®] may only be provided by or under the supervision of a physician. When a physician signs the Prescriber's Agreement/ Account Setup Form, he/she is agreeing to the following:

That he or she:

- has the following qualifications:
 - the ability to assess the duration of pregnancy accurately;
 - the ability to diagnose ectopic pregnancies;
 - the ability to provide surgical intervention in the event of an incomplete abortion or severe bleeding or have made plans to provide such care through others;
 - the ability to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary.

That he or she:

- has read and understood the prescribing information of Mifeprex[®];
- will provide each patient with a Medication Guide and give her an opportunity to read and discuss it;
- will provide each patient with the Patient Agreement, give her an opportunity to read and discuss it, obtain her signature, and sign it;
- will fully explain the procedure to each patient;
- understands that the patient's follow-up visit at approximately 14 days is very important to confirm a complete termination of pregnancy and that there have been no complications;
- will notify Danco Laboratories in writing in the event of an on-going pregnancy which is not subsequently terminated;
- will report any hospitalization, transfusion, or other serious event to Danco; and
- will record each Mifeprex[®] package's serial number in the patient's record.

Danco may discontinue distribution of the drug to any provider who does not follow the guidelines enumerated in the Prescriber's Agreement.

Alternative Evidence-Based Regimens

Historically, the FDA has not attempted to regulate a clinician's exercise of medical judgment in prescribing approved drugs for off-label or alternative evidence-based uses. The FDA has recognized that alternative evidence-based use of drugs by clinicians is often appropriate and may represent the standard of practice. The American Medical Association has estimated that 40-60% of prescriptions are for alternative evidence-based uses.

It is important to note that the Danco Prescriber's Agreement for Mifeprex[®] neither explicitly forbids nor endorses alternative evidence-based regimens. It also does not preclude providing information about alternative evidence-based regimens or additional consent forms. In fact, since the Patient Agreement, which the patient and provider must sign at the time of the first office visit, omits information needed for informed consent, such as alternatives to abortion, providers will need to use their own consent forms in addition to the Patient Agreement. Providers employing an alternative evidence-based regimen should use additional consent forms to detail the regimen being used and informed consent requirements not listed in the Patient Agreement.

When a provider breaches established standards of medical care, he or she is at risk for claims of medical malpractice. While alternative evidence-based use of a medication could be a factor in a lawsuit for medical malpractice, as long as it does not violate the standard of care, a provider should not be liable. However, providers should be aware that anti-choice groups exist which specifically target abortion providers for lawsuits. Each provider will need to assess his or her patients' needs, and his or her own level of comfort regarding alternative evidence-based use.

Laws governing abortion, informed consent, and medical malpractice vary widely among states. These materials are intended strictly for informational purposes. They do not constitute legal service, advice, or representation. NAF specifically disclaims any liability incurred as a consequence of reliance upon this information. Please consult an attorney in your area for advice regarding the legal requirements in your state.