

iPLEDGE Allegiance

Jeffrey M. Weinberg, MD

When I first learned the details of the new iPLEDGE™ program, I felt insecure and more fearful of terrorism. Why terrorism you ask? Because at first glance, I thought it might be easier for someone to construct a weapon of mass destruction than for a doctor to actually prescribe isotretinoin under the new iPLEDGE guidelines.

The iPLEDGE prescribers' guide states¹:

Because of isotretinoin's teratogenicity and to minimize fetal exposure, isotretinoin is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE™. Isotretinoin must only be prescribed by prescribers who are registered and activated with the iPLEDGE program. Isotretinoin must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE.

Are you following so far?

The program has specific and strict requirements for patients, pharmacists, prescribers, and wholesalers. The key features of the iPLEDGE program are:

- It tracks and verifies critical program elements that control access to isotretinoin.
- Only prescribers who have activated their registration with and in the iPLEDGE program can prescribe isotretinoin.
- Only patients who are registered by prescribers in the iPLEDGE program can receive isotretinoin.
- Only pharmacies registered with and activated in the iPLEDGE program can dispense isotretinoin.
- Prescribers or their office designee must enter the required information (pregnancy test results, 2 forms of contraception used, and confirmation

of patient counseling) in the iPLEDGE system monthly for patients to receive a prescription.

- Prescribers must document that all patients, and specifically female patients of childbearing potential, meet the requirements in the iPLEDGE program.
- Female patients of childbearing potential must enter required information (2 forms of contraception used, answer questions on program requirements) in the iPLEDGE system to receive a prescription. This is important because now a prescription alone is not enough; if these individuals do not perform this role, they will not receive the drug.
- Pharmacists must access the iPLEDGE system to receive authorization to fill and dispense every isotretinoin prescription.
- Telephone, fax, and electronic transmission (eg, e-mail) prescriptions are permitted in the iPLEDGE program.

At this point, most of you are probably thinking that minocycline and doxycycline are looking better and better or maybe that the dermatologist down the block would love to get all of your isotretinoin referrals. I think these feelings are totally natural. We did not ask for this program, and very few of us are likely to be happy about it. Despite the hassle, we have to remember the lives that have benefited and will continue to benefit from this important drug. The transition to this system will require a great deal of effort, time, and education of office staff, but once we are plugged in, hopefully it will be manageable. High-speed Web access in the office will make the process a lot more palatable. Thankfully, the implementation of the program has been delayed until March 2006.

REFERENCE

1. The iPLEDGE program guide to best practices for isotretinoin. Available at: <http://www.ipledgeprogram.com>. Accessed October 23, 2005.

The author reports no conflict of interest.