

New iPLEDGE Rules: What's Changing for Isotretinoin Rx's

Top Takeaways

- Anticipate upcoming modifications to the iPLEDGE REMS, including the option for home pregnancy testing in certain situations.
- Be aware you'll no longer receive a "Do Not Dispense to Patient After" date for isotretinoin Rx's in patients who cannot get pregnant.
- Continue to follow unchanged rules, such as only filling up to a 30-day supply of isotretinoin per Rx.

You'll see **updates to the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) for isotretinoin Rx's starting November 15, 2026.**

Pharmacies must still get a Risk Management Authorization (RMA) from the iPLEDGE website before dispensing isotretinoin...to verify that prescribers and patients are registered and requirements to prevent pregnancy are met.

But look for some iPLEDGE requirements to be rolled back...to try to ease the burden on patients and clinicians while maintaining safe use.

HOME pregnancy tests will be allowed in certain situations...to help reduce barriers to treatment.

For example, patients who can become pregnant will still be required to get initial pregnancy tests in a medical setting (office, lab, etc) before starting isotretinoin.

But subsequent monthly pregnancy tests may be completed at HOME...if the prescriber allows. Ask your pharmacist about offering these patients home pregnancy tests for purchase...so they have a supply on hand.

Prescription pickup windows will be adjusted...to help avoid delays.

Be aware that patients who can become pregnant will no longer face a 19-day "lockout" if they don't get isotretinoin within the required 7-day dispensing window. Instead, they can repeat a pregnancy test right away.

Also take note that patients who CANNOT become pregnant will no longer be required to get their isotretinoin Rx within 30 days of the prescriber visit. So iPLEDGE will not issue a "Do Not Dispense to Patient After" date on the RMA for these Rx's.

But if an Rx for these patients isn't picked up in your pharmacy's usual timeframe, be sure to reverse the RMA and return the Rx to stock.

Continue to enforce iPLEDGE-specified "Do Not Dispense to Patient After" dates for isotretinoin Rx's in patients who can get pregnant.

Pharmacy requirements will be clarified...to specify that staff training must occur annually. Many pharmacies do this already...but check that training is properly documented to avoid issues in an audit.

Continue to follow other established rules. For example, remember you can only fill up to a 30-day supply of isotretinoin per Rx...Rx's can't be refilled...and isotretinoin can't be loaned or sold among pharmacies.

Review tips to optimize safe use of isotretinoin in our chart, *Pharmacotherapy of Acne*. And see our *Drugs With Prescribing, Dispensing, or REMS Requirements* chart for other drugs with special rules.

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Key References:

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