

Miudella REMS Requirements

How to get certified now so you're ready when Miudella reaches clinics in late 2026



No fixed deadline: certify before your first insertion. You can't order or place Miudella until both you and your practice are certified. REMS enrollment opened August 11, 2026.

What to know

ABOUT MIUDELLA

- **Hormone-free copper IUD:** The first new one approved in the U.S. in over 40 years, joining Paragard as the second copper IUD available.
- **Up to 3 years** of pregnancy prevention. The FDA is reviewing an application to extend that to up to 6 years (decision expected in 2027).
- **Available late 2026:** Distributed to certified healthcare settings and through Organon's specialty pharmacy network.

THE REMS REQUIREMENT

Two REMS certifications are required before Miudella can be dispensed for insertion: one for each individual provider and a separate one for each healthcare setting.

No in-person practical training, unlike the Nexplanon REMS requirements for new or inactive providers.

Common questions

Does my practice need its own certification?

Yes, even if a provider there is already certified. Certified settings may dispense Miudella only to certified providers.

I already place IUDs. Do I still need training?

Yes. Prior IUD experience doesn't exempt you, because Miudella's inserter design and insertion instructions differ from other IUDs.

How to get certified

INDIVIDUAL HEALTHCARE PROVIDERS

- 1 At miudellarems.com, review the [Prescribing Information](#), including the Instructions for Use.
- 2 Register and complete the [Insertion Training Program](#) for Healthcare Providers.
- 3 Complete the Healthcare Provider Knowledge Assessment [online](#), or fax the [completed form](#) to 1-855-781-2610.

HEALTHCARE SETTINGS (PRACTICES, CLINICS)

- 1 Designate an authorized representative to oversee REMS certification and compliance.
- 2 The representative [registers](#), reviews the [Healthcare Setting Guide](#), and submits the Enrollment Form online or by [fax](#) to 1-855-781-2610.
- 3 Train all staff involved in dispensing Miudella on the REMS requirements.



Questions about the Miudella REMS?

1-855-337-0772

Miudella REMS Coordinating Center · miudellarems.com

Links, forms, and more at
providers.bedsider.org

Read the full article

