

Why NEXPLANON has a REMS

NEXPLANON is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS). Improper insertion and removal increases the risk of complications. Proper training prior to first use can minimize this risk.

Note: There is no patient enrollment or patient tracking associated with the NEXPLANON REMS Program.

Healthcare Provider (HCP) Certification — All Providers Complete Steps 1–4

Before you start, have ready:

- ✓ **NPI number**
- ✓ **State license number**
- ✓ **First name and last name**
- ✓ **Personal email address**
— avoid work email (may block
REMS communications)

To create an account, start at:

NEXPLANONREMS.com/healthcareproviders

1. Create Your Account

- Go to NEXPLANONREMS.com/healthcareproviders
- Enter NPI, state license number, name, and contact info
- Check email for a link to create your password and log in
- Authenticate with a security code sent by email or text

- Must pass to advance
- If locked after failed attempts, call 1-833-NXP-REMS to unlock
- **Two confirmation emails sent immediately upon passing**

2. Review Required Materials (Mandatory)

- Prescribing Information (PI), including Instructions for Use
- Healthcare Provider Guide (2-page REMS summary)
- **Both must be reviewed before proceeding to the Knowledge Assessment**

4. Submit the Healthcare Provider Enrollment Form

- Confirm provider and practice details
- Answer training history questions—your answers determine which track below applies to you
- Submit form to complete this phase of enrollment
- **Allow 48–72 hours for your dashboard to reflect certification status**

3. Complete the Knowledge Assessment

- 7 questions based on the reviewed materials

TRACK A

Previously Trained and Active

You qualify for Track A if you have completed the Clinical Training Program (CTP) AND have inserted or removed NEXPLANON within the last 3 years.

- ✓ **Certification is complete after Step 4.**

No additional training is required. Your provider dashboard will confirm full certification status within 48–72 hours of submitting your Enrollment Form.

TRACK B

New, Inactive, or Incomplete Training

You qualify for Track B if you have never been trained or have not inserted or removed NEXPLANON in the last 3 years.

A Clinical Training Program (CTP) will be assigned after Step 4.

1 Training Step 1 of 2: Online Didactic Module

Assigned automatically after Enrollment Form submission
Link sent via email; must be completed 3–4 days before live session

- **Reminders sent at 15, 10, and 5 days before your scheduled session**

2 Training Step 2 of 2: In-Person Practical Training

Scheduled with an Organon Clinical Account Specialist (CAS)
Covers proper insertion and removal technique
Competency checklist completed at the session

- **Full certification confirmed upon successful completion of both training steps**

NON-COMPLIANCE CRITERIA

- Loaned or sold NEXPLANON to any person or entity
- Failed to report IRRs immediately to Organon
- Transferred NEXPLANON to any non-certified stakeholder
- Refused or failed to cooperate with a REMS audit

ADVERSE EVENT/IRRE REPORTING:

- **Report IRRs immediately via form at NEXPLANONREMS.com or call 1-833-NXP-REMS**

Pharmacy Enrollment: Who Needs to Certify?



SPECIALTY PHARMACIES

Specialty pharmacies within Organon's existing network must be certified with the NEXPLANON REMS to dispense.

See enrollment steps



INPATIENT & IDN PHARMACIES

No action required. Pharmacy requirements apply only to Organon's limited distribution specialty pharmacy network.

ENROLLMENT STEPS

1. Designate an Authorized Representative

- May be: Pharmacist-in-Charge or designated pharmacy staff
- Oversees certification and ongoing REMS compliance for the pharmacy

2. Review the Pharmacy REMS Guide

- Available at NEXPLANONREMS.com prior to enrollment)

3. Submit the Pharmacy Enrollment Form

- Complete and submit at NEXPLANONREMS.com
- Provide pharmacy NPI, address, and authorized contact details
- **Certified pharmacies may only dispense NEXPLANON to certified HCPs**

4. Train Relevant Staff

- All staff involved in dispensing must be trained on REMS requirements
- Maintain training records for REMS audit readiness

5. Establish Verification Procedures

- Verify the inserting HCP is certified before every dispense
- Monitor for 3-year HCP inactivity—recertification required before dispensing
- **Confirm HCP certification status at each transaction**

6. Before Each Dispense

- Confirm the HCP is currently certified in the NEXPLANON REMS
- Document the transaction per REMS data reporting requirements
- Dispense records reported to REMS administrator via daily data feed
- **Dispensing to a non-certified HCP is a critical noncompliance event**

ONCE CERTIFIED: PHARMACY PORTAL

- Verify HCP certification status before every dispense
- Manage dispensing records and REMS data submissions
- View certification status for all associated HCPs
- Manage staff accounts and dispensing authorization
- Request HCP recertification after 3-year inactivity

RECERTIFICATION: 3-YEAR INACTIVITY RULE

If an affiliated HCP has not inserted or removed NEXPLANON in 3 years, the pharmacy must not dispense to that provider until recertification is complete:

- Identify lapsed HCPs via the pharmacy portal
- Request recertification before the next dispense

NON-COMPLIANCE: SPECIALTY PHARMACY

- Dispensed NEXPLANON to a non-certified HCP
- Dispensed to an HCP who did not recertify after 3-year inactivity
- Distributed NEXPLANON outside REMS-certified channels
- Failed to submit required dispense data to REMS administrator
- Failed to comply with REMS audit requirements

Enroll Now NEXPLANONREMS.com
1-833-NXP-REMS (1-833-697-7367)

