

This **Pharmacy Guide** describes the responsibilities of pharmacists and authorized representatives in the NEXPLANON REMS.

## What Is the NEXPLANON REMS?

The NEXPLANON **Risk Evaluation and Mitigation Strategy** (REMS) is required by the U.S. Food and Drug Administration (FDA) to ensure the benefits of NEXPLANON outweigh its risk of complications due to improper insertion and removal.

## How Does a Pharmacy Become Certified?

Note: Only pharmacies certified in the NEXPLANON REMS can dispense NEXPLANON.

A pharmacy must first designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.

### The authorized representative must:

- Review this **Pharmacy Guide**.
- Enroll in the REMS by completing and submitting the **Pharmacy Enrollment Form** to the REMS by fax at 1-833-430-2807.
- Train all relevant staff involved in dispensing NEXPLANON on the REMS requirements.
- Establish processes and procedures to verify that NEXPLANON is dispensed only to certified healthcare providers.

## What Are the Responsibilities of Pharmacy Staff?

### Before dispensing, all pharmacy staff must:

- Verify that NEXPLANON is dispensed only to certified healthcare providers through the processes and procedures established as a requirement of the REMS.

### At all times, my pharmacy must:

- Not distribute, transfer, loan, or sell NEXPLANON except to certified pharmacies.
- Maintain records of staff training and of all processes and procedures including compliance with those processes and procedures.
- Comply with audits carried out by Organon or a third party acting on behalf of Organon to ensure that REMS processes and procedures are in place and are being followed.

### To maintain certification to dispense, any new authorized representative must:

- Enroll by completing and submitting the **Pharmacy Enrollment Form** to the REMS.

**For more information, please visit [www.NEXPLANONREMS.com](http://www.NEXPLANONREMS.com) or contact the NEXPLANON REMS Coordinating Center at 1-833-NXP-REMS (1-833-697-7367).**

**You are encouraged to report all adverse events of NEXPLANON to Organon at 1-844-674-3200 or the FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

**To review complete safety information about NEXPLANON, please refer to the Prescribing Information at [www.NEXPLANONREMS.com](http://www.NEXPLANONREMS.com)**