

Communication from: The TIRF REMS Access Program

The TIRF REMS Access Program, now called the TIRF REMS, has been modified and the requirements of the program have changed. You will need to take action in order to continue dispensing TIRF medicines.

Beginning March 29, 2021, you will need to re-certify in order to continue dispensing TIRF medicines if you remain as a qualified dispenser.

Key Modifications:

Only pharmacies certified in the modified TIRF REMS, effective March 29, 2021, will be able to dispense TIRF medicines to patients.

- All pharmacies will be required to obtain an authorization to dispense from the TIRF REMS, either online or over the phone, for every TIRF medicine prescription.
- As of March 29, 2021, pharmacies that are not certified in the TIRF REMS will not be able to dispense TIRF medicines and will be required to return all currently stocked TIRF products to the distributor or manufacturer.
- TIRF medicines can only be obtained from qualified wholesalers/distributors that are enrolled in the TIRF REMS.

Starting March 29, 2021, you may only fill prescriptions when:

1. Your pharmacy has re-certified in the modified TIRF REMS,
2. You obtain stock of TIRF medicines from a qualified and enrolled wholesaler-distributor, and
3. You obtain a TIRF REMS dispense authorization issued by the TIRF REMS prior to dispensing a prescription for a TIRF medicine.

What must a pharmacy do to participate in the modified TIRF REMS?

Beginning March 29, 2021, all current pharmacies must re-certify in the modified program.

The pharmacy must designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. To re-certify the pharmacy, the authorized representative must review the modified **Education Program**, successfully complete the **Knowledge Assessment**, and complete the **Outpatient Pharmacy Enrollment Form** through the TIRF REMS website, or complete and fax the signed **Knowledge Assessment** and enrollment form to the TIRF REMS.

Beginning March 29, 2021, go to www.TIRFREMSAccess.com to re-enroll and become certified online. You can also find all the materials you need to download and fax to the TIRF REMS to become certified on this website.

Pharmacies must re-certify prior to dispensing a TIRF medicine.

Pharmacies must complete and submit an **Outpatient Pharmacy Enrollment Form** before dispensing a TIRF medicine.

Pharmacies must check the Patient's Opioid Tolerance.

Before obtaining a dispense authorization, the pharmacy must check the patient's opioid tolerance. This could include reviewing data from various sources; for example:

- available state Prescription Drug Monitoring Programs (PDMPs),
- the patient's records in the pharmacy's management system, and
- information provided by the TIRF REMS.

Talk to Patients who are Not Opioid-tolerant.

- Tell patients who are not opioid-tolerant to work with their doctors to transition off their TIRF medicine.

What if the Pharmacy does not re-certify in the modified TIRF REMS?

- The pharmacy will not be able to dispense TIRF medicines and will be required to return all currently stocked TIRF products to the distributor or manufacturer.
- You may need to assist patients in finding a pharmacy certified in the TIRF REMS.

Beginning March 29, 2021, updated materials can be found at www.TIRFREMSAccess.com