

<Date>

Changes to Requirements of the TIRF REMS

- Subject:**
- Current outpatient pharmacies must re-certify in TIRF REMS
 - Currently stocked TIRF medicines must be returned if you do not re-certify
 - Program changes effective (DATE).

Dear Outpatient Pharmacy:

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.

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 <DATE>, will be able to dispense TIRF medicines to patients.

- All pharmacies will be required to obtain an authorization to dispense from the TIRF REMS, online or over the phone, for every prescription for a TIRF medicine.
- As of <DATE>, 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 (DATE), 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 wholesale 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 I do to participate in the modified TIRF REMS?

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.

The TIRF REMS: Dear Outpatient Pharmacy Letter re: Modification

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.

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 of 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 by (date).
- You may need to assist patients in finding a pharmacy certified in the TIRF REMS.

All materials can be found at www.TIRFREMSAccess.com

For additional information related to the TIRF REMS and recent program modifications, please call **1-866-822-1483**.

Sincerely,

TIRF REMS