

<Date>

Changes to Requirements of the TIRF REMS

- Subject:**
- Program changes effective (DATE)
 - Current prescribers must re-enroll in TIRF REMS
 - Prescribers must document that patients are opioid-tolerant
 - Patients who are not opioid-tolerant must be transitioned to alternate therapy

Dear Healthcare Provider:

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 within the TIRF REMS system in order to continue to prescribe TIRF medicines.

You will need to re-certify in order to continue dispensing TIRF medicines. Only patients who are opioid-tolerant (see definition below) will be able to receive a TIRF medicine.

Key Modifications:

Only prescribers enrolled and certified in the modified TIRF REMS, effective <DATE>, will be able to prescribe TIRF medicines for outpatient use.

- The prescriber must document and provide verification of the patient's opioid tolerance, per the product labeling, to the TIRF REMS prior to each prescription being authorized for dispense at an outpatient pharmacy every time a TIRF medicine is prescribed.
- As of <DATE>, patients who are not opioid-tolerant will not be able to obtain a TIRF medicine; they must be transitioned off of their TIRF medicine, and to an alternate therapy if appropriate.
- All patients in the outpatient setting must be enrolled into the new TIRF REMS registry to assess safe use and trends in accidental exposure, misuse, abuse, addiction, and overdose.

Starting (DATE), prescriptions will only be filled when:

1. The prescriber is enrolled in the new TIRF REMS,
2. The patient has been enrolled in the new TIRF REMS, and
3. The patient's opioid tolerance has been documented.

What must I do to participate in the modified TIRF REMS?

All current prescribers must re-enroll and re-certify into the modified program

Prescribers must review the modified **Prescriber Education**, complete the **Knowledge Assessment** and sign the **Prescriber Enrollment Form**.

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.

Prescribers must enroll all OUTPATIENTS prior to prescribing a TIRF medicine

Products covered under the TIRF REMS include: ACTIQ® (fentanyl citrate) oral transmucosal lozenge • FENTORA® (fentanyl citrate) buccal tablet • Lazanda® (fentanyl) nasal spray • Onsolis® (fentanyl buccal soluble film) • Subsys™ (fentanyl sublingual spray) • Approved generic equivalents of these products

All outpatients must be enrolled, including those currently receiving a TIRF medicine, starting on <Date>.

Prescribers must complete and submit a **Patient Enrollment Form** before prescribing a TIRF medicine for every patient in an outpatient setting. This will automatically enroll the patient into the TIRF REMS registry.

Prescribers must document Patient's Opioid Tolerance per the labeling definition

Patients are considered opioid-tolerant if they are currently taking (exclusive of the TIRF medicine) one or more of the following opioid regimens daily and they have been on the regimen(s) for one week or longer:

- ≥ 60 mg oral morphine/day
- ≥ 30 mg oral oxycodone/day
- ≥ 25 mg oral oxymorphone/day
- an equianalgesic dose of another opioid
- ≥ 25 mcg transdermal fentanyl/hour
- ≥ 8 mg oral hydromorphone/day
- ≥ 60 mg oral hydrocodone/day

What if my patient is not opioid-tolerant?

You must transition a patient who is not opioid-tolerant from a TIRF medicine to another treatment if needed.

Under the modified program as of <DATE>, the patient will no longer be able to receive a TIRF medicine at the pharmacy.

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