

## The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program

An Overview for Inpatient Pharmacies (e.g. hospitals, in-hospital hospices, and long-term care facilities that dispense for inpatient use).

To dispense TIRF medicines, your Inpatient Pharmacy must enroll in the TIRF REMS Access program.

What is the TIRF REMS Access Program?

The TIRF REMS (Risk Evaluation and Mitigation Strategy) Access program is designed to ensure informed risk-benefit decisions before initiating treatment and, while patients are on treatment, to ensure appropriate use of TIRF medicines. TIRF medicines are available only through a restricted distribution program required by the Food and Drug Administration (FDA), because of the risk for misuse, abuse, addiction, overdose, and serious complications due to medication errors. A list of TIRF medicines available through the TIRF REMS Access program is located on the TIRF Products web page at [www.TIRFREMSaccess.com/TirfUI/rems/products.action](http://www.TIRFREMSaccess.com/TirfUI/rems/products.action).

How does the TIRF REMS Access program work?

The TIRF REMS Access program requires pharmacies, prescribers, patients and wholesalers to enroll in the program in order to utilize TIRF medications. The supply of TIRF medicines to pharmacies is controlled by enrolled distributors, who will verify the current enrollment status of the pharmacy prior to shipment of TIRF medicines. Pharmacies are required to verify the prescriber and the patient are enrolled in the TIRF REMS Access program before dispensing any TIRF medication.

Does your pharmacy qualify as an Inpatient Pharmacy?

For the purposes of this REMS, an inpatient pharmacy is defined as a pharmacy **where the patient's care is coordinated on-site** at a care facility and the pharmacy claims are submitted as a medical benefit.

### *Important Information about Outpatient Pharmacies within the Facility*

Outpatient pharmacies, within or associated with the healthcare facility, that provide dispensing services to outpatients must be separately enrolled in the TIRF REMS Access program and comply with the TIRF REMS Access program to dispense TIRF medicines to outpatients. **Please refer to "An Overview for Outpatient Pharmacies" for more information.** Additionally, any prescribers who prescribe TIRF medicines to outpatients must also be enrolled in the TIRF REMS Access program.

Overview of the TIRF REMS Access Program for Inpatient Pharmacies: Steps for Enrollment and Program Requirements

Inpatient Pharmacy Education and Enrollment

All enrollment activities can be completed at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)

## The TIRF REMS Access Program: An Overview for Inpatient Pharmacies

If I have previously enrolled in an individual TIRF REMS do I need to enroll in the shared TIRF REMS Access Program?

All pharmacy enrollment information was transferred from the individual TIRF REMS to the TIRF REMS Access program on March 12, 2012. Your enrollment in the shared TIRF REMS Access program allows dispensing of all TIRF medicines that are covered under the TIRF REMS Access program. The website for the shared TIRF REMS Access program can be accessed at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com).

You will be required to re-enroll in the shared TIRF REMS two (2) years after your last enrollment in an individual REMS program if you wish to continue dispensing these products. You will be notified by the TIRF REMS Access program in advance of the need to re-enroll.

The following two sections provide detailed information on the Enrollment Process (Section 1) and the Implementation Processes (Section 2) for TIRF medicines in an inpatient pharmacy.

### Section 1: Enrollment Process

#### Summary of Enrollment

1. Select an individual to be your Authorized Inpatient Pharmacy Representative.
2. Create an account and complete registration at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com).
3. Complete the TIRF REMS Access Education Program and Knowledge Assessment.
4. Complete and submit an Inpatient Pharmacy Enrollment form.
5. Train pharmacy staff.

#### Detailed Enrollment Process

Step 1: Select an individual to be your Authorized Chain Representative

- Select an authorized pharmacy representative to establish and oversee the TIRF REMS Access program requirements.

Step 2: Create an account and complete registration at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)

- Create an account at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) and then complete registration on behalf of your pharmacy.

How do I create an account and complete the TIRF REMS Access registration on-line?

- Select the Create Account button on the home page
- Complete the Create Account Information section
- **Select 'No' if you have not submitted an enrollment form via fax at the 'Already enrolled via Fax and have an enrollment ID?' prompt.**
- Create User ID and password and select 'Create My Account'

## The TIRF REMS Access Program: An Overview for Inpatient Pharmacies

- Select 'Pharmacy' as the option to best describe you and select 'Continue'
- Select 'Inpatient Pharmacy – Authorized Pharmacy Representative'
- Review the content in the pop-up box and select 'Confirm' to continue
- Complete required fields on the Inpatient Pharmacy Registration page and select 'Submit' to continue

### Step 3: Complete the TIRF REMS Access Education Program and Knowledge Assessment

How do I complete the TIRF REMS Access Education Program by fax?

- Review the TIRF REMS Access Education Program. A printable version of the TIRF REMS Access Education Program is available online at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) or by contacting the TIRF REMS Access call center at 1-866-822-1483.
- Once you have reviewed the Education Program complete the Knowledge Assessment and submit by fax to 1-866-822-1487
- The TIRF REMS Access program will notify you of the status of your Knowledge Assessment via your indicated preferred method of communication (fax or e-mail)

How do I complete the TIRF REMS Access Education Program online?

- Select the 'Start the TIRF REMS Access Education Program' to proceed to the training upon completion of registration
- Select 'Go To Knowledge Assessment' button and complete upon completion of the Education Program
- A Knowledge Assessment Confirmation Code will be provided once the assessment is completed successfully.

### Step 4: Complete and submit Inpatient Pharmacy Enrollment

- To finalize enrollment in the TIRF REMS Access program complete Inpatient Pharmacy Enrollment
- If you are unable to enroll online, please call the TIRF REMS Access program call center at 1-866-822-1483 for further assistance.

How do I complete the TIRF REMS Access Enrollment on-line?

- Upon successful completion of the TIRF REMS Access Education Program and Knowledge Assessment, you will be prompted to read the TIRF REMS Access **attestation and enter your electronic signature, today's date, and check the attestation box before clicking 'Submit'.**

NOTE: You are required to re-enroll every two (2) years. You will be notified by the TIRF REMS Access program in advance of the need to re-enroll.

## Section 2: Implementation Process

### Summary of Implementation Process

1. Ensure appropriate patient selection and compliance with TIRF REMS Access program requirements
2. Train Pharmacy Staff

### Detailed Implementation Process

#### Step 1: Ensure appropriate patient selection and compliance with TIRF REMS Access program requirements

- The authorized inpatient pharmacist must establish or oversee the system, order sets, protocols, and/or other measures to help ensure appropriate patient selection and compliance with the requirements of the TIRF REMS Access program.
- The authorized inpatient pharmacist must ensure the inpatient pharmacy does not sell, loan or transfer any TIRF medicines to any other pharmacy, institution, distributor, or prescriber.
- Inpatient pharmacies may not dispense TIRF medicines for outpatient use.

#### Step 2: Train Pharmacy Staff

- The authorized inpatient pharmacist must ensure that inpatient pharmacists and other relevant inpatient staff are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the Education Program.
  - Pharmacy staff can register online to access the Education Program and take the Knowledge Assessment for training purposes.

### Reporting Adverse Events and Monitoring

To report any adverse events including the misuse, abuse, addiction, or overdose of TIRF medication contact:

- TIRF REMS Access program at 1-866-822-1483 and/or
- FDA MedWatch program by phone at 1-800-FDA-1088 or online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

If you have any questions, need additional information, or need additional copies of any TIRF REMS Access documents, please visit [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com), or call the TIRF REMS Access program at 1-866-822-1483.