

The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program

An Overview for Prescribers

To prescribe TIRF medicines for outpatient use, Prescribers 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.

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.

NOTE: There are different requirements for inpatient prescribers that only prescribe TIRF medicines for inpatient use. For inpatient administration (e.g. hospitals, in-hospital hospices, and long-term care facilities that prescribe for inpatient use), of TIRF medicines, patient and prescriber enrollment in the TIRF REMS Access program is not required. Only the inpatient pharmacy and distributors are required to be enrolled to be able to order and dispense TIRF medicines for inpatient use. Inpatient pharmacies may not dispense TIRF medicines for outpatient use.

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Overview of the TIRF REMS Access Program for Prescribing to Outpatients:
Steps for Enrollment and Program Requirements

Prescriber Education & Enrollment (Outpatient Use)

All enrollment activities can be completed at www.TIRFREMSaccess.com

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

All prescriber enrollment information was transferred from the individual TIRF REMS to the TIRF REMS Access program on March 12, 2012.

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 three sections provide detailed information on the Enrollment Process (Section 1), the Patient Program Requirements (Section 2), and the Prescribing Process (Section 3) for outpatient prescribing of TIRF medicines.

Section 1: Enrollment Process

Summary of Enrollment Process

1. Create an account and complete registration at www.TIRFREMSaccess.com.
2. Complete the TIRF REMS Access Education Program and Knowledge Assessment.
3. Complete and submit a Prescriber Enrollment form.

Detailed Enrollment Process

Step 1: Create an account and complete registration at www.TIRFREMSaccess.com

- Create an account and complete registration at www.TIRFREMSaccess.com.

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

- **Select the 'Create My 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?' question
- Create User ID and Password and select 'Create My Account'
- Select 'Prescriber' as the option to best describe you and select 'Continue'

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- Complete required fields on the Prescriber Registration page and select **'Submit' to continue**
- **Complete required fields in the 'Site Information' section by adding your site and select 'Submit'**

Step 2: 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 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'**, complete the Knowledge Assessment, **and select 'Submit Assessment'**
- A Knowledge Assessment Confirmation Code will be provided once the assessment is completed successfully
- **Select 'Complete Enrollment' to continue**

Step 3: Complete and submit Prescriber Enrollment

- To finalize enrollment in the TIRF REMS Access program complete Prescriber 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 review the demographic information previously submitted, 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: Patient Program Requirements

Summary of Patient Program Requirements

1. Identify appropriate patients
2. Counsel patients
3. Complete and submit the TIRF REMS Access Program Patient-Prescriber Agreement Form

Detailed Patient Program Requirements Process

Step 1: I identify appropriate patients

- Identify appropriate patients based on the guidance provided in the TIRF REMS Access Education Program and the product-specific Full Prescribing Information. Full Prescribing Information is available on-line at www.TIRFREMSaccess.com or by contacting the TIRF REMS Access call center at 1-866-822-1483.

Step 2: Counsel Patients

- Counsel the patient about the benefits and risks of TIRF medicines and together review the appropriate product-specific Medication Guide. A Patient and Caregiver Overview is available online at www.TIRFREMSaccess.com or by contacting the TIRF REMS Access call center at 1-866-822-1483.

Step 3: Complete and submit the TIRF REMS Access Patient-Prescriber Agreement Form

- Complete the TIRF REMS Access Program Patient-Prescriber Agreement Form, for each new patient, which must be signed by both you and your patient (not required for inpatients).

NOTE: A prescriber must be enrolled in the TIRF REMS Access program to submit a Patient-Prescriber Agreement Form for a patient.

How do I complete the TIRF REMS Access Patient-Prescriber Agreement Form by fax?

- Obtain a TIRF REMS Access Patient-Prescriber Agreement Form. A printable version of the Patient-Prescriber Agreement Form is available on-line at www.TIRFREMSaccess.com or by contacting the TIRF REMS Access call center at 1-866-822-1483.
- Review the TIRF REMS Access Patient-Prescriber Agreement Form with your patient.
- Complete Prescriber required fields.
- Have the patient or caregiver complete the patient required fields.
- Submit Patient-Prescriber Agreement Form by fax to 1-866-822-1487.

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How do I complete the TIRF REMS Access Patient-Prescriber Agreement Form online?

- Log in to the TIRF REMS Access program from the home page by entering in your User ID and Password
- **Select the heading labeled 'My Account'**
- **Select the 'PPAF' link**
- Review the TIRF REMS Access Patient-Prescriber Agreement Form
- **Enter your electronic signature, today's date, and check the attestation box**
- Enter the required patient information
- **Have the patient enter their electronic signature, today's date, and check the attestation box**
 - (NOTE: If applicable, a Patient Representative can enter in their information in the required section on behalf of the patient)
- **Print off two copies of the form by selecting the 'Print' button**
- Provide one copy to the patient and keep one for your records
- **Select the 'Submit' button to submit the PPAF for the patient**
- **You can print the confirmation by selecting the 'Print Confirmation' button**

Section 3: Summary of Prescribing Process

1. Write TIRF medicine prescription.
2. Help patient find an enrolled pharmacy.

Detailed Prescribing Process

Step 1: Write TIRF medicine prescription

- Write a prescription for the appropriate TIRF medicine.

Step 2: Help patient find an enrolled pharmacy

- Help each patient find pharmacies which are enrolled in the TIRF REMS Access program. A list of enrolled pharmacies can be found on www.TIRFREMSaccess.com, or by calling 1-866-822-1483.
- Inform patients that they can also find a participating pharmacy by calling the TIRF REMS Access program at 1-866-822-1483.

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

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- FDA MedWatch program by phone at 1-800-FDA-1088 or online at 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, or call the TIRF REMS Access program at 1-866-822-1483.