

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

## An Overview for Independent Outpatient Pharmacies

**To dispense TIRF medicines, your Independent Outpatient 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/ProductList](http://www.TIRFREMSaccess.com/TirfUI/ProductList).

### **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 Independent Outpatient Pharmacy?**

For the purposes of this REMS, an independent outpatient pharmacy is defined as an outpatient pharmacy such as a retail, mail or institutional outpatient pharmacy having an authorized pharmacy representative that is responsible for ensuring enrollment and training of the pharmacy staff within an individual outpatient pharmacy. Each store will individually enroll in TIRF REMS Access as a single pharmacy location. Additionally, to qualify as an independent outpatient pharmacy, your pharmacy must use a pharmacy management system to electronically transmit the required validation and claim information to the TIRF REMS Access program using established telecommunication standards.

**NOTE:** There are different requirements for inpatient pharmacies that only dispense for inpatient use. Please refer to "An Overview for Inpatient Pharmacies" for more information.

## **Options and Requirements for the TIRF REMS Access Program for Independent Outpatient Pharmacies**

### **Pharmacy Education, Enrollment & Pharmacy Management Systems**

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

## **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. If the authorized pharmacist or pharmacy representative logged onto the TIRF REMS Access program website and agreed to the shared program terms and conditions before September 12, 2012, your pharmacy is able to order and dispense all TIRF medications. If the authorized pharmacist or pharmacy representative has not agreed to the shared terms and conditions, your pharmacy will need to enroll in the TIRF REMS Access program (see how to enroll below).

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 Dispensing Process ([Section 2](#)) for TIRF medicines in an independent outpatient pharmacy.

## **Section 1: Enrollment Process**

### **Summary of Enrollment:**

1. Select an individual to be your Authorized Independent Outpatient 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 Independent Outpatient Pharmacy Enrollment form.
5. Enable the pharmacy management system to support communication with the TIRF REMS Access system.
6. 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'
- Select 'Pharmacy' as the option to best describe you and select 'Continue'
- Select 'Independent Outpatient Authorized Pharmacist'
- Review the content in the pop-up box and select 'Confirm' to continue
- Complete required fields on the Independent Outpatient 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', complete the Knowledge Assessment, and select 'Submit Assessment'
- A Knowledge Assessment Confirmation Code will be provided once the assessment is completed successfully

### **Step 4: Complete and submit Independent Outpatient Pharmacy Enrollment**

- To finalize enrollment in the TIRF REMS Access program complete Independent Outpatient 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.

### **Step 5: Confirm the Pharmacy Management System supports communication with the TIRF REMS Access system**

- Following completion of steps 1-4 above, you will receive instruction on how to submit test transactions to the TIRF REMS Access program. Successful submission of the test transaction confirms the pharmacy management system supports communication with the TIRF REMS Access system.
- After successful completion of the test transactions you will receive enrollment confirmation.

### **Step 6: Train Pharmacy Staff**

- Ensure that all pharmacy staff involved in the processing and dispensing of TIRF medicines have been trained to only dispense TIRF medicines in accordance with the TIRF REMS Access program requirements.
  - Pharmacy staff can register online to access the Education Program and take the Knowledge Assessment for training purposes.
- Ensure that this training is documented and retained by the pharmacy. This documentation should include the pharmacist/pharmacy staff member's name, the date training was completed and the method of training as a minimum.

## **Section 2: Dispensing Process**

### **Summary of Dispensing Process**

1. Confirm pharmacy staff is trained.
2. Confirm patient and prescriber enrollment in TIRF REMS Access Program.
3. Dispense TIRF medication.
4. Counsel patient and provide medication guide.

### **Detailed Dispensing Process**

#### **Step 1: Confirm that the Pharmacy staff is trained**

- Ensure all pharmacy staff involved in the processing and dispensing of TIRF medicines have been trained to specifically dispense TIRF medicines in accordance with the TIRF REMS Access program requirements available at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com). (see [Section 1, Step 6 : Train Pharmacy Staff](#)).

## **Step 2: Confirm prescriber and patient enrollment**

- Each pharmacy site must confirm that the prescriber and patient are enrolled in the TIRF REMS Access program prior to dispensing each TIRF prescription by submitting a pharmacy billing claim via the chain pharmacy practice management system. This includes third party insurance claims, cash claims and any other claims (i.e.: workers compensation). Submitting a claim for a patient's first TIRF prescription through the pharmacy management system will automatically enroll that patient in the TIRF REMS Access program.
- To allow the TIRF REMS Access program to confirm prescriber and patient enrollment the pharmacy practice management system must populate the following fields in the pharmacy billing claim\*:
  - Patient First Name,
  - Patient Last Name,
  - Patient Date of Birth,
  - Patient ZIP / Postal Zone,
  - Quantity Dispensed,
  - Days Supply,
  - Prescriber ID,
  - Prescriber Last Name

\*Use BIN 014780 for all cash and non-third party claims.
- If the prescriber or patient enrollment is not confirmed, or if any other rejection message is received that prevents the prescription from being filled, contact the TIRF REMS Access call center at **1-866-822-1483** for further instruction.

## **Step 3: Dispense TIRF Medication**

- Receive approval from the TIRF REMS Access program and then prepare, label and dispense the medication.

## **Step 4: Counsel Patient and Provide Medication Guide**

- Advise the patient on how to take, store and dispose of TIRF medicine appropriately.
- Provide a copy of the product specific Medication Guide to the patient with each prescription.

## **Reporting Adverse Events and Monitoring**

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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.**