

The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program

An Overview for Closed System Outpatient Pharmacies

To dispense TIRF medicines, your Closed System 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, while patients are on treatment, and to ensure appropriate use of TIRF medicines. TIRF medicines are available only through a required Food and Drug Administration (FDA) restricted distribution program, 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.

Does your institution qualify as a Closed System Outpatient Pharmacy?

For the purposes of this REMS, a closed system outpatient pharmacy is defined as an outpatient pharmacy that uses a pharmacy management system that does not support the process of electronically transmitting the validation and claim information currently required by the TIRF REMS Access program. For example, some pharmacies that are part of integrated healthcare delivery systems may qualify as closed system outpatient pharmacies.

NOTE: There are different requirements for outpatient pharmacies that support the process of electronically transmitting claim information, and for inpatient pharmacies that only dispense for inpatient use. Please refer to **"An Overview for Chain Outpatient Pharmacies"**, **"An Overview for Independent Outpatient Pharmacies"** or **"An Overview for Inpatient Pharmacies"** for more information. If you do not qualify as a closed system outpatient pharmacy, please refer to the requirements for the other type of pharmacies.

The following two sections provide detailed information on the Enrollment Process (Section 1) and the Dispensing Processes (Section 2) for TIRF medicines in a closed system outpatient pharmacy.

Section 1: Enrollment Process

Summary of Enrollment Process

1. Confirm that your facility qualifies as a closed system outpatient pharmacy.
2. Select an individual to be your Authorized Closed System Outpatient Pharmacy Representative.
3. Complete the TIRF REMS Access Education Program and Knowledge Assessment.
4. Complete and submit a Closed System Outpatient Pharmacy Enrollment Form.
5. Train pharmacy staff.

Detailed Enrollment Process

Step 1: Confirm your facility qualifies as a Closed System Outpatient Pharmacy

- Notify the TIRF REMS Access program by phone at 1-866-822-1483 or by email to information@TIRFREMSaccess.com that you are a closed system outpatient pharmacy.
- When your pharmacy is validated as a closed system outpatient pharmacy, a Closed System Outpatient Pharmacy Enrollment Form will be provided.

Step 2: Select an individual to be your Authorized Closed System Outpatient Pharmacy Representative

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

Step 3: Complete the TIRF REMS Access Education Program

- Review the TIRF REMS Access Education Program and successfully complete the Knowledge Assessment. The TIRF REMS Access Education Program is available online at the TIRF REMS Access program website www.TIRFREMSaccess.com or by contacting the TIRF REMS Access call center at 1-866-822-1483.
- If Knowledge Assessment was completed on paper, Fax to 1-855-474-3062 or email the Knowledge Assessment to information@TIRFREMSaccess.com with enrollment form (see Step 4: Complete and submit enrollment form).

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

- Select the Create Account button on the home page
- Complete the Create Account Information section
- **'Already enrolled via Fax and have an enrollment ID?' - Select No**
- Create User ID and password and select the Create my Account button
- **Select 'Pharmacy' as the option to best describe you and select 'Continue'**
- **In response to Question 2, select 'Pharmacy Staff'**
- Review the content in the pop-up box and select **'Confirm'** to continue

The TIRF REMS Access Program: An Overview for Closed System Outpatient Pharmacies

- Complete required fields in Pharmacy Staff details
- Select **'Other'** from the dropdown list in the Chain Pharmacy name and populate the name of your closed system outpatient pharmacy organization in the **'Other'** field and submit form
- Select the **'Start the TIRF REMS Access Education Program'** to proceed to the training
- Once you have completed the Education Program, select the **'Go To Knowledge Assessment'** button and complete
- A Knowledge Assessment Confirmation Code will be provided once the assessment is completed successfully

Step 4: Complete and Submit Enrollment Form

- Complete and return the Closed System Outpatient Pharmacy Enrollment Form by fax to 1-855-474-3062. The authorized closed system outpatient pharmacy representative will receive an Enrollment Confirmation letter and instructions for enrolling dispensing locations within the closed system outpatient pharmacy by using a standard file template provided by the TIRF REMS Access program.
- If you did not complete the Education Program online then you need to submit the Knowledge Assessment form with the Enrollment form.
- 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: Train Pharmacy Staff

- All closed system outpatient pharmacy staff involved in processing and dispensing of TIRF medications must be trained to dispense TIRF medicines in accordance with the TIRF REMS Access Education Program requirements available at www.TIRFREMSaccess.com.
- Ensure that this training is documented and retained by the closed system outpatient 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. (see Section 1, Step 5: Train pharmacy staff).

Step 2: Confirm prescriber and patient enrollment:

Prior to dispensing each TIRF medicine prescription, confirm that the prescriber and patient are enrolled in the TIRF REMS Access program by contacting the TIRF REMS Access program by phone at 1-866-822-1483 or fax at 1-855-474-3062. This includes third party insurance claims, cash claims and any other claims (i.e., workers compensation).

- To confirm enrollment confirmation by phone:
 - Contact the TIRF REMS Access program at 1-866-822-1483 and select option # 2.
 - Provide the following required data from the TIRF prescription to obtain an authorization to dispense:

Dispensing Pharmacy DEA	Patient Date of Birth	Rx Date of Service
Dispensing Pharmacy NPI	Patient First Name	Rx Number
Dispensing Pharmacy Phone #	Patient Last Name	Rx NDC
Dispensing Pharmacy Fax #	Patient Zip Code	Days Supply
Prescriber DEA or NPI	Prescriber Last Name	Quantity for Dispense

- If validated, you will be supplied a *prescription authorization number* which indicates you can dispense TIRF medicine.
 - If not validated, you will be provided a rejection reason and information regarding how to resolve the rejection.
- To confirm enrollment confirmation by fax:
 - Populate all of the required fields on the TIRF REMS Access Prescription Authorization Form and fax to 1-855-474-3062. To obtain a TIRF REMS Access Prescription Authorization Form which may be reproduced to use continually, please email information@TIRFREMSaccess.com.

The TIRF REMS Access Program: An Overview for Closed System Outpatient Pharmacies

- If validated, you will be supplied a *prescription authorization number* via fax within one (1) business day which indicates you can dispense the TIRF medicine.
- If not validated, you will be provided a rejection reason and information regarding how to resolve the rejection using the phone number provided on the request.

Step 3: Dispensing

- Receive the *prescription authorization number* from the TIRF REMS Access program and then prepare, label and dispense the medication.

Step 4: Counsel patient and provide Medication Guide

- Counsel the patient on the appropriate use, safe storage, and the proper disposal procedures of TIRF medicines.
- Provide a copy of the product specific Medication Guide to the patient with each prescription.

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

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.