

**The Transmucosal Immediate Release Fentanyl (TIRF) REMS Access Program  
Chain Pharmacy Enrollment Form**

For real-time processing of this enrollment form electronically, please go to [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com) and 'Log In' (if you have previously enrolled in a REMS program for one of the TIRF medicines) or 'Create an Account' to get started.

To submit this form via fax, please complete all required fields below and fax pages 1, 2, 3 and 4 to 1-866-822-1487. You will receive enrollment confirmation via email or fax.

I understand that TIRF medicines are only available through the TIRF REMS (Risk Evaluation and Mitigation Strategy) Access program and that I must comply with the program requirements. In addition, as the designated authorized chain pharmacy representative, I acknowledge that:

1. I have reviewed the TIRF REMS Access Education Program, and I have completed the Knowledge Assessment. I understand the risks and benefits associated with TIRF medicines and the requirements of the TIRF REMS Access program for pharmacies.
2. I will ensure that all pharmacy staff who participate in dispensing TIRF medicines are educated on the risks associated with TIRF medicines and the requirements of the TIRF REMS Access program, as described in the Education Program. This training should be documented and is subject to audit.
3. I understand that converting patients from one TIRF medicine to a different TIRF medicine must not be done on a microgram-per-microgram basis. I understand that TIRF medicines are not interchangeable with each other, regardless of route of administration, and that conversion may result in fatal overdose, unless conversion is done in accordance with labelled product-specific conversion recommendations (refer to the 'List of the TIRF medicines Available only through the TIRF REMS Access program' in Attachment 1). Note, a branded TIRF medicine and its specific generic product(s) are interchangeable.
4. I understand that TIRF medicines are contraindicated for use in opioid non-tolerant patients.
5. I understand that the initial starting dose for TIRF medicines for all patients is the lowest dose, unless individual product labels provide product-specific conversion recommendations, and I understand that patients must be titrated individually.
6. I understand the importance of discussing the risks and benefits of TIRF medicines with patients and their caregivers, and in particular the importance of taking the drug as prescribed, not sharing with others, and proper disposal.
7. I understand that the product-specific Medication Guide must be given to the patient or their caregiver each time a TIRF medicine is dispensed.
8. I understand that a TIRF medicine will not be dispensed without verifying through our pharmacy management system that the prescriber and pharmacy are enrolled and active, and that the patient has not been inactivated in the program.
9. I understand that ALL TIRF medicine prescriptions, regardless of the method of payment, must be processed through our pharmacy management system.
10. I understand that all dispensing locations must be enrolled in the TIRF REMS Access program to dispense TIRF medicines.
11. I understand that TIRF medicines can only be obtained from wholesalers/distributors that are enrolled in the TIRF REMS Access program.
12. I understand that our pharmacy will not sell, loan or transfer TIRF medicine inventory to any other pharmacy, institution, distributor, or prescriber.

Chain ID\*: \_\_\_\_\_

**Current as of 6/1/2013. This document may not be part of the latest approved REMS.**

The TIRF REMS Access Program: Chain Pharmacy Enrollment Form

- 13. I understand that our pharmacy must re-enroll in the TIRF REMS Access program and successfully complete the enrollment requirements every two (2) years.
- 14. I understand that TIRF medicines are only available through the REMS program. I understand that the pharmacy must comply with the TIRF REMS Access program requirements for outpatient pharmacies and the terms of the agreement that follow this form.

**Authorized Chain Pharmacy Representative:**

**Authorized Pharmacy Representative Signature\*** \_\_\_\_\_ **Date** \_\_\_\_\_

**First Name\*** \_\_\_\_\_ **Last Name\*** \_\_\_\_\_ **Title** \_\_\_\_\_

**Phone Number\*** \_\_\_\_\_ **Email\*** \_\_\_\_\_

**Chain Pharmacy Information:**

**Pharmacy Name\*** \_\_\_\_\_ **Chain ID\*** \_\_\_\_\_

**Address\*** \_\_\_\_\_ **Phone Number\*** \_\_\_\_\_

**City\*** \_\_\_\_\_ **Fax Number\*** \_\_\_\_\_

**State\*** \_\_\_\_\_ **ZIP\*** \_\_\_\_\_

**\*Required Fields**

**Preferred Method of Communication (please select one):**       Fax       Email

After submitting this form, you will receive a fax or email with instructions on how to submit test transaction(s) to the TIRF REMS Access program to ensure that your pharmacy management system has been successfully configured to allow for communication with the TIRF REMS Access program.

After successful completion of the test transaction(s) you will receive enrollment confirmation via fax or email.

Pharmacy sites that have been trained can then be updated to an enrolled status through the Chain Pharmacy Dashboard which will list all chain stores at [www.TIRFREMSaccess.com](http://www.TIRFREMSaccess.com)

The following pharmacy information will need to be provided for each trained pharmacy site.

**Pharmacy Information:**

**Pharmacy Name\*** \_\_\_\_\_ **DEA Number\*** \_\_\_\_\_

**Address\*** \_\_\_\_\_ **National Provider Identifier (NPI)\*** \_\_\_\_\_

**City\*** \_\_\_\_\_ **Medicaid ID** \_\_\_\_\_

**State\*** \_\_\_\_\_ **ZIP** \_\_\_\_\_ **State Issued** \_\_\_\_\_

**Phone Number\*** \_\_\_\_\_ **NCPDP Number\*** \_\_\_\_\_

**Fax Number\*** \_\_\_\_\_ **Store Number\*** \_\_\_\_\_

**\*Required Fields**

Chain ID\*: \_\_\_\_\_

**Current as of 6/1/2013. This document may not be part of the latest approved REMS.**

The TIRF REMS Access Program: Chain Pharmacy Enrollment Form

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

Chain ID\*: \_\_\_\_\_

**The TIRF REMS Access Program Additional Terms and Conditions**

Pharmacy ("Pharmacy") agrees to the following requirements, with respect to the Transmucosal Immediate Release Fentanyl (TIRF) REMS program (the "Program"), sponsored by the Transmucosal REMS Industry Group (hereinafter "TRIG" or "Program Sponsor") and supported, under the direction of TRIG by McKesson Specialty Arizona Inc and its affiliates including NDCHealth Corporation d/b/a RelayHealth ("RelayHealth") and McKesson Canada, and any other pharmacy transaction switch system (collectively, "the Providers").

Pharmacy represents that (i) it shall perform its obligations under these terms and conditions in compliance with all applicable laws and regulations, (ii) Pharmacy's participation in the Program does not conflict with its obligations under any contracts or other arrangements with any third party, and (iii) Pharmacy is authorized to submit patient information to the Providers for purposes of verifying and tracking each patient's eligibility to participate in the Program and Pharmacy authorizes Providers and Program Sponsor and their respective designees and agents to use the submitted information for such purposes.

Pharmacy agrees to the following Program Requirements: (a) If applicable, enable Pharmacy's pharmacy practice management system to support the Program, including submission of required data fields and display of Program messages; (b) Respond appropriately to Program messages and alerts in order to comply with Program requirements, including contacting the call center when an exception process occurs; (c) Report all Program Drug dispensing activity for all transmucosal immediate release fentanyl Program Drug NDC #'s:

42747-221-32, 42747-222-32, 42747-223-32, 42747-224-32, 42747-226-32, 42747-228-32  
63459-502-30, 63459-504-30, 63459-506-30, 63459-508-30, 63459-512-30, 63459-516-30,  
63459-541-28, 63459-542-28, 63459-544-28, 63459-546-28, 63459-548-28,  
51772-311-01, 51772-314-01, 0037-5200-30, 0037-5400-30, 0037-5600-30, 0037-5800-30, 0037-5120-30,  
00093-5370-65, 00093-5371-65, 00093-5372-65, 00093-5373-65, 00093-5374-65, 00093-5375-65, 0406-  
9202-30, 0406-9204-30, 0406-9206-30, 0406-9208-30, 0406-9212-30, 0406-9216-30,  
55253-0070-30, 55253-0071-30, 55253-0072-30, 55253-0073-30, 55253-0074-30, 55253-0075-30,  
20482-001-30, 20482-002-30, 20482-004-30, 20482-006-30, 20482-008-30, 20482-012-30, 20482-016-30,  
49884-459-55, 49884-460-55, 49884-461-55, 49884-462-55, 49884-463-55, 49884-464-55

This includes any future drug deemed by FDA to be included in the TIRF REMS Access Program to Providers via submission of all billing and reversal request.

Pharmacy acknowledges that billing request for the Program Drug will not pass to the payer, or cash prescription processor, if the prescriber, pharmacy or patient registration is not verified.

Pharmacy authorizes and directs the Providers to de-identify, in accordance with the Health Insurance Portability and Accountability Act of 1996, as amended, its historical and prospective prescriptions claims data submitted to the Providers and/or their affiliates in connection with or related to the Program on behalf of Pharmacy, and to use that de-identified data for purposes of (i) analyzing, identifying, designing and/or enabling a REMS service; (ii) developing communication documentation for such services for both Program Sponsors and Pharmacy; (iii) providing the Program Sponsors with reports and information (including any fees paid, which will be aggregated), for purposes of implementing, maintaining, supporting, monitoring or improving a Program, and (iv) any other purpose required by law. These reports may contain information aggregated by NCPDP number. Further, Pharmacy authorizes Providers to deliver all of the above enumerated data and reports otherwise to be delivered to Program Sponsor to the designee or agent of Program Sponsor.

Chain ID\*: \_\_\_\_\_

In addition, Pharmacy authorizes Program Sponsor and its contracting Providers, to receive from

**Current as of 6/1/2013. This document may not be part of the latest approved REMS.**

The TIRF REMS Access Program: Chain Pharmacy Enrollment Form

wholesaler(s) of the Program Drug(s) distribution and purchasing data, including 867 data, with respect to the Program Drug(s).

Pharmacy acknowledges that the FDA or Program Sponsor may mandate modification, suspension or termination of a Program. The Providers reserve the right to modify, suspend or terminate any REMS service for any reason, without liability to Switch Systems.

EXCEPT FOR PROVIDER'S FRAUD OR INTENTIONAL MISCONDUCT ARISING OUT OF THE SERVICES OR THE PROGRAM, IN NO EVENT WILL THE PROGRAM SPONSOR OR PROVIDER BE LIABLE TO PHARMACY UNDER, IN CONNECTION WITH, OR RELATED TO THE PROGRAM OR THE SERVICES FOR ANY DIRECT, SPECIAL, INCIDENTAL, INDIRECT, OR CONSEQUENTIAL DAMAGES, INCLUDING, BUT NOT LIMITED TO, LOST PROFITS OR LOSS OF GOODWILL, WHETHER BASED ON BREACH OF CONTRACT, WARRANTY, TORT, PRODUCT LIABILITY, OR OTHERWISE, AND WHETHER OR NOT PROVIDERS OR PROGRAM SPONSOR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE.

To the extent any of these terms and conditions conflict with any other written agreement between the parties with respect to the Program, the terms and conditions of such other written agreement shall prevail.

Chain ID\*: \_\_\_\_\_

**Attachment 1**

**List of TIRF Medicines Available only through the TIRF REMS Access Program**

- ABSTRAL® (fentanyl) sublingual tablets
- 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 are also covered under this program.