Risk Evaluation and Mitigation Strategy (REMS) Document
Transmucosal Immediate Release Fentanyl (TIRF)
Shared System REMS Program

I. Administrative Information

Initial Shared System REMS Approval: 12/2011
Most Recent REMS Update: 12/2020

II. REMS Goals

The goals of the TIRF REMS are to:

1. Mitigate the risk of overdose by:

a) Requiring documentation of opioid tolerance with every TIRF prescription for outpatient use.

b) Requiring inpatient pharmacies to develop policies and procedures to verify opioid tolerance in inpatients who require TIRF medicines while hospitalized.

c) Educating prescribers, pharmacists and patients that the safe use of TIRF medicines requires patients to be opioid-tolerant throughout treatment.

2. Mitigate the risk of accidental exposure by educating prescribers, pharmacists and patients about proper storage and disposal of TIRF medicines.

3. Monitor for accidental exposure, misuse, abuse, addiction, and overdose by enrolling all patients who receive a TIRF medicine for outpatient use into a registry and using surveillance systems and other data sources.

III. REMS Requirements

TIRF Applicants must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe TIRF medicines for outpatient use must:	
To become certified to prescribe	1. Review each drug's Prescribing Information. 2. Review the following: Prescriber Education. 3. Successfully complete the Prescriber Knowledge Assessment and submit it to the REMS program. 4. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS program.

Reference ID: 4721752

Before treatment initiation	5. Assess the patient for risk factors of opioid addiction, abuse, and misuse. 6. Counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Provide a copy of the materials to the patient. *7.* Assess the patient's opioid tolerance. Document and submit to the REMS program using the Patient Enrollment Form. *8.* Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS program.
During treatment, before each prescription	9. Assess the patient's health status for opioid tolerance, appropriateness of dose, misuse, abuse, addiction, and overdose. Document and submit to the REMS program using the Patient Status and Opioid Tolerance Form.
During treatment, every 2 years	10. Counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Provide a copy of the materials to the patient. 11. Re-enroll the patient in the REMS by completing the Patient Enrollment Form and submitting it to the REMS program.
Before treatment re-initiation, lapse in treatment of 6 months or longer	12. Counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Provide a copy of the materials to the patient.
To maintain certification to prescribe, every 2 years	13. Review the Prescribing Information for the TIRF medicines. 14. Review the following: Prescriber Education. 15. Successfully complete the Prescriber Knowledge Assessment and submit it to the REMS program. 16. Re-enroll in the REMS by completing the Prescriber Enrollment Form.
At all times	17. Counsel the patient using the Medication Guide for any new TIRF medicine not previously prescribed. Provide a copy to the patient. 18. Report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose to the REMS program using the Adverse Events of Special Interest Reporting Form. 19. Report treatment discontinuations to the REMS Program using the Patient Discontinuation Form.

Reference ID: 4721752

2. Patients who are prescribed TIRF medicines for outpatient use:	
Before treatment initiation	1. Receive counseling from the prescriber on the safe use of TIRF medicines using the Medication Guide and the Patient Counseling Guide. 2. Enroll in the REMS program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS program.
Before treatment re-initiation, lapse in treatment of 6 months or longer	3. Receive counseling from the prescriber on the safe use of TIRF medicines using the Medication Guide and the Patient Counseling Guide.
During treatment, every 2 years	4. Receive counseling from the prescriber on the safe use of TIRF medicines using the Medication Guide and the Patient Counseling Guide. 5. Re-enroll in the REMS program by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the REMS program.
At all times	6. Adhere to safe use conditions: taking around-the-clock opioid pain medicine when using TIRF medicines, not sharing TIRF medicines, properly storing and disposing your TIRF medicines. 7. Inform the prescriber if your TIRF medicine does not relieve your pain. Do not change your dose or take a TIRF medicine more often than your prescriber directed. 8. Receive counseling from the prescriber on the safe use of each new TIRF medicine you are prescribed. 9. Inform the prescriber of serious adverse events of accidental exposure, abuse, misuse, addiction, and overdose.
3. Pharmacies that dispense TIRF medicines for outpatient use must:	
To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS program on behalf of the pharmacy. 2. Have the authorized representative review the Pharmacy Education. 3. Have the authorized representative successfully complete the Pharmacy Knowledge Assessment and submit it to the REMS program. 4. Establish processes and procedures to assess the patient's medication use for a change in opioid tolerance.

Reference ID: 4721752

	5. Have the authorized representative enroll in the REMS Program by completing and submitting the Outpatient Pharmacy Enrollment Form. 6. Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS program using the Pharmacy Education.
Before dispensing	7. Provide the patient with the product-specific Medication Guide. 8. Assess the patient's medication use for a change in opioid tolerant status. Document and submit the results to the REMS Program. 9. Obtain authorization to dispense each prescription by contacting the REMS program to verify that the prescriber and the patient are enrolled, and the patient is opioid tolerant.
To maintain certification to dispense	10. Have any new authorized representative enroll in the REMS Program by reviewing the Pharmacy Education, successfully completing the Pharmacy Knowledge Assessment and the Outpatient Pharmacy Enrollment Form and submitting both to the REMS Program.
At all times	11. Not distribute, transfer, loan, or sell TIRF medicines. 12. Maintain records of staff training. 13. Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed. 14. Report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose to the REMS program using the Adverse Events of Special Interest Reporting Form.

Reference ID: 4721752

4. Pharmacies that dispense TIRF medicines for inpatient use must:

To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS program on behalf of the pharmacy. 2. Have the authorized representative review the Pharmacy Education. 3. Have the authorized representative successfully complete the Pharmacy Knowledge Assessment and submit it to the REMS program. 4. Have the authorized representative enroll in the REMS program by completing the Inpatient Pharmacy Enrollment Form and submitting it to the REMS program. 5. Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS program using the Pharmacy Education. 6. Establish processes and procedures to verify that the patient is opioid tolerant.
Before dispensing	7. Verify the patient is opioid tolerant through the processes and procedures established as a requirement of the REMS program.
To maintain certification to dispense	8. Have any new authorized representative enroll in the REMS Program by reviewing Pharmacy Education, successfully completing the Pharmacy Knowledge Assessment and the Inpatient Pharmacy Enrollment Form and submitting both to the REMS Program.
At all times	9. Not distribute, transfer, loan, or sell TIRF medicines. 10. Maintain records of staff training. 11. Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed. 12. Not dispense TIRF medicines for outpatient use.

Reference ID: 4721752

5. Wholesalers-Distributors that distribute TIRF medicines must:	
To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies. 2. Train all relevant staff involved in distributing TIRF medicines on the procedures and the REMS program requirements.
At all times	3. Distribute only to certified pharmacies. 4. Maintain records of shipments to certified pharmacies. 5. Comply with audits carried out by TIRF Applicants or a third party acting on behalf of the TIRF Applicants to ensure that all processes and procedures are in place and are being followed.

TIRF Applicants must provide training to healthcare providers who prescribe TIRF medicines. The training includes the following educational material: Prescriber Education. The training must be made available on a website and by calling the REMS program.

TIRF Applicants must provide training to pharmacies that dispense TIRF medicines. The training includes the following educational material: Pharmacy Education. The training must be made available on a website and by calling the REMS program.

To inform healthcare providers about the REMS program and the risks and safe use of TIRF medicines, TIRF Applicants must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials & Dissemination Plans

Inpatient and outpatient pharmacies that dispense Schedule II drugs and may be involved in dispensing TIRF medicines	REMS Letter: Inpatient Pharmacy Letter with attachment Pharmacy Education; Outpatient Pharmacy Letter with attachment Pharmacy Education.
	
	a. Email within 30 calendar days of the approval of the REMS modification and again 1 month later.
	  a. Send by mail or fax within 45 calendar days of the date the second email was sent if email was undeliverable or unopened.
	
	b. Disseminate through the following professional societies and request the letter or content be provided to their members:
	  b. American Association of Colleges of Pharmacy (AACP), American College of Clinical Pharmacy (ACCP), Accreditation Council for Pharmacy Education (ACPE), Academy of Managed Care Pharmacy (AMCP), American Pharmacists Association (APhA), American Society of Consultant Pharmacists (ASCP), American Society of Health-System Pharmacists (ASHP), Board of Pharmacy Specialties (BPS), Board Certified Oncology Pharmacists (BCOP), National Association of Boards of Pharmacy (NABP), National Community Pharmacists Association (NCPA), National Alliance of State Pharmacy Associations (NASPA)

Reference ID: 4721752

Inpatient and outpatient pharmacies previously enrolled in the TIRF REMS	REMS Letter: Inpatient Pharmacy Letter with attachment Pharmacy Education; Outpatient Pharmacy Letter with attachment Pharmacy Education 1. Mail or fax within 45 calendar days of approval of the REMS modification (12/23/2020).
Inpatient and outpatient pharmacies, and wholesaler-distributors previously enrolled in the TIRF REMS	REMS Letter: Urgent Notification Regarding TIRF Products Stock Letter Mail or fax within 120 calendar days of approval of the REMS modification (12/23/2020).
Healthcare providers who are likely to prescribe TIRF medicines	REMS Letter: Healthcare Provider Letter with attachment Prescriber Education 1. Email within 30 calendar days of the approval of the REMS modification and again 1 month later. a. Send by mail or fax within 45 calendar days of the date the second email was sent if email was undeliverable or unopened. 2. Disseminate through the following professional societies and request the letter or content be provided to their members: a. American Academy of Hospice and Palliative Medicine, American Academy of Pain Management, American Academy of Pain Medicine, American Association of Poison Control Centers, American College of Physicians, American Chronic Pain Association, American Pain Society, American Society of Pain Educators, National Hospice and Palliative Care Organization
Prescribers previously enrolled in the TIRF REMS	REMS Letter: Healthcare Provider Letter with attachment Prescriber Education 1. Mail or fax within 45 calendar days of approval of the REMS modification (12/23/2020).

To support REMS program operations, TIRF Applicants must:

1. Authorize dispensing for each patient based on receipt of the Patient Status and Opioid Tolerance Form and pharmacy assessment for a change in opioid tolerance. The authorization is valid for one dispensing for up to 30 calendar days from date the prescriber initiates the authorization.
2. Establish and maintain a REMS program website, www.TIRFREMSaccess.com. The REMS program website must include the capability to complete prescriber, pharmacy, and patient enrollment online, document Adverse Events of Special Interest, document opioid tolerance, obtain authorization to dispense, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS program website. The REMS program website must not link back to the promotional product website(s).
3. Make the REMS program website fully operational and all REMS materials available through the website and coordinating center within 180 calendar days of the REMS modification (12/23/2020).
4. Establish and maintain a REMS program coordinating center for REMS participants at 1-866-822-1483.

Reference ID: 4721752

5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the TIRF REMS program. The database must contain information on their enrollment status.
6. Ensure that prescribers and pharmacies are able to complete enrollment by fax and online.
7. Ensure prescribers are able to document opioid tolerance using the Patient Status and Opioid Tolerance Form by fax and online.
8. Ensure prescribers are able to report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose using the Adverse Events of Special Interest Reporting Form by fax and online.
9. Ensure pharmacies are able to report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose using the Adverse Events of Special Interest Reporting Form by phone, fax, and online.
10. Ensure pharmacies are able to enroll as an inpatient pharmacy (hospitals, in-hospital hospices, and long-term care facilities that dispense for inpatient use) or as an outpatient pharmacy.
11. Ensure outpatient pharmacies are able to document changes in opioid tolerance by phone and online.
12. Ensure outpatient pharmacies are able to obtain authorization to dispense TIRF medicines by phone and online.
13. Provide Prescriber Enrollment Form, Patient Enrollment Form, Outpatient Pharmacy Enrollment Form, Inpatient Pharmacy Enrollment Form, Prescriber Education, Prescriber Knowledge Assessment, Patient Counseling Guide, Pharmacy Education, Pharmacy Knowledge Assessment, and the Prescribing Information to REMS participants who (1) attempt to prescribe/dispense/distribute TIRFs and are not yet certified or (2) inquire about how to become certified.
14. Notify prescribers and pharmacies within three business days after they become certified in the REMS program.
15. Notify REMS participants 30 calendar days before their enrollment expires and of the need to re-enroll.
16. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.
17. Provide certified outpatient pharmacies access to the database of certified prescribers and enrolled patients.
18. Establish and maintain a registry which includes a reporting and collection system for all outpatients to provide information on serious adverse events including accidental exposure, abuse, misuse, addiction, and overdose.
19. Follow up with the healthcare provider to obtain the reason for discontinuation if the patient is not dispensed a TIRF medicine after 2.5 times the days' supply of their last prescription's days' supply.
20. Ensure that once a report suggestive of accidental exposure, abuse, misuse, addiction, or overdose is received, TIRF Applicants follow up with the healthcare provider to obtain all required data for complete adverse event reporting related to accidental exposure, abuse, misuse, addiction, and overdose under the REMS.
21. Report any overdose that results in a death associated with a TIRF medicine, as soon as possible to FDA but no later than 15 calendar days from the initial receipt of the information by the TIRF Applicants. This requirement does not affect the applicants' other reporting and follow-up requirements under FDA regulations.

To ensure REMS participants' compliance with the REMS program, TIRF Applicants must:

22. Ensure a Patient Status and Opioid Tolerance Form is received, and the pharmacy assesses for a change in opioid tolerance for each patient for each dispensing.

Reference ID: 4721752

23. Verify every two years that the pharmacy's authorized representative's name and information correspond to the designated authorized healthcare for the certified pharmacy, and if different, require the pharmacy to recertify with a new authorized representative.

24. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: TIRF distribution and dispensing; certification of prescribers, pharmacies; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.

25. Establish a plan for addressing noncompliance with REMS program requirements.

26. Monitor prescribers, pharmacies, and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.

27. Annually audit all certified outpatient pharmacies and 10% but no less than 50 certified inpatient pharmacies no later than 90 calendar days after they have become certified/re-certified in the TIRF REMS to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. Similarly, annually audit all wholesalers-distributors no later than 90 calendar days after they become authorized to distribute TIRFs to ensure that all REMS processes and procedures are in place, functioning, and support the REMS program requirements.

28. Take reasonable steps to improve operations of and compliance with the requirements in the TIRF REMS program based on monitoring and evaluation of the TIRF REMS program.

IV. REMS Assessment Timetable

TIRF NDA Applicants must submit REMS Assessments at 12 months from 12/23/2020, and annually thereafter. To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. TIRF NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the TIRF REMS program**:**

Enrollment Forms

Prescriber:

1. Prescriber Enrollment Form

Patient:

2. Patient Enrollment Form

Pharmacy:

3. Outpatient Pharmacy Enrollment Form
4. Inpatient Pharmacy Enrollment Form

Training and Educational Materials

Prescriber:

5. Prescriber Education
6. Prescriber Knowledge Assessment

Patient:

7. Patient Counseling Guide

Reference ID: 4721752

8. Medication Guides (available at www.TIRFREMSaccess.com)

Pharmacy:

9. Pharmacy Education
10. Pharmacy Knowledge Assessment

Patient Care Forms

11. Patient Status and Opioid Tolerance Form
12. Adverse Events of Special Interest Reporting Form
13. Patient Discontinuation Form

Communication Materials

14. Healthcare Provider Letter
15. Outpatient Pharmacy Letter
16. Inpatient Pharmacy Letter
17. Urgent Notification Regarding TIRF Products Stock Letter

Other Materials

18. Website (www.TIRFREMSaccess.com)

Reference ID: 4721752

Prescriber Enrollment Form

TIRF REMS

Instructions

To become certified in the TIRF REMS and prescribe TIRF medicines:

1. Review all TIRF medicines Prescribing Information
2. Review the **Prescriber Education**
3. Complete and submit the **Prescriber Knowledge Assessment** to the TIRF REMS
4. Complete and submit this **Prescriber Enrollment Form** to the TIRF REMS

For real time processing of enrollment, visit www.TIRFREMSaccess.com

Or submit completed Prescriber Enrollment Form by fax to 1-866-822-1487.

1 Prescriber Information (PLEASE TYPE OR PRINT)

First Name	Middle Initial	Last Name

Individual NPI #	Clinic / Practice Name

Specialty	Credentials
	☐ MD ☐ NP ☐ PA ☐ DO ☐ Other

Address	City	State	Zip

Phone	Ext.	Fax	Email Address
( )		( )	

Preferred Time of Contact	Preferred Method of Contact
☐ Morning ☐ Afternoon ☐ Evening	☐ Text to Mobile # ☐ Email ☐ Phone Call

2 Office Contact Information (PLEASE TYPE OR PRINT)

First and Last Name	Phone	Fax

Email Address	Preferred Time of Contact	Preferred Method of Contact
	☐ Morning ☐ Afternoon ☐ Evening	☐ Text to Mobile # ☐ Email ☐ Phone Call

3 Prescriber Attestation

By signing below, you attest to the following:

I have:

- Reviewed each drug's **Prescribing Information**.
- Reviewed the **Prescriber Education**.
- Successfully completed the **Prescriber Knowledge Assessment** and submitted it to the REMS.

Before treatment initiation, I must:

- Assess the patient for risk factors of opioid addiction, abuse, and misuse including personal and family history of substance abuse or mental illness.
- Counsel the patient on the safe use of TIRF medicines using the **Medication Guide** for the prescribed TIRF medicine and the **Patient Counseling Guide**.
- Provide a copy of the materials to the patient.
- Assess the patient's opioid tolerance.
- Document the patient's opioid tolerance using the **Patient Enrollment Form** and submit to the REMS.
- Enroll the patient by completing and submitting the **Patient Enrollment Form** to the TIRF REMS.

During treatment, and before each prescription, I must:

- Assess the patient's health status for opioid tolerance, appropriateness of dose, misuse, abuse, addiction, and overdose.
- Document and submit this information to the REMS using the **Patient Status and Opioid Tolerance Form**.

During treatment, every 2 years, I must:

- Counsel the patient on the safe use of TIRF medicines using the **Medication Guide** for the prescribed TIRF medicine, and the **Patient Counseling Guide**.
- Provide a copy of the materials to the patient.
- Re-enroll the patient in the REMS by completing the **Patient Enrollment Form** and submitting it to the REMS.

Before treatment re-initiation, after a lapse in treatment of 6 months or longer, I must:

- Counsel the patient on the safe use of TIRF medicines using the **Medication Guide** for the prescribed TIRF medicine and the **Patient Counseling Guide**.
- Provide a copy of the materials to the patient.

At all times, I must:

- Counsel the patient using the **Medication Guide** for any new TIRF medicine not previously prescribed and provide a copy to the patient.
- Report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose to the REMS using the **Adverse Events of Special Interest Reporting Form**.
- Report treatment discontinuation to the REMS using the **Patient Discontinuation Form**.

To maintain certification to prescribe, every 2 years, I must:

- Review each drug's **Prescribing Information**.
- Review the **Prescriber Education**.
- Successfully complete the **Prescriber Knowledge Assessment** and submit it to the REMS.
- Re-enroll in the REMS by completing the **Prescriber Enrollment Form**.

Required for all prescribers	**Prescriber Signature** **X**	**Date:** / /

If you have additional practice sites that you use when prescribing TIRF medicines, you may provide this information online.

Patient Enrollment Form

TIRF REMS

Instructions

Transmucosal Immediate Release Fentanyl (TIRF) medicines are available only through the TIRF REMS. Prescribers must enroll each patient in the TIRF REMS by submitting this completed form. Patients must review and sign the Patient Attestation section.

For real-time processing of patient enrollment, visit www.TIRFREMSaccess.com.

For fax submission, complete all required fields below and submit all pages to 1-855-474-3062.

Allow one (1) business day for processing before the patient can obtain their prescription fill.

All fields with asterisks (*) are required.

1 Patient Information (PLEASE TYPE OR PRINT)

First Name*	Middle Initial*	Last Name*	Date of Birth*
			mm / dd / yyyy

Sex
☐ Male ☐ Female ☐ Other

Ethnicity
Are you Hispanic or Latino?
☐ Yes ☐ No

Race (check all that apply)
☐ White ☐ Asian ☐ Black or African American
☐ American Indian or Alaska Native
☐ Native Hawaiian or Other Pacific Islander
☐ Other (please specify): _____

Address*	City*	State*	Zip*

Phone*	Email Address*
( )	

Preferred Time of Contact*
☐ Morning ☐ Afternoon ☐ Evening

Preferred Method of Contact*
☐ Text to Mobile # ☐ Email ☐ Phone Call ☐ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
☐ Yes ☐ No

Do you have a safe and secure place to store your medicine?*
☐ Yes ☐ No

2 Patient Representative (if required) (PLEASE TYPE OR PRINT)

First Name*	Last Name*	Relationship to Patient*

Phone*	Email Address*
( )	

3 Patient Attestation

TIRF Medicines can cause your breathing to stop – which can lead to death.

Safety Rules for TIRF Medicines

You have agreed to take a TIRF Medicine and to follow all the safety rules to make it less likely you or others will experience serious harm.

- My healthcare provider has talked to me about the safe use of TIRF medicines using the **Medication Guide** and **Patient Counseling Guide**.
- I will only use this medicine if I am regularly using another opioid, around-the-clock, for constant pain.
- If I stop taking my around-the-clock-opioid pain medicine, I **MUST** stop taking my TIRF medicine.
- I will never share or give my TIRF medicine to anyone else, even if they have the same symptoms.
  - My TIRF medicine could cause harm to others or even death. A dose that is okay for me could cause an overdose and death for someone else.
- I will store my TIRF medicine in a safe and secure place away from children. I understand that accidental use by a child, or anyone for whom the medicine was not prescribed, can cause death.

Continued on next page

- I have been told how to properly dispose of my partially used or unneeded TIRF medicine remaining from my prescription. I will dispose of my TIRF medicine properly as soon as I no longer need it.
- I will contact my healthcare provider if my TIRF medicine does not relieve my pain. I will not change the dose of my TIRF medicine myself or take it more often than my healthcare provider has directed.
- I must enroll in the TIRF REMS and Patient Registry by completing the **Patient Enrollment Form** with my healthcare provider.
- I understand that the TIRF REMS and its agents may use and share my personal information to manage the program, and that information about patients who get TIRF medicines will be stored in a private and secure database. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the TIRF REMS. However, my name will not be shared.
- I give permission for the TIRF REMS and its agents or vendors to contact me by phone, mail, or email to support the administration of the TIRF REMS Program.
- I will tell my healthcare provider if I, or anyone else, experience an adverse event of accidental exposure, abuse, misuse, addiction, and overdose.
- I will re-enroll in the TIRF REMS by completing the **Patient Enrollment Form** with my healthcare provider every two years during treatment.

Required for all patients	**Patient or Patient Representative Signature:** **X**	**Date:** mm / dd / yyyy

The following sections to be completed by the prescriber

4	**Prescriber Information** (PLEASE PRINT)		
First Name*		**Last Name***	
Address*	**City***	**State***	**Zip***
Phone* ( )	**Fax*** ( )	**Individual NPI #***	**Email Address***

5	**Medical Information**		
Prior TIRF Use within the last 6 months*: ☐ Yes ☐ No			
TIRF Product Name*	**Strength***	**Dose***	**Frequency***
Type of Pain* ☐ Cancer ☐ Non-cancer pain			

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6 Verify Opioid Tolerance*

Moiety*	Formulation*	Strength*	Route*	Dose*	Frequency*

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply)*:

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ an equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

7 Concomitant Medications

Concomitant Medications (check all that apply)*:

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Required for all prescribers	**Prescriber Signature***	**Date***
	X	mm / dd / yyyy

The following events are of special interest to the TIRF REMS: overdose, addiction, misuse, abuse, and accidental exposure. If the patient experiences any of these events associated with a TIRF medicine, report them on the Adverse Events of Special Interest Reporting Form which is available on the TIRF REMS website at www.TIRFREMSaccess.com or fax the completed form to 1-855-474-3062.

If you have any questions, require additional information, or need copies of any TIRF REMS documents, visit www.TIRFREMSaccess.com or call the TIRF REMS at 1-866-822-1483.

Outpatient Pharmacy Enrollment Form

TIRF REMS

Instructions

To become certified in the TIRF REMS and dispense TIRF medicines, a pharmacy must designate an Authorized Representative to:

1. Review the **Pharmacy Education**
2. Complete and submit the **Pharmacy Knowledge Assessment** to the TIRF REMS
3. Complete and submit this **Pharmacy Enrollment Form** to the TIRF REMS

For real time processing of enrollment, visit www.TIRFREMSaccess.com

Or submit completed Pharmacy Enrollment Form by fax to 1-866-822-1487.

1 Pharmacy Information (PLEASE TYPE OR PRINT)

Pharmacy Name			**Organizational NPI #**	
Address		**City**	**State**	**Zip**
Phone ( )	**Ext.**	**Fax** ( )	**Chain ID**	

2 Authorized Representative Information (PLEASE TYPE OR PRINT)

First Name	**Last Name**	**Credentials** ☐ RPh ☐ PharmD ☐ BCPS ☐ Other	**Position/Title**
Email Address		**Phone** ( )	**Fax** ( )

Preferred Method of Contact
☐ Text to Mobile # ☐ Email ☐ Phone Call

3 Pharmacy Attestation

As the Authorized Representative, I must:

- Review the **Pharmacy Education**.
- Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS.
- Establish processes and procedures to check the patient's medication use for a change in opioid tolerance.
- Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS using the **Pharmacy Education**.

Before dispensing, all pharmacy staff must:

- Provide the patient with the product-specific **Medication Guide**.
- Assess the patient's medication use for a change in opioid tolerant status. Document and submit the results to the REMS.
- Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber and the patient are enrolled, and the patient is opioid tolerant.

All pharmacy staff must:

- Not distribute, transfer, loan, or sell TIRF medicines.
- Maintain records of staff training.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.
- Report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose associated with the TIRF medicine to the REMS using the **Adverse Events of Special Interest Reporting Form**.

CONTINUED ON THE NEXT PAGE

To maintain certification to dispense, any new authorized representative must:
• Review the **Pharmacy Education**. • Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS. • Enroll in the REMS by completing the **Outpatient Pharmacy Enrollment Form.**
The name, location, and phone number of your pharmacy will be publicly available on www.TIRFREMSaccess.com. If you do not want your information available, please call the TIRF REMS at 1-866-822-1483.

Required	Pharmacy Authorized Representative Signature X	Date: / /

You may add additional pharmacy locations below.

Pharmacy Information (PLEASE TYPE OR PRINT)				
Pharmacy Name			Organizational NPI #	
Address		City	State	Zip
Phone ( )	Ext.	Fax ( )	Chain ID	

Pharmacy Information (PLEASE TYPE OR PRINT)				
Pharmacy Name			Organizational NPI #	
Address		City	State	Zip
Phone ( )	Ext.	Fax ( )	Chain ID	

Pharmacy Information (PLEASE TYPE OR PRINT)				
Pharmacy Name			Organizational NPI #	
Address		City	State	Zip
Phone ( )	Ext.	Fax ( )	Chain ID	

Pharmacy Information (PLEASE TYPE OR PRINT)				
Pharmacy Name			Organizational NPI #	
Address		City	State	Zip
Phone ( )	Ext.	Fax ( )	Chain ID	

Pharmacy Information (PLEASE TYPE OR PRINT)				
Pharmacy Name			Organizational NPI #	
Address		City	State	Zip
Phone ( )	Ext.	Fax ( )	Chain ID	

Inpatient Pharmacy Enrollment Form

TIRF REMS

Instructions

To become certified in the TIRF REMS and dispense TIRF medicines, a pharmacy must designate an Authorized Representative to:

1. Review the **Pharmacy Education**
2. Complete and submit the **Pharmacy Knowledge Assessment** to the TIRF REMS
3. Complete and submit this **Pharmacy Enrollment Form** to the TIRF REMS

For real time processing of enrollment, visit www.TIRFREMSaccess.com

Or submit completed Pharmacy Enrollment Form by fax to 1-866-822-1487.

1 Pharmacy Information (PLEASE TYPE OR PRINT)

Pharmacy Name			**Organizational NPI #**	
Address		**City**	**State**	**Zip**
Phone ( )	**Ext.**	**Fax** ( )	**Chain ID**	

2 Authorized Representative Information (PLEASE TYPE OR PRINT)

First Name	**Last Name**	**Credentials** ☐ RPh ☐ PharmD ☐ BCPS ☐ Other	**Position/Title**
Email Address		**Phone** ( )	**Fax** ( )

Preferred Method of Contact
☐ Text to Mobile # ☐ Email ☐ Phone Call

3 Pharmacy Attestation

As the Authorized Representative, I must:

- Review the **Pharmacy Education**.
- Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS.
- Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS using the **Pharmacy Education**.
- Establish processes and procedures to verify that the patient is opioid tolerant.

All pharmacy staff must:

- Verify the patient is opioid tolerant through the processes and procedures established as a requirement of the REMS.

All pharmacy staff must:

- Not distribute, transfer, loan, or sell TIRF medicines.
- Maintain records of staff training.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.
- Not dispense TIRF medicines for outpatient use.

To maintain certification to dispense, any new authorized representative must:

- Review the following: **Pharmacy Education**.
- Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS.
- Enroll in the REMS by completing the **Inpatient Pharmacy Enrollment Form.**

Required	**Pharmacy Authorized Representative Signature** X	**Date:** / /

TIRF REMS

Transmucosal Immediate-Release Fentanyl (TIRF) REMS

Prescriber Education

This education program includes information about:

- **The TIRF REMS requirements**
- **Serious risks of:**
  - **life-threatening and/or fatal respiratory depression**
  - **increased risk of overdose, especially in children, due to accidental ingestion or exposure**
- **Counseling your patient**

Reference ID: 4721752

The purpose of this educational material is to inform prescribers about the **Risk Evaluation and Mitigation Strategy (REMS)** for transmucosal immediate-release fentanyl (TIRF) medicines. This education presents important safety issues and messages about the TIRF REMS needed to manage and counsel patients about the safe use of TIRF products.

What is the TIRF REMS (Risk Evaluation and Mitigation Strategy)?

The TIRF REMS is a safety program to manage the risk of overdose and accidental exposure by ensuring that patients prescribed a TIRF medicine are opioid tolerant and ensuring that prescribers, pharmacists, and patients are educated about proper storage and disposal of TIRF medicines. The TIRF REMS registry helps to assess safe use and trends in accidental exposure, misuse, abuse, addiction, and overdose by enrolling all patients who receive a TIRF medicine for outpatient use.

The TIRF REMS is required by the U. S. Food and Drug Administration (FDA) to help ensure that the benefits of treatment with transmucosal fentanyl-containing products outweigh the known risks of these products.

Products Covered Under This Program:

- **Actiq®** (fentanyl citrate) oral transmucosal lozenge
- **Fentora®** (fentanyl buccal tablet)
- **Lazanda®** (fentanyl) nasal spray
- **Onsolis®** (fentanyl buccal soluble film)
- **Subsys®** (fentanyl sublingual spray)
- Approved generic equivalents of these products

How Does the TIRF REMS Work?

The TIRF REMS requires prescribers, pharmacies, patients, and wholesaler-distributors to enroll in the program to utilize TIRF medications. Prescribers must verify and document that patients are opioid-tolerant before each prescription.

Steps for Prescriber Enrollment in the TIRF REMS

1. Complete the Training Program:
    - review the **Prescriber Education**
2. Successfully complete the **Knowledge Assessment**; and
3. Complete and submit a signed **Prescriber Enrollment Form**

The enrollment process may be completed online at **www.TIRFREMSaccess.com**

Or

Materials and forms can be downloaded from the website on the Prescriber tab, then completed and faxed to the program at **1-866-822-1487**.

Prescribers must re-enroll in the TIRF REMS every two years. You will receive a reminder to renew your enrollment 30 days before your current enrollment expires.

Prescribing TIRF Medicines for Inpatient Use

Prescribers who prescribe TIRF medications for inpatient use only (e.g., hospitals, in-hospital hospices, and long-term care facilities) **do not need to enroll** in the TIRF REMS.

Patient enrollment in the TIRF REMS is not required for inpatient administration of TIRF medicines.

Prescribing TIRF Medicines for Outpatient Use

What actions must I take as an outpatient prescriber to comply with the TIRF REMS?

1. Enroll each patient
2. Document each patient's opioid tolerance
3. Counsel your patients on the risks
4. Report adverse events of concern

Prescribing Naloxone

Consider prescribing naloxone for the emergency treatment of opioid overdose.

If concomitant use with benzodiazepines, other CNS depressants, or muscle relaxants is warranted, consider prescribing naloxone for the emergency treatment of opioid overdose.

Educate patients and caregivers on how to recognize respiratory depression and emphasize the importance of calling 911 or getting emergency medical help right away in the event of a known or suspected overdose. (See the patient counseling section below.)

Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver both when initiating and renewing treatment with TIRF products.

Inform patients about the various ways to obtain naloxone.

1 - Enroll each patient

Enroll each patient into the TIRF REMS prior to their first prescription for a TIRF medicine. Inform the patient that they will be included in a registry to monitor for serious side effects, including fatal and non-fatal overdose.

- Use the **Patient Enrollment Form**

2 – Document each patient's opioid tolerance

Document patient's opioid tolerance before every prescription.

- Use the **Patient Enrollment Form** to document the patient's opioid tolerance for their first prescription.
- Use the **Patient Status and Opioid Tolerance Form** for documenting opioid tolerance prior to each prescription thereafter.
- Documentation of the patient's opioid tolerance must be on file with the TIRF REMS prior to each prescription being authorized for dispensing at the pharmacy. In addition, the program requires that the TIRF medicine prescriptions be written by the same prescriber listed on the **Patient Status and Opioid Tolerance Form**.
- The **Patient Status and Tolerance Opioid Form** can be submitted online from the Prescriber Dashboard on the TIRF REMS website, or by downloading and faxing to the TIRF REMS.

3 – Counsel your patient on the risks

Counsel each patient

- **Before initiating treatment with a TIRF medicine, review the product-specific Medication Guide with patients and/or caregivers.** Counsel them on the TIRF medicine's risks and conditions of safe use**. Use** the **Patient Counseling Guide** to assist in the discussion and provide the materials to the patient.

Tell the patient:

- You must be opioid tolerant to be able to take a TIRF medicine for your breakthrough cancer pain. Opioid tolerant means that you have been using around-the-clock daily opioid pain medicine for your persistent cancer pain for at least 1 week immediately preceding the start of the TIRF medicine.
- If you stop taking your around-the-clock opioid pain medicine for your persistent cancer pain, you **must stop taking your TIRF medicine for the breakthrough cancer pain because you may no longer be opioid tolerant**.

Note: Patients have had difficulty understanding this concept. Emphasize this requirement to your patients and explain that the risk of life-threatening and/or fatal breathing problems with their TIRF medicine increases if they are not taking around-the-clock opioid pain medicines.

- Inform patients of the risk of life-threatening and/or fatal respiratory depression, including information that the risk is greatest when starting the TIRF medicine, when the dosage is increased, or when changing TIRF medicines, and that it can occur even at recommended dosages.

- Tell patients exactly how to take the TIRF medicine. Instruct them to take the TIRF medicine strictly as prescribed, with special regard to dosage, dose titration, and administration.

Proper storage and disposal

- **Accidental ingestion or exposure, especially in children, may result in life-threatening breathing problems or death.**
- Explain that the TIRF medicine **must** be stored in a secure place safely out of sight and out of reach of all others, especially children. Encourage the use of a lockbox or locked medication bag.

Accidental use by a child, or anyone for whom a TIRF medicine was not prescribed, is a medical emergency and can cause death. Use the child safety kit if one is provided with your TIRF medicine.

TIRF medicines contain fentanyl, which can be a target for people who abuse prescription medications or street drugs. Protect your TIRF medicine from theft.

Properly dispose of partially used or unneeded TIRF medicine remaining from a prescription. Refer to each product's Medication Guide for instructions for disposal.

Naloxone

- Naloxone rapidly reverses the effects of opioid overdose and is the standard treatment for overdose.

- An opioid overdose usually involves unconsciousness and shallow breathing. Other signs and symptoms of an overdose include:

  - Unresponsiveness
  - Limpness
  - Blue lips, gums or fingertips
  - Show or irregular heartbeat or pulse
  - Small pupils

- Advise your patient to be aware of these signs and symptoms in themselves or

if someone around them may be overdosing.

- If there is a suspected overdose, give naloxone immediately. Call 911 or get emergency help right away after administering the first dose of naloxone. Wait 2-3 minutes after the first dose is given to see if the overdose patient wakes up. If they do not wake up, give another dose and continue to give another dose every 2-3 minutes until the person wakes up. Stay with the overdose patient until the ambulance arrives. Give another dose if the overdose patient becomes sleepy again.

Misuse, abuse, addiction and overdose

- Prescribe a limited amount of medication to the patient that will last until the next visit.
- Continually monitor patients for appropriateness of dosing.
- Continually assess whether benefits of treatment outweigh the risks.
- Warn patients that it is dangerous to self-administer benzodiazepines or other CNS depressants including alcohol while taking TIRF medicines. Potentially fatal additive effects may occur if the TIRF medicine is used with benzodiazepines or other CNS depressants, including alcohol. Caution patients who are prescribed benzodiazepines or other CNS depressants to use them only as directed by their prescriber.
- The use of a TIRF medicine, even when taken as recommended, can result in misuse, abuse, addiction, overdose and death.
- Opioids could cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs – serotonin syndrome. Seek medical attention right away if you develop the following symptoms of serotonin syndrome: mental status changes such as confusion, agitation, restlessness, and anxiety; high fever, seizures, rapid breathing, profuse sweating, and irregular heartbeat.
- Avoid concomitant use of a TIRF medicine and a monoamine oxidase inhibitor (MAOI).

Frequency of counseling

Counseling is required:

- before treatment initiation,
- after two years of continuous treatment,
- before treatment re-initiation, and
- upon any lapse in treatment of six months or longer

Effective Patient Management and Follow-up

At follow-up visits:

- Assess appropriateness of dose and make any necessary dose adjustments to the TIRF medicine for the breakthrough cancer pain or the around-the-clock opioid medicine for the persistent cancer pain.
- Assess for side effects or adverse effects.
- Assess for signs of misuse, abuse, or addiction.
    - Assessment and reinforcement of patient's compliance with his/her treatment plan.
    - Assessment of appropriateness of TIRF medicine dosage prescribed depending on tolerability and therapeutic response.
    - Assessment of concomitant medications.

Check Your Knowledge - Scenario 1

Before initiating treatment with a TIRF medicine, prescribers must review the Medication Guide with the patient. Which of the following counseling statements are FALSE?

Select any statements which are false.

A. TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.

B. Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.

C. Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.

D. Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

E. Once a patient becomes familiar with the use of their TIRF medicine, if their BTCP is not controlled they can repeat their dose every 20 minutes until their pain is relieved.

See answer on page 17

4 – Report adverse events

Report adverse events, including misuse, abuse, addiction, overdose, and accidental exposure to TIRF medicines.

- Go to **www.TIRFREMSaccess.com** to complete the Patient Status and Opioid Tolerance Form or the Adverse Events of Special Interest Reporting Form online. These forms can also be obtained from the website, completed and faxed to **1-855-474-3062**; or call the TIRF REMS at **1-866-822-1483**.

Report patient's discontinuation of TIRF medicines

- Report discontinuation of a patient's use of TIRF medicines to the TIRF REMS. Go to **www.TIRFREMSaccess.com** to complete the **Patient Discontinuation Form** online. The form can also be obtained from the website, completed and faxed to **1-855-474-3062**; or you can report by calling **1-866-822-1483.**

KEY SAFETY INFORMATION

Risk of Life-threatening Respiratory Depression

Serious, life threatening, or fatal respiratory depression has been reported with the use of opioids even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death.

Indication:

TIRF medicines are indicated only for the management of breakthrough cancer pain (BTCP) in cancer patients 18 years of age or older **who are already receiving and who are tolerant to, around-the-clock opioid therapy for underlying persistent cancer pain**.

- The only exception is for ACTIQ, and its generic equivalents, which are approved for cancer patients **16** years of age or older.

Patients Must be Opioid Tolerant to be Prescribed a TIRF Medicine

Definition of Opioid Tolerance:

Patients are considered **opioid tolerant** if they are currently taking (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and have been on the regimen(s) **for one week or longer**:

- ≥ 60 mg oral morphine/day
- ≥ 25 mcg transdermal fentanyl/hour
- ≥ 30 mg oral oxycodone/day
- ≥ 8 mg oral hydromorphone/day
- ≥ 25 mg oral oxymorphone/day
- ≥ 60 mg oral hydrocodone/day
- an equianalgesic dose of another opioid

Patients must remain opioid tolerant to continue using a TIRF medicine.

TIRF medicines should only be prescribed by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids for the treatment of cancer pain.

Contraindications

TIRF medicines are contraindicated in:

- Patients who are not opioid tolerant. **Life-threatening respiratory depression could occur at any dose in patients who are not opioid tolerant, and deaths have occurred**.
- The management of acute or postoperative pain, including:
  - headache/migraine;
  - dental pain; or
  - acute pain in the emergency department
- Patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Patients with known or suspected gastrointestinal obstruction, including paralytic ileus
- Patients with known hypersensitivity to fentanyl or components of the TIRF medicine

Please see the Prescribing Information for each individual TIRF medicine for a complete list of contraindications.

Check Your Knowledge - Scenario 2

The patients described are experiencing breakthrough pain. A TIRF medicine is NOT appropriate for some of them. Which patients should not receive a TIRF medicine?

Select any that apply:

A. Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.

B. 12-year-old sarcoma patient whose underlying persistent cancer pain managed with 25 mcg/hour transdermal fentanyl patches for the past 2 months.

C. Adult female with localized breast cancer; just completed a mastectomy and reconstructive surgery; persistent cancer pain managed with 30 mg oral morphine daily for the past 6 weeks.

D. Adult male patient with advanced prostate cancer who, over the last 2 weeks, has been prescribed 100 mg oral morphine daily for pain due to bone metastasis.

E. Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

See answer on page 17

Accidental Ingestion or Exposure

- **TIRF medicines contain fentanyl, which can put patients at risk for overdose and death, especially in the following circumstances**:
  - Patients who are not opioid tolerant
  - Children who are accidentally exposed
  - Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers)
  - Concomitant use with benzodiazepines or other CNS depressants, including alcohol
- Inform patients that TIRF medicines have a rapid onset of action.
- **Instruct patients to store their TIRF medicines in a safe and secure place, out of the sight and out of reach of all others, especially children.**
- Accidental or deliberate ingestion of a TIRF medicine by a child may cause severe, possibly even fatal, respiratory depression. Advise patients to seek immediate medical attention if a child is exposed to a TIRF medicine. Immediately give the child naloxone if naloxone is available.
- Prescribers must specifically question patients or their caregivers about the presence of children in the home (on a full-time or visiting basis) and counsel them regarding the dangers to children from accidental exposure.
- Talk with your patients about safe and appropriate storage and disposal of TIRF medicines.

Check Your Knowledge - Scenario 3

There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate?

Select one option.

A. TIRF medicines can be fatal if taken by children.
B. TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
C. TIRF medicines can be fatal if taken by anyone who is not opioid tolerant.
D. All of the above.

See answer on page 17

Dosage and Administration

- The risk of life-threatening or fatal respiratory depression is greatest during the initiation of therapy or following a dosage increase.

- **A TIRF medicine MUST be initiated at the lowest dose available for that specific product, even if the patient is currently or has taken another TIRF medicine in the past. Titration, if needed, starts at the lowest dose available for that specific product.** Carefully review the initial dosing instructions in each product's specific Prescribing Information.

- **Appropriate Conversion Rules:**

    - TIRF medicines are **not interchangeable**, regardless of route of administration. Significant differences exist in the pharmacokinetic profiles of fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in a fatal overdose.

    - TIRF medicines are **not equivalent** on a microgram-per-microgram basis to any other fentanyl product, including another TIRF medicine. The only exception is for substitution of a generic equivalent for a branded TIRF medicine.

    - **Because of these differences, conversion of a TIRF medicine to another TIRF medicine on a microgram-per-microgram basis may result in fatal overdose.**

    - Therefore, converting from one TIRF medicine to a different TIRF medicine **must not be done on a microgram-per-microgram basis**. The new TIRF medicine must be titrated according to the labeled dosing instructions for each new TIRF medicine the patient begins.

        - The only exception is for substitutions between a branded TIRF medicine and its generic **equivalents**.

Reference ID: 4721752

Check Your Knowledge - Scenario 4

A patient is already taking a TIRF medicine but wants to change their medicine. His/her doctor decides to prescribe a different TIRF medicine (that is not a bioequivalent generic version of a branded product) in its place. How should the prescriber proceed?

Select any correct option:

A. The prescriber can safely convert to the equivalent dosage of the new TIRF medicine as it has the same effect as other TIRF medicines.
B. The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.
C. Convert from the other TIRF medicine to the new TIRF medicine at half of the dose.
D. The prescriber should base the starting dose of the newly prescribed TIRF medicine on the dose of the opioid medicine used for their underlying persistent cancer pain.
E. The dose that the prescriber believes is appropriate based on their clinical experience.

See answer on page 17

- **Drug Interactions**
  - Fentanyl is metabolized mainly by the cytochrome P450 (CYP3A4) isoenzyme system; therefore, potential drug interactions may occur when TIRF medicines are administered concurrently with agents that affect CYP3A4 activity.
    - Concomitant use of TIRF medicines with CYP3A4 inhibitors (e.g., certain protease inhibitors, ketoconazole, fluconazole, diltiazem, erythromycin, verapamil) may increase plasma concentrations of fentanyl and prolong opioid adverse reactions, which may cause potentially fatal respiratory depression.
      - Patients receiving TIRF medicines who begin therapy with or increase the dose of CYP3A4 inhibitors must be carefully monitored for signs of opioid toxicity over an extended period. Dosage increases should be done conservatively.
    - Concomitant use of TIRF medicines with CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin), can decrease the plasma concentration of fentanyl, resulting in decreased efficacy or onset of a withdrawal syndrome in patients who have developed physical dependence to fentanyl.

Reference ID: 4721752

- If concomitant use with a CYP3A4 inducer is necessary, consider increasing the dose of the TIRF medicine until stable drug effects are achieved. Monitor for signs of opioid withdrawal. If a CYP3A4 inducer is discontinued, consider reducing the dose of the TIRF medicine and monitor for signs of respiratory depression.

Note: This list does not include a complete list of drug interactions with TIRF medications. Check each drug's PI for a complete list.

Maintenance/Dose Adjustments for all TIRF Medicines

- Once a dose that provides adequate analgesia and minimizes adverse reactions is found, that dose should be prescribed for each subsequent episode of breakthrough cancer pain (BTCP).
- Patients must wait at least 2 or 4 hours before treating another episode of breakthrough pain with their TIRF medicine. Please refer to the specific TIRF medicine's Prescribing Information to determine the appropriate dosing interval.
- Limit the use of TIRF medicines to no more than 4 doses per day.
- If the prescribed dose no longer adequately manages the BTCP for several consecutive episodes, increase the dose as described in the titration section of the Prescribing Information.
- Consider re-evaluating the dose of the around-the-clock opioid medicine used for persistent cancer pain in patients experiencing more than 4 BTCP episodes per day.

REPORTING ADVERSE EVENTS

Serious adverse events and adverse events of special interest, including misuse, abuse, addiction, overdose, death or accidental exposure associated with a TIRF medicine, can be reported online at **www.TIRFREMSaccess.com** by use of the:

- **Patient Status and Opioid Tolerance Form**, or
- **Events of Special Interest Reporting Form**

Adverse events may also be reported by contacting the TIRF REMS at **1-866-822-1483**.

Reference ID: 4721752

Products* Covered Under this Program:

Product	Dosage and Administration			
	Initial dose	Maximum Dose Per Episode	Frequency	Titration
Actiq® (fentanyl citrate) oral transmucosal lozenge	Always 200 mcg.	If the breakthrough pain episode is not relieved after 30 minutes, patients may take one (1) additional dose using the same strength. Patients should not take more than two (2) doses of ACTIQ per breakthrough pain episode.	Patients must wait at least Four (4) hours before treating another breakthrough pain episode with ACTIQ.	Closely follow patients and change the dosage level until adequate analgesia with tolerable side effects is achieved with angle unit.
FENTORA® (fentanyl buccal tablet)	Always 100 mcg (unless the patient is being converted from ≥600 mcg ACTIQ - please see Prescribing Information)	If the breakthrough pain episode is not relieved after 30 minutes, patients may take one (1) additional dose using the same strength. Patients should not take more than two (2) doses of FENTORA per breakthrough pain episode. Patients must wait at least four (4) hours before treating another breakthrough pain episode with FENTORA.	For patients being converted from ACTIQ, prescribers must use the Initial Dosing Recommendations for Patients on ACTIQ found in Table 1 of the Prescribing Information. The doses of FENTORA in the table are starting doses and not intended to represent equip-analgesic doses to ACTIQ.	Closely follow patients and change the dosage level until adequate analgesia is achieved with a single tablet. During titration, patients can be instructed to use multiple tablets (one on each side of the mouth in the upper/lower buccal cavity) until a maintenance dose is achieved.

Product	Dosage and Administration			
	Initial dose	Maximum Dose Per Episode	Frequency	Titration
Lazanda® (fentanyl) nasal spray	Always 100 mcg	Only use LAZANDA once (1 time) per cancer breakthrough pain episode; i.e., do not re-dose LAZANDA within an episode. Patients must wait at least two (2) hours before treating another episode of breakthrough pain with LAZANDA.	Limit LAZANDA use to four (4) or fewer doses per day.	If adequate analgesia was not obtained with the first 100 mcg dose, continue dose escalation in a stepwise manner over consecutive breakthrough pain episodes until adequate analgesia with tolerable side effects is achieved. Patients should confirm the dose of LAZANDA that works for them with a second episode of breakthrough pain.
Subsys® (fentanyl sublingual spray)	Always 100 mcg (unless the patient is being converted from >600 mcg ACTIQ – please see Prescribing Information.	If the breakthrough pain episode is not relieved after 30 minutes, patients may take one (1) additional dose using the same strength. Patients should not take more than 2 doses of SUBSYS per episode of breakthrough pain.	Patients must wait at least four (4) hours before treating another episode of breakthrough pain with SUBSYS.	Closely follow patients and change the dosage level until adequate analgesia is achieved using a single dose per episode of breakthrough cancer pain.

Note: This table is also available to print for use as a quick reference guide. Please visit www.TIRFREMSaccess.com for further information and resources.

* This includes approved generic equivalents of these products.

For more information about TIRF medicines, see the Prescribing Information, including the BOXED WARNING, for each product.

Resources for More Information

If you have any questions and/or need additional information or copies of any TIRF REMS documents, please visit the program website at www.TIRFREMSaccess.com or call the TIRF REMS at 1-866-822-1483.

ANSWER KEY

Scenarios: Answers and Rationales

Scenario 1: Patient Counseling on use of ATC Opioids

Item A, B, and D Response. This statement is correct.

Item C Response: This statement is incorrect. Patients should be instructed that, if they stop taking their around-the-clock opioid medicine, they must discontinue taking their TIRF medicine.

Item E Response: This statement is incorrect. Individual TIRF medicines have different and product-specific number of times they may be repeated per BTCP occurrence. Patients should be counseled that: they must never use more doses of their TIRF medicine than directed per instance of BTCP occurrence due to the toxicity of fentanyl; and, when their breakthrough pain is not controlled by their TIRF medicine, they should call their prescriber for evaluation.

Scenario 2: Patient Selection/Opioid Tolerance:

Item A, D, and E Response: This patient is appropriate for treatment with a TIRF medicine.

Item B Response: This patient is not appropriate for treatment with a TIRF medicine. TIRF medicines are indicated for use in treatment of BTCP in patients who are 18 years of age or older (or 16 years of age and older in the case of ACTIQ use.)

Item C Response: This patient is not appropriate for treatment with a TIRF medicine. This patient does not meet the definition of “opioid-tolerant” which in the case of oral morphine use as her opioid background regimen would require daily use for at least one previous week of 60 mg or more of morphine.

Scenario 3: Accidental Ingestion or Exposure

Item D: Correct, TIRF medicines can be fatal if taken by children, by anyone for whom it is not prescribed, or by anyone who is opioid non-tolerant.

Items A, B, C: This answer is correct however Answer D most accurate. TIRF medicines can be fatal if taken by children, by anyone for whom it is not prescribed, or by anyone who is opioid non-tolerant.

Scenario 4: Dosage and Administration General

Item B and D Response: Correct. Conversions must not occur on a microgram-for-microgram basis due to the difference in the absorption and bioavailability profiles of the different TIRF products.

Item A or C or E Response: Incorrect. The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose, a simple ½ reduction of the microgram dosage or estimates based on prior clinical experience. Because TIRF medicines have different absorption and bioavailability profiles, conversion to an alternate TIRF product must be done at the newly prescribed TIRF medicine’s lowest available dose. Conversions must be based on individual product provided product-specific guidance obtained from the Prescribing Information.

Prescriber Knowledge Assessment

TIRF REMS

Instructions

To submit this form via fax, please fill in the prescriber information below, answer all questions below, and fax all pages to 1-866-822-1487. You will receive enrollment confirmation via email or fax.

For real-time processing of this Knowledge Assessment, please go to www.TIRFREMSaccess.com.

1 Prescriber Information (PLEASE TYPE OR PRINT)

First Name	Middle Initial	Last Name

Individual NPI #

Address	City	State	Zip

Phone	Ext.	Fax	Email Address
( )		( )	

2 Knowledge Assessment

Question 1

The patients described are all experiencing breakthrough cancer pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine?

Select one option

A. 12-year-old sarcoma patient, using transdermal fentanyl for her underlying persistent cancer pain.
B. Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
C. Adult male with advanced lung cancer, his underlying persistent pain is managed with 25 mcg/hour transdermal fentanyl patches for the past 3 months.
D. Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.

Question 2

The patients described are experiencing breakthrough cancer pain. A TIRF medicine is NOT appropriate for one of them. Which patient should not receive a TIRF medicine?

Select one option.

A. Adult male with advanced lung cancer; underlying persistent cancer pain managed with 25 mcg/hour transdermal fentanyl patches for the past 2 months.
B. Adult female with localized breast cancer; just completed a mastectomy and reconstructive surgery; persistent cancer pain managed with 30 mg oral morphine daily for the past 6 weeks.
C. Adult male patient with advanced prostate cancer who, over the last 2 weeks, has been prescribed 100 mg oral morphine daily for pain due to bone metastasis.
D. Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

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Question 3

Certain factors may increase the risk of abuse and/or diversion of opioid medications. Which of the following is most accurate?

Select one option.

A. A history of alcohol abuse with the patient or close family members.
B. The patient has a household member with a street drug abuse problem.
C. The patient has a history of prescription drug misuse.
D. All of the above.

Question 4

A patient is already taking a TIRF medicine but wants to change their medicine. His/her doctor decides to prescribe a different TIRF medicine (that is not a bioequivalent generic version of a branded product) in its place. How should the prescriber proceed?

Select one option.

A. The prescriber can safely convert to the equivalent dosage of the new TIRF medicine as it has the same effect as other TIRF medicines.
B. The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.
C. Convert from the other TIRF medicine to the new TIRF medicine at half of the dose.
D. The prescriber should base the starting dose of the newly prescribed TIRF medicine on the dose of the opioid medicine used for their underlying persistent cancer pain.

Question 5

A patient is starting titration with a TIRF medicine. What dose must they start with?

Select one option.

A. An appropriate dose based on the dose of the opioid medicine used for underlying persistent cancer pain.
B. The dose that the prescriber believes is appropriate based on their clinical experience.
C. The lowest available dose, unless individual product Prescribing Information provides product-specific guidance.
D. The median available dose.

Question 6

A prescriber has started titrating a patient with the lowest dose of a TIRF medicine. However, after 30 minutes, the breakthrough cancer pain has not been sufficiently relieved. What should they advise the patient to do?

Select one option.

A. Take another (identical) dose of the TIRF medicine immediately.
B. Take a dose of an alternative rescue medicine.
C. Provide guidance based on the product-specific Prescribing Information because the instructions are not the same for all TIRF medicines.
D. Double the dose and take immediately.

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Question 7

A patient is taking a TIRF medicine and the doctor would like to prescribe erythromycin, a CYP3A4 inhibitor. Which of the following statements is TRUE?

Select one option.

A. The patient can't be prescribed erythromycin, because using it at the same time as a TIRF medicine could be fatal.
B. Use of a TIRF medicine with a CYP3A4 inhibitor may require dosage adjustment of the TIRF medicine; carefully monitor the patient for opioid toxicity, otherwise such use may cause serious life threatening, and/or fatal respiratory depression.
C. There is no possible drug interaction between CYP3A4 inhibitors and TIRF medicines.
D. The dose of the TIRF medicine must be reduced by one half if a CYP3A4 inhibitor is prescribed in the same patient.

Question 8

Before initiating treatment with a TIRF medicine, prescribers must review the Medication Guide and Patient Counseling Guide with the patient. Which of the following counseling statements is FALSE?

Select one option.

A. TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.
B. Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.
C. Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.
D. Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

Question 9

There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate?

Select one option.

A. TIRF medicines can be fatal if taken by children.
B. TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
C. TIRF medicines can be fatal if taken by anyone who is not opioid-tolerant.
D. All of the above.

Question 10

Which one of the following statements is most accurate regarding the safe storage and disposal of TIRF medicines?

Select one option.

A. TIRF medicines should be kept in in a safe and secure place, out of sight and out of reach of all others, especially children.
B. TIRF medicines should be protected from theft.
C. Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
D. All of the above.

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Question 11:

Which of the following statements is FALSE?

Select one option.

The TIRF REMS mitigates the risk of overdose by:

A. Educating prescribers, pharmacist and patients that respiratory depression is more common in patients who are not opioid tolerant.
B. Requiring that patients remain opioid-tolerant throughout their treatment with TIRF medicines.
C. Requiring inpatient pharmacies to verify opioid tolerance in inpatients who require TIRF medicine while hospitalized.
D. Requiring documentation of opioid tolerance with only the initial prescription of a TIRF medicine

Required for all prescribers	**Prescriber Signature** **X**	**Date:** / /

Prescriber Knowledge Assessment Key

Question #	Answer
1	A
2	B
3	D
4	B
5	C
6	C
7	B
8	C
9	D
10	D
11	D

Patient Counseling Guide

TIRF REMS

What You need to Know about Your TIRF Medicine

Read and keep this guide and the Medication Guide that was given to you by your pharmacy with your medicine.

Go over this information with your healthcare provider and ask about anything you do not understand.

What are TIRF Medicines?

- A transmucosal immediate-release fentanyl (TIRF) medicine is a prescription medicine that contains fentanyl, a very strong opioid pain reliever.
- TIRF medicines are used to manage breakthrough cancer pain in patients who are already routinely taking another opioid pain medicine around-the-clock, for at least one week or longer.
- TIRF medicines are started only after you have been taking other opioid pain medicines and your body has become use to them (meaning you are opioid tolerant).
- You must stop taking your TIRF medicine if you stop taking your around-the-clock opioid pain medicine.

What are the serious risks of using TIRF Medicines?

- Too much TIRF medicine in your body can cause your breathing to stop—which could lead to death.
- Accidental use of a TIRF medicine by a child, or anyone else can cause death.
- Avoid accidental exposure by storing your TIRF medicine in a place where it cannot be reached by children, and where it cannot be stolen by other family members or visitors to your home. Use a lockbox or locking medication bag to keep your TIRF medicine safe and secure.
- TIRF medicines, like other opioids, have serious risks of misuse, abuse and addiction that can lead to death.
- These serious risks can occur even when you use your TIRF medicine as recommended.

The risk of life-threatening breathing problems is greatest:

- if you are not opioid-tolerant
- when you start your TIRF medicine,
- when the dose is increased or
- when changing TIRF medicines

The risk is also greater for people taking other medicines that make them feel sleepy or people with sleep apnea.

How can I take a TIRF Medicine Safely?

- Take your TIRF medicine exactly as your healthcare provider has directed.
- Call your healthcare provider if the TIRF medicine is not controlling your breakthrough cancer pain. Do not increase the dose on your own or take the TIRF medicine more frequently than was directed.

Unless prescribed by your healthcare provider, do not take any of the following with a TIRF medicine. The combination can cause severe drowsiness, confusion, breathing problems, coma and death.

- Alcohol, including any prescription or over-the-counter medicines containing alcohol
- Benzodiazepines, tranquilizers, and anti-anxiety medicines (like Valium or Xanax)
- Muscle relaxants (like Soma or Flexeril)
- Sleep medicines (like Ambien or Lunesta)

- Do not switch from your TIRF medicine to another medicine containing fentanyl without talking to your healthcare provider first.
- It is against the law to share your TIRF medicine or give it to anyone else even if they have the same symptoms.
- If you become aware that a child or anyone else takes your TIRF medicine, get emergency medical help immediately. These are medical emergencies that can cause death. A dose that is okay for you could cause an overdose and death in someone else.

How can I dispose of my TIRF Medicine safely?

- When you no longer need your TIRF medicine, dispose of it properly and as quickly as possible.
- NEVER dispose of an unused TIRF medicine in an open trash bin where children, family or pets may accidentally come into contact with the TIRF medicine. Accidental exposure to a TIRF medicine by anyone who is not opioid tolerant is a medical emergency.

The Medication Guide received from your pharmacy with your TIRF medicine, tells the proper way to dispose of the unused portion of your TIRF medicine. Follow the disposal instructions provided in the Medication Guide exactly.

What is Naloxone and When should I use it?

- Naloxone is a medicine that helps reverse an opioid overdose. It is sprayed inside your nose or injected into your body. Some naloxone products are designed for people to use in their home.
- If either of the following occurs, immediately use naloxone:
  - You or someone else has taken an opioid medicine, including a TIRF medicine, and is having trouble breathing, is short of breath, or is unusually sleepy
- A child has accidentally taken an opioid medicine, including a TIRF medicine, or you think they might have.
- Giving naloxone to a person, even a child, who has not taken an opioid medicine will not hurt them.
- Naloxone is never a substitute for emergency medical care. Always call 911 and go to the emergency room if the patient or someone else has used or been given naloxone. This is because they may have had an opioid overdose.
- Ask your healthcare provider how you can get naloxone. Naloxone is available in pharmacies, and in some states, you may not need a prescription.
- Keep naloxone in a place where you, your family, or friends can quickly get to it in an emergency.

Patient Counseling Guide

TIRF REMS

What should I know about the specific TIRF Medicine I am taking?

- Read the Medication Guide that comes with your TIRF medicine prescription for specific information about your medicine.
- You or your healthcare provider can write notes below about things you should know about your TIRF medicine. (This might include dosing instructions, other medicines that you should avoid when taking your specific TIRF medicine, or anything else that you or your healthcare provider want to write down.)

NOTES:

_____
_____
_____
_____
_____
_____

What if I have more questions?

- Talk to your healthcare provider or pharmacist and ask them any questions you may have.
- Visit www.fda.gov/opioids for more information about opioid medicines.

For information about the TIRF REMS call 1-866-822-1453 or visit www.TIRFREMSAccess.com

Reference ID: 4721752

TIRF REMS

Transmucosal Immediate-Release Fentanyl (TIRF) REMS

Pharmacy Education

This education program includes information about:

- **The TIRF REMS requirements**
- **Serious risks of:**
  - **life-threatening and/or fatal respiratory depression**
  - **increased risk of overdose, especially in children, due to accidental ingestion or exposure**
- **Patient Counseling**

Reference ID: 4721752

The purpose of this educational material is to inform pharmacies about the **Risk Evaluation and Mitigation Strategy (REMS)** for transmucosal immediate-release fentanyl (TIRF) medicines. This education provides important safety issues and messages about the TIRF REMS required to dispense and counsel patients about the safe use of these products.

What is the TIRF REMS (Risk Evaluation and Mitigation Strategy)?

The TIRF REMS is a safety program to manage the risk of life-threatening and/or fatal respiratory depression and increased risk of overdose, especially in children, due to accidental ingestion or exposure.

The TIRF REMS is required by the U. S. Food and Drug Administration (FDA) to help ensure that the benefits of treatment with transmucosal immediate-release fentanyl-containing products outweigh the known risks of these products.

Products Covered Under This Program:

- **Actiq®** (fentanyl citrate) oral transmucosal lozenge
- **Fentora®** (fentanyl buccal tablet)
- **Lazanda®** (fentanyl) nasal spray
- **Onsolis®** (fentanyl buccal soluble film)
- **Subsys®** (fentanyl sublingual spray)
- Approved generic equivalents of these products

How Does the TIRF REMS Work for Pharmacies?

The TIRF REMS requires prescribers, pharmacies, patients, and wholesaler-distributors to enroll in the program in order to utilize TIRF medications.

- The outpatient pharmacy must establish policies and procedures to assess the patient's medication use for a change in opioid tolerance. This could include reviewing data from various sources (e.g. - available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.) The pharmacist will document and submit results to the REMS for any discrepancies.
- The outpatient pharmacy is required to obtain authorization to dispense each prescription online or by contacting the TIRF REMS Call Center at **1-866-822-1453** to verify that the prescriber and the patient are enrolled, and the patient is opioid tolerant.
- Enrolled wholesaler-distributors will verify the current enrollment status of the pharmacy prior to shipment of TIRF medicines.
- Inpatient hospital pharmacies are required to develop policies and procedures to verify the patient's opioid tolerance prior to dispensing. This could include reviewing data from various sources (e.g. - available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)

What Actions Must Be Taken in an Outpatient Pharmacy to Comply with the TIRF REMS?

- Pharmacies must be enrolled in the program to be able to dispense TIRF medicines

Steps for Pharmacy Enrollment in the TIRF REMS

1. Designate an authorized representative to carry out the enrollment process and oversee the implementation and compliance with the TIRF REMS on behalf of the pharmacy.
2. Complete the Training Program:
   - review the **Pharmacy Education**
3. Successfully complete the **Pharmacy Knowledge Assessment**; and
4. Complete and submit a signed **Outpatient Pharmacy Enrollment Form**
5. Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS.

The enrollment process may be completed online at **www.TIRFREMSaccess.com**

Or

Materials and forms can be downloaded from the website on the Pharmacy tab, then completed, and faxed to the program at **1-866-822-1487**.

Requirements for Dispensing TIRFs

- Pharmacies must establish policies and procedures to assess **the patient's opioid tolerance** prior to dispensing. This could include reviewing data from available various sources (e.g. state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)
  - Data found during this review must be compared against the opioid tolerance verification data provided by the prescriber. This can be done online while obtaining a REMS Dispense Authorization or by calling the TIRF REMS Call Center at **1-866-822-1453**.
  - Contact the prescriber if there is a discrepancy in data or if the data indicates that the patient is not opioid tolerant.
- For each outpatient prescription, obtain a REMS Dispense Authorization number from the TIRF REMS prior to dispensing each TIRF medicine prescription. This verifies that the patient, prescriber, and pharmacy are enrolled, and the prescriber has confirmed that the patient is opioid tolerant.
  - A REMS Dispense Authorization can be obtained online or by calling the TIRF REMS Call Center at **1-866-822-1453**.

To obtain a REMS Dispense Authorization online at **www.TIRFREMSaccess.com**:

1. Log in to the TIRF REMS website
2. Select the Obtain a Patient RDA option
3. Enter the patient's name and date of birth; the patient's phone or email address, the prescriber's name and NPI number; and the NDC code and the number of days' supply being dispensed
4. Select the Obtain RDA button

If any requirements are not satisfied when obtaining an RDA, the system will generate a rejection and the prescription must not be dispensed.

- Provide a Medication Guide with every refill of a TIRF medicine and discuss the risks and side effects associated with fentanyl-containing products, including what to do if patients experience side effects.

Other TIRF REMS Requirements

- Pharmacies must obtain TIRF medicine product stock only from an enrolled wholesaler-distributor.
- If the pharmacy's authorized representative changes, the new authorized representative must enroll in the TIRF REMS by reviewing the **Pharmacy Education**, successfully completing the **Pharmacy Knowledge Assessment** and the **Outpatient Pharmacy Enrollment Form** and submitting both to the TIRF REMS.
- Outpatient pharmacies must comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed. Outpatient pharmacies must maintain records of staff training and records of opioid tolerance verification data for each dispensing including moiety, formulation, strength, route, dose, and frequency of around-the-clock opioids for the patient. These records must be available for audits.

What Actions Must be Taken in an Inpatient Pharmacy to Comply with the TIRF REMS?

- Pharmacies must be enrolled in the program to be able to dispense TIRF medicines

Steps for Pharmacy Enrollment in the TIRF REMS

1. Designate an authorized representative to carry out the enrollment process and oversee the implementation and compliance with the TIRF REMS on behalf of the pharmacy.
2. Complete the Training Program:
   - review the **Pharmacy Education**
3. Successfully complete the **Knowledge Assessment**; and
4. Complete and submit a signed **Inpatient Pharmacy Enrollment Form**

5. Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS using the Pharmacy Education.

The enrollment process may be completed online at **www.TIRFREMSaccess.com**

Or

Materials and forms can be downloaded from the website on the Resources tab, then completed, and faxed to the program at **1-866-822-1487**.

- Pharmacies must obtain TIRF medicine product stock only from an enrolled distributor.
- Inpatient pharmacies are required to develop policies and procedures to verify the patient's opioid tolerance in patients who require TIRF medicines while hospitalized prior to dispensing. This could include reviewing data from various sources (e.g. - available state Prescription Drug Monitoring Programs (PDMPs) the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.) Inpatient pharmacies do not need to obtain a REMS Dispense Authorization to dispense a TIRF medicine within the inpatient setting.
- If the pharmacy's authorized representative changes, the new authorized representative must enroll in the TIRF REMS by reviewing the **Pharmacy Education**, successfully completing the **Pharmacy Knowledge Assessment** and the **Inpatient Pharmacy Enrollment Form** and submitting both to the TIRF REMS.
- Inpatient pharmacies must comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed. Inpatient pharmacies must maintain records of staff training. These records must be available for audits.

KEY SAFETY INFORMATION

Risk of Life-threatening Respiratory Depression

Serious, life threatening, or fatal respiratory depression has been reported with the use of opioids even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death.

Indication:

TIRF medicines are indicated only for the management of breakthrough cancer pain (BTCP) in cancer patients 18 years of age or older **who are already receiving and who are tolerant to, around-the-clock opioid therapy for underlying persistent cancer pain**.

- The only exception is for ACTIQ, and its generic equivalents, which are approved for cancer patients **16** years of age or older.

Patients Must be Opioid Tolerant to be Prescribed a TIRF Medicine

Definition of Opioid Tolerance:

Patients are considered **opioid tolerant** if they are currently taking (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and have been on the regimen(s) **for one week or longer**:

- ≥ 60 mg oral morphine/day
- ≥ 25 mcg transdermal fentanyl/hour
- ≥ 30 mg oral oxycodone/day
- ≥ 8 mg oral hydromorphone/day
- ≥ 25 mg oral oxymorphone/day
- ≥ 60 mg oral hydrocodone/day
- an equianalgesic dose of another opioid

- Patients must remain opioid tolerant to continue using a TIRF medicine.
- TIRF medicines are intended for use only by opioid-tolerant patients with cancer. They should only be prescribed by healthcare professionals who are knowledgeable of and skilled in the use of Schedule II opioids for the treatment of breakthrough cancer pain.

Check Your Knowledge - Scenario 1

The patients described are experiencing breakthrough pain. A TIRF medicine is NOT appropriate for some of them. Which patients should NOT receive a TIRF medicine?

Select any that apply:

A. Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.

B. 12-year-old sarcoma patient whose underlying persistent cancer pain managed with 25 mcg/hour transdermal fentanyl patches for the past 2 months.

C. Adult female with localized breast cancer; just completed a mastectomy and reconstructive surgery; persistent cancer pain managed with 30 mg oral morphine daily for the past 6 weeks.

D. Adult male patient with advanced prostate cancer who, over the last 2 weeks, has been prescribed 100 mg oral morphine daily for pain due to bone metastasis.

E. Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

See answer on page 18

Contraindications

TIRF medicines are contraindicated in:

- Patients who are not opioid tolerant. **Life-threatening respiratory depression could occur at any dose in patients who are not opioid tolerant, and deaths have occurred**.
- The management of acute or postoperative pain, including:
  - headache/migraine;
  - dental pain; or
  - acute pain in the emergency department
- Patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment
- Patients with known or suspected gastrointestinal obstruction, including paralytic ileus
- Patients with known hypersensitivity to fentanyl or components of the TIRF medicine

Please see the Prescribing Information for each individual TIRF medicine for a complete list of contraindications.

Accidental Ingestion or Exposure

- **TIRF medicines contain fentanyl, which can put patients at risk for overdose and death, especially in the following circumstances**:
  - Patients who are not opioid tolerant
  - Children who are accidentally exposed
  - Concomitant use with CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers)
  - Concomitant use with benzodiazepines or other CNS depressants, including alcohol
- TIRF medicines have a rapid onset of action.
- **Instruct patients to store their TIRF medicines in a safe and secure place, out of the sight and out of reach of all others, especially children.**
- **Accidental or deliberate ingestion of a TIRF medicine by a child may cause severe, possibly even fatal, respiratory depression. Advise patients to seek immediate medical attention if a child is exposed to a TIRF medicine.**

- Prescribers must specifically question patients or their caregivers about the presence of children in the home (on a full-time or visiting basis) and counsel them regarding the dangers to children from accidental exposure.

- Talk with your patients about safe and appropriate storage and disposal of TIRF medicines.

Check Your Knowledge - Scenario 2

There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate?

Select one option.

A. TIRF medicines can be fatal if taken by children.
B. TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
C. TIRF medicines can be fatal if taken by anyone who is not opioid tolerant.
D. All of the above.

See answer on page 18

Dosage and Administration

- The risk of life-threatening or fatal respiratory depression is greatest during the initiation of therapy or following a dosage increase.

- **A TIRF medicine MUST be initiated at the lowest dose available for that specific product, even if the patient is currently taking a TIRF medicine or has taken another TIRF medicine in the past. Titration, if needed, starts at the lowest dose available for that specific product.** Carefully review the initial dosing instructions in each product's specific Prescribing Information.

- **Appropriate Conversion Rules:**

  - TIRF medicines are **not interchangeable**, regardless of route of administration. Significant differences exist in the pharmacokinetic profiles of fentanyl products that result in clinically important differences in the extent of absorption of fentanyl that could result in a fatal overdose.

  - TIRF medicines are **not equivalent** on a microgram-per-microgram basis to any other fentanyl product, including another TIRF medicine. The only exception is for substitution of a generic equivalent for a branded TIRF medicine.

  - **Because of these differences, conversion of a TIRF medicine to another TIRF medicine on a microgram-per-microgram basis may result in fatal overdose.**

  - Therefore, converting from one TIRF medicine to a different TIRF medicine **must not be done on a microgram-per-microgram basis**. The new TIRF medicine must be titrated according to the labeled dosing instructions for each new TIRF medicine the patient begins.

  - The only exception is for substitutions between a branded TIRF medicine and its generic **equivalents**.

Check Your Knowledge - Scenario 3

A patient is already taking a TIRF medicine but wants to change their medicine. His/her doctor decides to prescribe a different TIRF medicine (that is not a bioequivalent generic version of a branded product) in its place. How should the prescriber proceed?

Select any correct option:

A. The prescriber can safely convert to the equivalent dosage of the new TIRF medicine as it has the same effect as other TIRF medicines.
B. The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.
C. Convert from the other TIRF medicine to the new TIRF medicine at half of the dose.
D. The prescriber should base the starting dose of the newly prescribed TIRF medicine on the dose of the opioid medicine used for their underlying persistent cancer pain.
E. The dose that the prescriber believes is appropriate based on their clinical experience.

See answer on page 18

Drug Interactions

- Fentanyl is metabolized mainly by the cytochrome P450 (CYP3A4) isoenzyme system; therefore, potential drug interactions may occur when TIRF medicines are administered concurrently with agents that affect CYP3A4 activity.
  - Concomitant use of TIRF medicines with CYP3A4 inhibitors (e.g., certain protease inhibitors, ketoconazole, fluconazole, diltiazem, erythromycin, verapamil) may increase plasma concentrations of fentanyl and prolong opioid adverse reactions, which may cause potentially fatal respiratory depression.
    - Patients receiving TIRF medicines who begin therapy with or increase the dose of CYP3A4 inhibitors must be carefully monitored for signs of opioid toxicity over an extended period. Dosage increases should be done conservatively.
  - Concomitant use of TIRF medicines with CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin) can decrease the plasma concentration of fentanyl, resulting in decreased efficacy or onset of a withdrawal syndrome in patients who have developed physical dependence to fentanyl.
    - If concomitant use with a CYP3A4 inducer is necessary, consider increasing the dose of the TIRF medicine until stable drug effects are achieved. Monitor for signs of opioid withdrawal. If a CYP3A4 inducer is discontinued, consider reducing the dose of the TIRF medicine and monitor for signs of respiratory depression.

Note: This list does not include a complete list of drug interactions with TIRF medications. Check each drug's Prescribing Information for a complete list.

Maintenance/Dose Adjustments for all TIRF Medicines

- Once a dose that provides adequate analgesia and minimizes adverse reactions is found, that dose should be prescribed for each subsequent episode of breakthrough cancer pain (BTCP).
- Patients must wait at least 2 or 4 hours before treating another episode of breakthrough pain with their TIRF medicine. Please refer to the specific TIRF medicine's Prescribing Information to determine the appropriate dosing interval.
- Limit the use of TIRF medicines to no more than 4 doses per day.
- If the prescribed dose no longer adequately manages the BTCP for several consecutive episodes, increase the dose as described in the titration section of the Prescribing Information.
- Consider increasing the dose of the around-the-clock opioid medicine used for persistent cancer pain in patients experiencing more than 4 BTCP episodes per day.

Naloxone

- Prescribers should consider prescribing naloxone for the emergency treatment of opioid overdose.
- If concomitant use with benzodiazepines, other CNS depressants, or muscle relaxants is warranted, prescribers should consider prescribing naloxone for the emergency treatment of opioid overdose.
- Educate patients and caregivers on how to recognize respiratory depression and emphasize the importance of calling 911 or getting emergency medical help right away in the event of a known or suspected overdose. *(See patient counseling section below).*
- Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver both when initiating and renewing treatment with TIRF products.
- Inform patients about the various ways to obtain naloxone.

Counsel Patients Concerning Risks of TIRF Medicines

- Tell patients exactly how to take the TIRF medicine. Instruct them to take the TIRF medicine strictly as prescribed, with special regard to dosage, dose titration, administration and proper disposal of partially used or unneeded TIRF medicine.
- Remind patients they **must be** opioid tolerant to be able to take a TIRF medicine for their breakthrough cancer pain. Opioid tolerant means that the patient is

already using around-the-clock daily opioid pain medicine for constant pain for 1 week or longer.

- If the patient stops taking around-the-clock opioid pain medicine for their constant pain, the patient **must stop taking their TIRF medicine because they may no longer be opioid tolerant**.
    - **Note:** Patients have had difficulty understanding this concept. Emphasize this requirement to your patients and explain that the risk of life-threatening and/or fatal breathing problems with their TIRF medicine increases if they are not taking around-the-clock opioid pain medicines.
- TIRF medicines can cause serious side effects, including life-threatening breathing problems that can lead to death. The patient must take the TIRF medicine exactly as prescribed.
- Instruct patients to store their TIRF medicines in a safe and secure place, out of the sight and reach of all others, especially children. Accidental or deliberate ingestion of a TIRF medicine by a child may cause severe, possibly even fatal, respiratory depression. Advise patients to seek immediate medical attention if a child is exposed to a TIRF medicine.
- Talk with patients about Naloxone.
    - Naloxone is a medicine that helps reverse opioid overdose. It is sprayed inside the nose or injected into the body. Some naloxone products are designed for people to use in their home.
    - The patient should immediately use naloxone if they have it and call 911 and wait for emergency medical services if:
        - The patient or someone else has taken an opioid medicine, including a TIRF medicine, and is having trouble breathing, is short of breath, or is unusually sleepy.
        - A child has accidentally taken an opioid medicine, including a TIRF medicine, or if it is suspected that they might have.
    - Giving naloxone to a person, even a child, who has not taken an opioid medicine will not hurt them.
    - Naloxone is never a substitute for emergency medical care. Always call 911 and go to the emergency room if the patient or someone else has used or been given naloxone.
    - Ask your healthcare provider how you can get naloxone. Naloxone is available in pharmacies, and in some states, you may not need a prescription.
    - Keep naloxone in a place where the patient, the patient's family or friends can get to it in an emergency.
- Talk with patients about safe and appropriate disposal of TIRF medicines.

- Inform patients that TIRF medicines have a rapid onset of action.
- Pharmacists and prescribers must specifically question patients or their caregivers about the presence of children in the home (on a full-time or visiting basis) and counsel them regarding the dangers to children from inadvertent exposure.
- Refer patients to their prescribing healthcare provider if they have additional questions about their regimen(s) or dosing.
- Inform patients that TIRF medicines have significant risks for drug-drug interactions:
    - Fentanyl is metabolized mainly by the cytochrome P450 (CYP3A4) isoenzyme system; therefore, potential drug interactions may occur when TIRF medicines are administered concurrently with agents that affect CYP3A4 activity. Concurrent use of TIRF medicines with CYP3A4 inhibitors such as certain protease inhibitors, ketoconazole, fluconazole, diltiazem, erythromycin, verapamil may <u>increase</u> plasma concentrations of fentanyl and prolong opioid adverse reactions, which could lead to potentially fatal respiratory depression. Concomitant use of TIRF medicines with CYP3A4 inducers (e.g., rifampin, carbamazepine, phenytoin) can decrease the plasma concentration of fentanyl, resulting in <u>decreased</u> efficacy or onset of a withdrawal syndrome in patients who have developed physical dependence to fentanyl.
    - Due to the additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS depressants, including alcohol, <u>increases</u> the risk of respiratory depression, profound sedation, coma, and death. Warn patients that it is extremely dangerous to self-administer non-prescribed benzodiazepines or other CNS depressants including alcohol while taking TIRF medicines. Caution patients who are prescribed benzodiazepines or other CNS depressants to use them only as directed by their prescriber.
    - The concomitant use of opioids with other drugs that affect the serotonergic neurotransmitter system can induce serotonin syndrome.
    - Monoamine oxidase inhibitors (MAOIs) interactions with opioids may manifest as serotonin syndrome.
    - Mixed agonist/antagonist and partial agonist opioid analgesics may <u>reduce</u> the analgesic effect of TIRF medicines and/or precipitate withdrawal symptoms.
    - Fentanyl may <u>enhance</u> the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.

Check Your Knowledge - Scenario 4

Before initiating treatment with a TIRF medicine, prescribers must review the Medication Guide with the patient. Which of the following counseling statements are FALSE?

Select any statements which are false.

A. TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.

B. Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.

C. Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.

D. Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

E. Once a patient becomes familiar with the use of their TIRF medicine, if their BTCP is not controlled they can repeat their dose every 20 minutes until their pain is relieved.

See answer on page 18

REPORTING ADVERSE EVENTS

S**erious** Adverse events, **including adverse events** of special interest, including the misuse, abuse, addiction, overdose, death or accidental exposure of a TIRF medicine, s**hould** be reported online at **www.TIRFREMSaccess.com** by use of the:

- **Patient Status and Opioid Tolerance Form**, or
- **Adverse Events of Special Interest Reporting Form**

Adverse events may also be reported by contacting the TIRF REMS at **1-866-822-1483.**

Products* Covered Under this Program:

Product	Dosage and Administration			
	Initial dose	Maximum Dose Per Episode	Frequency	Titration
Actiq® (fentanyl citrate) oral transmucosal lozenge	Always 200 mcg.	If the breakthrough pain episode is not relieved after 30 minutes, patients may take one (1) additional dose using the same strength. Patients should not take more than two (2) doses of ACTIQ per breakthrough pain episode.	Patients must wait at least Four (4) hours before treating another breakthrough pain episode with ACTIQ.	Closely follow patients and change the dosage level until adequate analgesia with tolerable side effects is achieved with angle unit.
FENTORA® (fentanyl buccal tablet)	Always 100 mcg (unless the patient is being converted from ≥600 mcg ACTIQ - please see Prescribing Information)	If the breakthrough pain episode is not relieved after 30 minutes, patients may take one (1) additional dose using the same strength. Patients should not take more than two (2) doses of FENTORA per breakthrough pain episode. Patients must wait at least four (4) hours before treating another breakthrough pain episode with FENTORA.	For patients being converted from ACTIQ, prescribers must use the Initial Dosing Recommendations for Patients on ACTIQ found in Table 1 of the Prescribing Information. The doses of FENTORA in the table are starting doses and not intended to represent equip-analgesic doses to ACTIQ.	Closely follow patients and change the dosage level until adequate analgesia is achieved with a single tablet. During titration, patients can be instructed to use multiple tablets (one on each side of the mouth in the upper/lower buccal cavity) until a maintenance dose is achieved.

Product	Dosage and Administration			
	Initial dose	Maximum Dose Per Episode	Frequency	Titration
Lazanda® (fentanyl) nasal spray	Always 100 mcg	Only use LAZANDA once (1 time) per cancer breakthrough pain episode; i.e., do not re-dose LAZANDA within an episode. Patients must wait at least two (2) hours before treating another episode of breakthrough pain with LAZANDA.	Limit LAZANDA use to four (4) or fewer doses per day.	If adequate analgesia was not obtained with the first 100 mcg dose, continue dose escalation in a stepwise manner over consecutive breakthrough pain episodes until adequate analgesia with tolerable side effects is achieved. Patients should confirm the dose of LAZANDA that works for them with a second episode of breakthrough pain.
Subsys® (fentanyl sublingual spray)	Always 100 mcg (unless the patient is being converted from >600 mcg ACTIQ – please see Prescribing Information.	If the breakthrough pain episode is not relieved after 30 minutes, patients may take one (1) additional dose using the same strength. Patients should not take more than 2 doses of SUBSYS per episode of breakthrough pain.	Patients must wait at least four (4) hours before treating another episode of breakthrough pain with SUBSYS.	Closely follow patients and change the dosage level until adequate analgesia is achieved using a single dose per episode of breakthrough cancer pain.

Note: This table is also available to print for use as a quick reference guide. Please visit www.TIRFREMSaccess.com for further information and resources.

* This includes approved generic equivalents of these products.

For more information about TIRF medicines, see the Prescribing Information, including the BOXED WARNING, for each product.

Resources for More Information

If you have any questions and/or need additional information or copies of any TIRF REMS documents, please visit the program website at www.TIRFREMSaccess.com or call the TIRF REMS at 1-866-822-1483.

ANSWER KEY

Scenarios: Answers and Rationales

Scenario 1: Patient Counseling on use of ATC Opioids

Item A, B, and D Response. This statement is correct.

Item C Response: This statement is incorrect. Patients should be instructed that, if they stop taking their around-the-clock opioid medicine, they must discontinue taking their TIRF medicine.

Item E Response: This statement is incorrect. Individual TIRF medicines have different and product-specific number of times they may be repeated per BTCP occurrence. Patients should be counseled that: they must never use more doses of their TIRF medicine than directed per instance of BTCP occurrence due to the toxicity of fentanyl; and, when their breakthrough pain is not controlled by their TIRF medicine, they should call their prescriber for evaluation.

Scenario 2: Patient Selection/Opioid Tolerance:

Item A, D, and E Response: This patient is appropriate for treatment with a TIRF medicine.

Item B Response: This patient is not appropriate for treatment with a TIRF medicine. TIRF medicines are indicated for use in treatment of BTCP in patients who are 18 years of age or older (or 16 years of age and older in the case of ACTIQ use.)

Item C Response: This patient is not appropriate for treatment with a TIRF medicine. This patient does not meet the definition of “opioid-tolerant” which in the case of oral morphine use as her opioid background regimen would require daily use for at least one previous week of 60 mg or more of morphine.

Scenario 3: Accidental Ingestion or Exposure

Item D: Correct, TIRF medicines can be fatal if taken by children, by anyone for whom it is not prescribed, or by anyone who is opioid non-tolerant.

Items A, B, C: This answer is correct however Answer D most accurate. TIRF medicines can be fatal if taken by children, by anyone for whom it is not prescribed, or by anyone who is opioid non-tolerant.

Scenario 4: Dosage and Administration General

Item B and D Response: Correct. Conversions must not occur on a microgram-for-microgram basis due to the difference in the absorption and bioavailability profiles of the different TIRF products.

Item A or C or E Response: Incorrect. The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose, a simple ½ reduction of the microgram dosage or estimates based on prior clinical experience. Because TIRF medicines have different absorption and bioavailability profiles, conversion to an alternate TIRF product must be done at the newly prescribed TIRF medicine’s lowest available dose. Conversions must be based on individual product provided product-specific guidance obtain from the Prescribing Information.

Pharmacy Knowledge Assessment

TIRF REMS

Instructions

To submit this form via fax, please fill in the authorized representative information, answer all questions, and fax all pages to 1-866-822-1487. You will receive enrollment confirmation via email or fax.

For real-time processing of this Knowledge Assessment, please go to www.TIRFREMSaccess.com.

1 Authorized Representative Information (PLEASE TYPE OR PRINT)

First Name	Last Name	Credentials
		☐ RPh ☐ PharmD ☐ BCPS ☐ Other

Email Address	Phone	Fax	Position/Title
	( )	( )	

2 Knowledge Assessment

Question 1

The patients described are all experiencing breakthrough cancer pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine?

Select one option

A. 12-year-old sarcoma patient, using 25 mcg/hour transdermal fentanyl patches for her underlying persistent cancer pain.
B. Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
C. Adult male with advanced lung cancer, his underlying persistent pain is managed with transdermal fentanyl patches for the past 3 months.
D. Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.
E. Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

Question 2

Pharmacists can assist in prevention of diversion or accidental exposure of TIRF medicines by people for whom they are not prescribed. Which of the following statements is TRUE?

Select one option.

A. Pharmacists should counsel TIRF medicine users to keep their TIRF medicine out of reach of children and pets.
B. Pharmacists should counsel TIRF medicine users to refer to safe disposal guidelines in the TIRF product-specific Medication Guide.
C. Pharmacists should counsel patients not to share their TIRF medicine with anyone else even if their symptoms are the same as it could result in serious life threatening and/or fatal respiratory depression.
D. Remind patients to call their prescriber if they have questions about usage of their TIRF medicine.
E. All of the above.

Continued on next page

Question 3

A patient's prescriber has ordered a new TIRF medicine for the patient. What dose must they start with?

Select one option.

A. An appropriate dose based on the dose of the opioid medicine used for underlying persistent cancer pain.
B. The dose the prescriber believes is appropriate based on the previous clinical history of TIRF medicine use.
C. The lowest available dose, unless individual product Prescribing Information provides product-specific guidance.
D. The median available dose.
E. The dose the prescriber believes is appropriate based on their clinical experience.

Question 4

Select the following statement which is FALSE.

Select one option.

A. Before dispensing, the pharmacy must check the patient's medication use for a change in opioid tolerance. This could include reviewing data from various sources (e.g. -available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)
B. When a patient's breakthrough cancer pain is not relieved by their TIRF medicine, he/she may repeat their dose of TIRF medicine every 20 minutes until they achieve pain relief.
C. TIRF medicines are not interchangeable on a microgram-per-microgram basis.
D. The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.

Question 5

Which of the following is not a pharmacy requirement in the TIRF REMS?

Select one option.

A. The authorized representative must train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the TIRF REMS using the Pharmacy Education.
B. The authorized representative must re-enroll in the TIRF REMS by completing the Outpatient Pharmacy Enrollment Form.
C. Before dispensing, the pharmacy must check the patient's medication use for a change in opioid tolerance. This could include reviewing data from various sources (e.g. - available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)
D. The pharmacy may dispense the first prescription to the patient before the patient is enrolled in the TIRF REMS as long as the patient is enrolled before the next dispensing.

Question 6

A patient is taking a TIRF medicine and the doctor would like to prescribe erythromycin, a CYP3A4 inhibitor. Which of the following statements is TRUE?

Select one option.

A. The patient cannot be prescribed erythromycin, because using it at the same time as a TIRF medicine could be fatal.
B. Use of a TIRF medicine with a CYP3A4 inhibitor may require dosage adjustment of the TIRF medicine; carefully monitor the patient for opioid toxicity, otherwise such use may cause potentially fatal respiratory depression.
C. There is no possible drug interaction between CYP3A4 inhibitors and TIRF medicines.
D. The dose of the TIRF medicine must be reduced by one half if a CYP3A4 inhibitor is prescribed in the same patient.

Continued on next page

Question 7

Before dispensing a TIRF medicine, pharmacists must provide a patient with the Medication Guide. Which of the following counseling statements is FALSE?

Select one option.

A. TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.
B. Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.
C. Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.
D. Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

Question 8

There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate?

Select one option.

A. TIRF medicines can be fatal if taken by children.
B. TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
C. TIRF medicines can be fatal if taken by anyone who is not opioid-tolerant.
D. All of the above.

Question 9

Which of the following statements is FALSE?

Select one option.

A. A REMS Dispense Authorization is required before dispensing TIRF medicines at all outpatient pharmacies.
B. A REMS Dispense Authorization is not required when the patient is paying by cash rather than submitting a traditional pharmacy benefit claim.
C. A REMS Dispense Authorization is not required prior to dispensing TIRF medicines to hospital inpatients.
D. A REMS Dispense Authorization at an outpatient pharmacy confirms that the required opioid tolerance verification is on file with the TIRF REMS prior to dispensing.

Question 10

Which one of the following statements is most accurate regarding the safe storage and disposal of TIRF medicines?

Select one option.

A. TIRF medicines should be stored in a safe and secure place, out of sight and out of reach of all others, especially children.
B. TIRF medicines should be protected from theft.
C. Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
D. All of the above.

Continued on next page

Question 11:

As an authorized representative for my pharmacy, which of the following is <u>not</u> my responsibility?

Select one option.

A. Make sure that my staff and I confirm pharmacy, patient and prescriber enrollment in the TIRF REMS and patient opioid tolerance by obtaining a REMS Dispense Authorization prior to every outpatient dispensing of a TIRF medicine.
B. Enroll and train all sub-stores if my pharmacy acts as a chain headquarters pharmacy in the TIRF REMS.
C. Provide a Patient Status and Opioid Tolerance Form to the TIRF REMS for every prescription prior to dispensing.
D. My pharmacy must not sell, loan or transfer TIRF medicine inventory to any other pharmacy, institution, distributor, or prescriber.

Required	**Pharmacy Authorized Representative Signature** **X**	**Date:** / /

Pharmacy Knowledge Assessment Key

Question #	Answer
1	A
2	E
3	C
4	B
5	D
6	B
7	C
8	D
9	B
10	D
11	C

Patient Status and Opioid Tolerance Form

INSTRUCTIONS:

- Patients receiving TIRF medicines for outpatient use must be enrolled in the TIRF REMS prior to receiving their first TIRF prescription.
- This form must be completed by the prescriber and submitted to the TIRF REMS prior to each subsequent prescription for outpatient use.
- All fields with asterisks (*) are required.
- For real time processing, complete this form online at TIRFREMSaccess.com.
- The form may also be faxed to the program at 1-855-474-3062. If faxed, allow one (1) business day for processing.
- **Prescriptions will not be authorized for dispensing until this continuation form is on file at the TIRF REMS.**

1 Patient Information (please type or print)

First Name*	M.I.*	Last Name*	Date of Birth* (MM/DD/YYYY)	Zip Code*

TIRF Product Name*	Strength*	Dose*	Frequency*

2 Concomitant Medications

Check all that apply*:

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

3 Medical Information

Type of Pain*:

- ☐ Cancer pain
- ☐ Non-cancer pain

4 Prescriber Information (please type or print)

First Name*	MI.	Last Name*	Individual NPI #*

Phone*	Extension*	Fax*

Email Address*

Continued on next page

5 Adverse Events of Special Interest

Adverse events that MUST be reported to the TIRF REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse events

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine? *

☐ **NO** ➡ Continue to section 6 (Verify Opioid Tolerance)

☐ **YES –** Complete and submit the **Adverse Events of Special Interest Reporting Form.** This form is available via www.TIRFREMSaccess.com or by contacting 1-866-822-1483.

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

6 Verify Opioid Tolerance*

Moiety*	Formulation*	Strength*	Route*	Dose*	Frequency*

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply)*:

☐ ≥ 60 mg oral morphine/day
☐ ≥ 30 mg oral oxycodone/day
☐ ≥ 25 mg oral oxymorphone/day
☐ An equianalgesic dose of another opioid
☐ ≥ 25 micrograms transdermal fentanyl/hour
☐ ≥ 8 mg oral hydromorphone/day
☐ ≥ 60 mg oral hydrocodone/day

I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

7 Prescriber Signature

Prescriber Signature*:	Date*:

Complete this form online at TIRFREMSaccess.com or fax the completed form to 1-855-474-3062.

Please visit TIRFREMSaccess.com or call 1-866-822-1483 for more information about the TIRF REMS.

TIRF REMS

Adverse Events of Special Interest Reporting Form

INSTRUCTIONS:

- **Adverse events related to accidental exposure, misuse, abuse, addiction, overdose or other serious adverse events must be reported to the TIRF REMS.**
- This form must be completed to report an adverse event of special interest to the TIRF REMS for any patient taking a TIRF medicine.
- For real-time processing, complete this form online at www.TIRFREMSaccess.com by logging on, selecting the patient, and reporting the Adverse Event of Special Interest.
- The form may also be faxed to the program at 1-855-474-3062. If faxed, allow one (1) business day for processing.

*Indicates required field

1 Patient Information (please print)

First Name*	M.I.	Last Name*	Date of Birth* (MM/DD/YYYY)	Zip Code*

TIRF Product Name (if known)	Strength (if known)	Dose (if known)	Frequency (if known)

2 Reporter Information (please print)

First Name*	MI.	Last Name*	Individual NPI # (if applicable)

Phone*	Extension*	Fax*

Email Address*	Best Time to Contact: ☐ Morning ☐ Afternoon ☐ Evening

3 Adverse Events of Special Interest

Adverse events related to accidental exposure, misuse, abuse, addiction, overdose or other serious adverse events must be reported to the TIRF REMS.
If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Check all that apply below

- ☐ **Experienced an overdose of their TIRF medicine** (**Overdose** - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)
- ☐ **Shown signs or symptoms of addiction to their TIRF medicine** (**Addiction** – a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)
- ☐ **Misused or been suspected of misusing their TIRF medicine** (**Misuse** - the use of a medicinal product without a prescription or in a manner other than as directed by a physician, including use without a prescription of one's own; use in greater amounts to feel euphoria (i.e. to get high), more often, or for a period longer than prescribed; or use in any other way not directed by the prescribing physician)
- ☐ **Abused or been suspected of abusing their TIRF medicine** (**Abuse** - intentional non-therapeutic use of a medicinal product, even once, for its rewarding psychological or physiological or euphoric effect, and often associated with physical dependence)
- ☐ **Someone else has been accidentally exposed to the patient's TIRF medicine** (**Accidental exposure** - unintended exposure of a medicinal product to someone other than to whom it was prescribed)
- ☐ **Another serious adverse event (Serious Adverse Event** – any adverse event at any dose that results in death, is life-threatening, requires inpatient hospitalization, or causes prolongation of existing hospitalization)

4 Reporter Signature

Reporter Signature*:	Date*:

Complete this form online at www.TIRFREMSaccess.com or fax the completed form to 1-855-474-3062.

Please visit TIRFREMSaccess.com or call 1-866-822-1483 for more information about the TIRF REMS.

TIRF REMS

Patient Discontinuation Form

INSTRUCTIONS:

- This form must be completed and submitted to the TIRF REMS by the prescriber when a patient discontinues treatment with TIRF medicines for any reason.
- For real time processing, complete this form online at TIRFREMSaccess.com.
- The form may also be faxed to the program at 1-855-474-3062. If faxed, allow one (1) business day for processing.
- **Adverse events related to accidental exposure, misuse, abuse, addiction, overdose or other serious adverse events must be reported to the TIRF REMS by the Adverse Events of Special Interest Reporting Form.**

*Indicates required field

1	Patient Information (please type or print)			
First Name*	M.I.	Last Name*	Date of Birth* (MM/DD/YYYY)	Zip Code*

2	Prescriber Information (please type or print)		
First Name*	MI.	Last Name*	Individual NPI #*
Phone*	Extension*	Fax*	
Email Address*			

3 Discontinuation of a TIRF Medicine

Was the TIRF medicine discontinued? ☐ **YES** ☐ **NO**

Date TIRF medicine was discontinued: _____

Reason for discontinuation (check all that apply):

- ☐ **No longer required to manage pain**
- ☐ **No longer on around-the-clock Opioid**
- ☐ **Death** ➡ **Date:** _____ **Cause of Death:** _____
- ☐ **Adverse event** ➡ Complete Section 4
- ☐ **Other (financial reasons, patient preference, etc.)**

4 Adverse Events of Special Interest

Adverse events related to accidental exposure, misuse, abuse, addiction, overdose or other serious adverse events must be reported to the TIRF REMS.

Has this patient experienced one or more of the following adverse events of special interest associated with the use of their TIRF medicine? *

☐ **NO ➡ Continue to Section 5 Prescriber Signature**

☐ **YES – Check all that apply below** (Adverse Events of Special Interest)

- ☐ **Experienced an overdose of their TIRF medicine** (**Overdose** - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)
- ☐ **Shown signs or symptoms of addiction to their TIRF medicine** (**Addiction** – a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)
- ☐ **Misused or been suspected of misusing their TIRF medicine** (**Misuse** - the use of a medicinal product without a prescription or in a manner other than as directed by a physician, including use without a prescription of one's own; use in greater amounts to feel euphoria (i.e. to get high), more often, or for a period longer than prescribed; or use in any other way not directed by the prescribing physician)
- ☐ **Abused or been suspected of abusing their TIRF medicine** (**Abuse** - intentional non-therapeutic use of a medicinal product, even once, for its rewarding psychological or physiological or euphoric effect, and often associated with physical dependence)
- ☐ **Someone else has been accidentally exposed to the patient's TIRF medicine** (**Accidental exposure** - unintended exposure of a medicinal product to someone other than to whom it was prescribed)
- ☐ **Another serious adverse event (Serious Adverse Event** – any adverse event at any dose that results in death, is life-threatening, requires inpatient hospitalization, or causes prolongation of existing hospitalization)

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

5 Prescriber Signature

Prescriber Signature*:	Date*:

Complete this form online at TIRFREMSaccess.com or fax the completed form to 1-855-474-3062.

Please visit TIRFREMSaccess.com or call 1-866-822-1483 for more information about the TIRF REMS.

<Date>

Changes to Requirements of the TIRF REMS

Subject: - Program changes effective (DATE)
- Current prescribers must re-enroll in TIRF REMS
- Prescribers must document that patients are opioid-tolerant
- Patients who are not opioid-tolerant must be transitioned to alternate therapy

Dear Healthcare Provider:

The TIRF REMS Access Program, now called the TIRF REMS, has been modified and the requirements of the program have changed. You will need to take action within the TIRF REMS system in order to continue to prescribe TIRF medicines.

You will need to re-certify in order to continue dispensing TIRF medicines. Only patients who are opioid-tolerant (see definition below) will be able to receive a TIRF medicine.

Key Modifications:
Only prescribers enrolled and certified in the modified TIRF REMS, effective <DATE>, will be able to prescribe TIRF medicines for outpatient use.

- The prescriber must document and provide verification of the patient's opioid tolerance, per the product labeling, to the TIRF REMS prior to each prescription being authorized for dispense at an outpatient pharmacy every time a TIRF medicine is prescribed.
- As of <DATE>, patients who are not opioid-tolerant will not be able to obtain a TIRF medicine; they must be transitioned off of their TIRF medicine, and to an alternate therapy if appropriate.
- All patients in the outpatient setting must be enrolled into the new TIRF REMS registry to assess safe use and trends in accidental exposure, misuse, abuse, addiction, and overdose.

Starting (DATE), prescriptions will only be filled when:

1. The prescriber is enrolled in the new TIRF REMS,
2. The patient has been enrolled in the new TIRF REMS, and
3. The patient's opioid tolerance has been documented.

What must I do to participate in the modified TIRF REMS?

All current prescribers must re-enroll and re-certify into the modified program

Prescribers must review the modified **Prescriber Education**, complete the **Knowledge Assessment** and sign the **Prescriber Enrollment Form**.

Go to www.TIRFREMSAccess.com to re-enroll and become certified online. You can also find all the materials you need to download and fax to the TIRF REMS to become certified.

Prescribers must enroll all OUTPATIENTS prior to prescribing a TIRF medicine

Products covered under the TIRF REMS include: 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

All outpatients must be enrolled, including those currently receiving a TIRF medicine, starting on <Date>.

Prescribers must complete and submit a **Patient Enrollment Form** before prescribing a TIRF medicine for every patient in an outpatient setting. This will automatically enroll the patient into the TIRF REMS registry.

Prescribers must document Patient's Opioid Tolerance per the labeling definition
Patients are considered opioid-tolerant if they are currently taking (exclusive of the TIRF medicine) one or more of the following opioid regimens daily and they have been on the regimen(s) for one week or longer:

- ≥ 60 mg oral morphine/day
- ≥ 30 mg oral oxycodone/day
- ≥ 25 mg oral oxymorphone/day
- an equianalgesic dose of another opioid
- ≥ 25 mcg transdermal fentanyl/hour
- ≥ 8 mg oral hydromorphone/day
- ≥ 60 mg oral hydrocodone/day

What if my patient is not opioid-tolerant?

You must transition a patient who is not opioid-tolerant from a TIRF medicine to another treatment if needed.

Under the modified program as of <DATE>, the patient will no longer be able to receive a TIRF medicine at the pharmacy.

All materials can be found at www.TIRFREMSAccess.com

For additional information related to the TIRF REMS and recent program modifications, please call **1-866-822-1483**.

Sincerely,

TIRF REMS

<Date>

Changes to Requirements of the TIRF REMS

Subject: - Current outpatient pharmacies must re-certify in TIRF REMS
- Currently stocked TIRF medicines must be returned if you do not re-certify
- Program changes effective (DATE).

Dear Outpatient Pharmacy:

The TIRF REMS Access Program, now called the TIRF REMS, has been modified and the requirements of the program have changed. You will need to take action in order to continue dispensing TIRF medicines.

You will need to re-certify in order to continue dispensing TIRF medicines if you remain as a qualified dispenser.

Key Modifications:
Only pharmacies certified in the modified TIRF REMS, effective <DATE>, will be able to dispense TIRF medicines to patients.

- All pharmacies will be required to obtain an authorization to dispense from the TIRF REMS, online or over the phone, for every prescription for a TIRF medicine.
- As of <DATE>, pharmacies that are not certified in the TIRF REMS will not be able to dispense TIRF medicines and will be required to return all currently stocked TIRF products to the distributor or manufacturer.
- TIRF medicines can only be obtained from qualified wholesalers/distributors that are enrolled in the TIRF REMS.

Starting (DATE), you may only fill prescriptions when:

1. Your pharmacy has re-certified in the modified TIRF REMS,
2. You obtain stock of TIRF medicines from a qualified and enrolled wholesale distributor, and
3. You obtain a TIRF REMS dispense authorization issued by the TIRF REMS prior to dispensing a prescription for a TIRF medicine.

What must I do to participate in the modified TIRF REMS?

All current pharmacies must re-certify in the modified program.
The pharmacy must designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. To re-certify the pharmacy, the authorized representative must review the modified **Education Program**, successfully complete the **Knowledge Assessment**, and complete the **Outpatient Pharmacy Enrollment Form** through the TIRF REMS website, or complete and fax the signed **Knowledge Assessment** and enrollment form to the TIRF REMS.

Go to www.TIRFREMSAccess.com to re-enroll and become certified online. You can also find all the materials you need to download and fax to the TIRF REMS to become certified.

Pharmacies must re-certify prior to dispensing a TIRF medicine
Pharmacies must complete and submit an **Outpatient Pharmacy Enrollment Form** before dispensing a TIRF medicine.

Pharmacies must check the Patient's Opioid Tolerance
Before obtaining a dispense authorization, the pharmacy must check the patient's opioid tolerance. This could include reviewing data from various sources, for example:

- available state Prescription Drug Monitoring Programs (PDMPs),
- the patient's records in the pharmacy's management system, and
- information provided by the TIRF REMS.

Talk to Patients who are Not Opioid-tolerant

- Tell patients who are not opioid-tolerant to work with their doctors to transition off of their TIRF medicine.

What if the Pharmacy does not re-certify in the modified TIRF REMS?

- The pharmacy will not be able to dispense TIRF medicines and will be required to return all currently stocked TIRF products to the distributor or manufacturer by (date).
- You may need to assist patients in finding a pharmacy certified in the TIRF REMS.

All materials can be found at www.TIRFREMSAccess.com

For additional information related to the TIRF REMS and recent program modifications, please call **1-866-822-1483**.

Sincerely,

TIRF REMS

<Date>

Changes to Requirements of the TIRF REMS

Subject: - Current inpatient pharmacies must re-certify in TIRF REMS
- Currently stocked TIRF medicines must be returned if you do not re-certify
- Program changes effective (DATE).

Dear Inpatient Pharmacy:

The TIRF REMS Access Program, now called the TIRF REMS, has been modified and the requirements of the program have changed. You will need to take action in order to continue dispensing TIRF medicines.

You will need to re-certify in order to continue dispensing TIRF medicines if you remain as a qualified dispenser.

Key Modifications:
Only pharmacies certified in the modified TIRF REMS, effective <DATE>, will be able to dispense TIRF medicines to patients.

- All pharmacies will be required to verify the patient is opioid tolerant through the processes and procedures established as a requirement of the TIRF REMS.
- As of <DATE>, pharmacies that are not certified in the TIRF REMS will not be able to dispense TIRF medicines and will be required to return all currently stocked TIRF products to the distributor or manufacturer.
- TIRF medicines can only be obtained from qualified wholesalers/distributors that are enrolled in the TIRF REMS.

Starting (DATE), you may only fill prescriptions when:

1. your pharmacy has re-certified in the modified TIRF REMS,
2. you obtain stock of TIRF medicines from a qualified and enrolled wholesale distributor and
3. you verify the patient is opioid tolerant through the processes and procedures established as a requirement of the REMS.

What must I do to participate in the modified TIRF REMS?

All current pharmacies must re-certify in the modified program.
All currently enrolled pharmacies must re-certify in the TIRF REMS and attest to the modified program requirements to be eligible to dispense TIRF medicines to patients.

The pharmacy must designate an authorized representative to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. To re-certify the pharmacy, the authorized representative must review the modified

Education Program, successfully complete the **Knowledge Assessment**, and complete the **Inpatient Pharmacy Enrollment Form** through the TIRF REMS website, or complete and fax the signed **Knowledge Assessment** and enrollment form to the TIRF REMS

Go to www.TIRFREMSAccess.com to re-enroll and become certified online. You can also find all the materials you need to download and fax to the TIRF REMS to become certified.

Pharmacies must re-certify prior to dispensing a TIRF medicine
Pharmacies must complete and submit an **Inpatient Pharmacy Enrollment Form** before dispensing a TIRF medicine.

Pharmacies must verify the Patient's Opioid Tolerance
Inpatient pharmacies are required to develop policies and procedures to verify the patient's opioid tolerance prior to dispensing. This could include reviewing data from various sources, for example:

- available state Prescription Drug Monitoring Programs (PDMPs),
- the patient's records in the pharmacy's management system, and
- information provided by the TIRF REMS.

What if the Pharmacy does not re-certify in the modified TIRF REMS?

- The pharmacy will not be able to dispense TIRF medicines and will be required to return all currently stocked TIRF products to the distributor or manufacturer.

All materials can be found at www.TIRFREMSAccess.com

For additional information related to the TIRF REMS and recent program modifications, please call **1-866-822-1483**.

Sincerely,

TIRF REMS

<Date>

Urgent Notification Regarding TIRF Products Stock

Subject:	**Returning TIRF products from wholesaler-distributor or pharmacy stock to the manufacturer for wholesalers-distributors not enrolled in the modified TIRF REMS or pharmacies not certified in the modified TIRF REMS.**

Dear Wholesaler-Distributor or Pharmacy:

The purpose of this letter is to inform wholesalers-distributors not enrolled in the modified TIRF REMS and pharmacies not certified in the modified TIRF REMS to immediately return TIRF products from stock to the manufacturer.

You have been identified as a previously enrolled wholesaler-distributor or certified pharmacy in the TIRF REMS.

If you plan to re-enroll/re-certify:

If you are planning on re-enrolling/re-certifying, please visit the TIRF REMS website at www.TIRFREMSaccess.com for information about enrollment in the modified REMS, including Frequently Asked Questions.

If you do not plan to re-enroll/re-certify:

Wholesalers-Distributors must be enrolled in the modified TIRF REMS to purchase and distribute TIRF products. Wholesalers-Distributors not enrolled in the modified TIRF REMS must immediately return TIRF products from stock to the manufacturer. **Only enrolled Wholesalers-Distributors can purchase and distribute TIRF products.**

Pharmacies must be certified in the modified TIRF REMS to dispense TIRF products. Pharmacies not certified in the modified TIRF REMS must immediately return TIRF products from stock to the manufacturer. **Only certified pharmacies can dispense TIRF products.** Patients will no longer be able to fill prescriptions at pharmacies not certified in the modified TIRF REMS.

TIRF medicines are sold in the following presentation:

Product Description	NDC	Package Size
Actiq® (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 200 mcg	63459-0502-30	30 lozenge per box
Actiq® (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 400 mcg	63459-0504-30	30 lozenge per box
Actiq® (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 600 mcg	63459-0506-30	30 lozenge per box
Actiq® (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 800 mcg	63459-0508-30	30 lozenge per box
Actiq® (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 1200 mcg	63459-0512-30	30 lozenge per box

<Date>

Product Description	NDC	Package Size
Actiq® (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 1600 mcg	63459-0516-30	30 lozenge per box
Authorized generic (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 200 mcg	00093-7865-65	30 lozenge per box
Authorized generic (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 400 mcg	00093-7866-65	30 lozenge per box
Authorized generic (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 600 mcg	00093-7867-65	30 lozenge per box
Authorized generic (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 800 mcg	00093-7868-65	30 lozenge per box
Authorized generic (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 1200 mcg	00093-7869-65	30 lozenge per box
Authorized generic (fentanyl citrate) oral transmucosal lozenge (NDA 20747) 1600 mcg	00093-7870-65	30 lozenge per box
Fentora® fentanyl buccal tablet (NDA 021947) 100 mcg	63459-0541-28	28 tablets per box
Fentora® fentanyl buccal tablet (NDA 021947) 200 mcg	63459-0542-28	28 tablets per box
Fentora® fentanyl buccal tablet (NDA 021947) 400 mcg	63459-0544-28	28 tablets per box
Fentora® fentanyl buccal tablet (NDA 021947) 600 mcg	63459-0546-28	28 tablets per box
Fentora® fentanyl buccal tablet (NDA 021947) 800 mcg	63459-0548-28	28 tablets per box
Authorized generic fentanyl buccal tablet (NDA 021947) 100 mcg	51862-634-28	28 tablets per box
Authorized generic fentanyl buccal tablet (NDA 021947) 200 mcg	51862-635-28	28 tablets per box
Authorized generic fentanyl buccal tablet (NDA 021947) 400 mcg	51862-636-28	28 tablets per box
Authorized generic fentanyl buccal tablet (NDA 021947) 600 mcg	51862-637-28	28 tablets per box
Authorized generic fentanyl buccal tablet (NDA 021947) 800 mcg	51862-638-28	28 tablets per box
Lazanda (fentanyl nasal spray), 100 mcg	71500-110-01	1 unit in 1 carton
Lazanda (fentanyl nasal spray), 400 mcg	71500-140-01	1 unit in 1 carton
Onsolis, fentanyl buccal soluble film, 200 mcg strength	0037-5200-30	30 units per carton
Onsolis, fentanyl buccal soluble film, 400 mcg strength	0037-5400-30	30 units per carton
Onsolis, fentanyl buccal soluble film, 600 mcg strength	0037-5600-30	30 units per carton
Onsolis, fentanyl buccal soluble film, 800 mcg strength	0037-5800-30	30 units per carton
Onsolis, fentanyl buccal soluble film, 1200 mcg strength	0037-5120-30	30 units per carton
Subsys (fentanyl) sublingual spray, 100 mcg	71500-001-10	10 units in 1 carton
Subsys (fentanyl) sublingual spray, 200 mcg	71500-002-30	30 units in 1 carton
Subsys (fentanyl) sublingual spray, 400 mcg	71500-004-30	30 units in 1 carton
Subsys (fentanyl) sublingual spray, 600 mcg	71500-006-30	30 units in 1 carton
Subsys (fentanyl) sublingual spray, 800 mcg	71500-008-30	30 units in 1 carton
Subsys (fentanyl) sublingual spray, 1200 mcg	71500-012-15	15 count (15 blisters of 2x 600 mcg)
Subsys (fentanyl) sublingual spray, 1600 mcg	71500-016-15	15 count (15 blisters of 2x 800 mcg)
Oral Transmucosal Fentanyl Citrate 200 mcg	0406-9202-30	30 units
Oral Transmucosal Fentanyl Citrate 400 mcg	0406-9204-30	30 units
Oral Transmucosal Fentanyl Citrate 600 mcg	0406-9206-30	30 units
Oral Transmucosal Fentanyl Citrate 800 mcg	0406-9208-30	30 units

Reference ID: 4721752

<Date>

Product Description	NDC	Package Size
Oral Transmucosal Fentanyl Citrate 1200 mcg	0406-9212-30	30 units
Oral Transmucosal Fentanyl Citrate 1600 mcg	0406-9216-30	30 units

If you are not enrolled or certified in the modified TIRF REMS, you need to **stop** distributing and immediately quarantine all listed TIRF medicines. Please examine your inventory and return all units of the listed TIRF medicines to your wholesaler within 21 days.

If you have any questions or require additional information, please call the TIRF REMS Call Center at 1-866-822-1483.

Sincerely,

TIRF REMS

What is the Transmucosal Immediate-Release Fentanyl (TIRF) REMS?

The Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Program is an FDA-required program designed to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines. The purpose of the REMS is to mitigate the misuse, abuse, addiction, overdose, and serious complications due to medication errors with the use of TIRF medicines.

You must enroll in the TIRF REMS to prescribe, dispense, or distribute TIRF medicines.

Patient

To receive treatment, a patient must be enrolled in the TIRF REMS by a certified doctor.

Enrollment Information

Pharmacy

Pharmacies must be certified in the TIRF REMS to receive and dispense TIRF medicines.

If you are the designated authorized representative of a pharmacy, you can certify below.

Certify Pharmacy

Prescriber

Prescribers must be certified in the TIRF REMS to prescribe TIRF medicines for outpatient use.

If you are a TIRF medicines prescriber, you can certify below.

Certify Prescriber

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

What is the Transmucosal Immediate-Release Fentanyl (TIRF) REMS?

The Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Program is an FDA-required program designed to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines. The purpose of the REMS is to mitigate the misuse, abuse, addiction, overdose, and serious complications due to medication errors with the use of TIRF medicines.

You must enroll in the TIRF REMS to prescribe, dispense, or distribute TIRF medicines.

Patient

To receive treatment, a patient must be enrolled in the TIRF REMS by a certified doctor.

Enrollment Information

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If you are a TIRF medicines prescriber, you can certify below.

Certify Prescriber

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Contact the TIRF REMS Call Center

Phone
1-866-822-1483

Fax
1-866-822-1487

Hours of Operation

MONDAY - FRIDAY	8:00-8:00 ET
SATURDAY - SUNDAY	Closed

Or

Contact a participating company about a specific product

Branded Products

Trade Name	Generic Name	Company	Links
Product1®	Oral Transmucosal Fentanyl Citrate Lozenge	Company1	U.S. Prescribing Information and Medication Guide
Product3®	Oral Transmucosal Fentanyl nasal spray	Company2	U.S. Prescribing Information and Medication Guide
Product4®	Oral Transmucosal Fentanyl sublingual spray	Company3	U.S. Prescribing Information and Medication Guide
Product8®	Oral Transmucosal Fentanyl sublingual tabletsL	Company7	U.S. Prescribing Information and Medication Guide

Generic Products

Trade Name	Generic Name	Company	Links
Product5	Oral Transmucosal Fentanyl Citrate Lozenge	Company4	U.S. Prescribing Information and Medication Guide
Product6	Oral Transmucosal Fentanyl Citrate Lozenge	Company5	U.S. Prescribing Information and Medication Guide
Product7	Oral Transmucosal Fentanyl Citrate Buccal Tablets	Company6	U.S. Prescribing Information and Medication Guide

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Find Speciality Pharmacies

Specialty pharmacies certified to dispense TIRF medicines.

OutPat Test Pharmacy
538 Deanna Forks
Filibertobury, VA 10726-7773
826-644-0463

XM Test Screen Shot Pharmacy
575 Lonly Forks
Johnstown, TN 54543-7773
628-987-6364

XM Test Sub01 Pharmacy
815 Daisy Gate
West Palls, ME 40254-1274
377-720-7654

XM Test Pharmacy
358 Gorgia Forks
Filbury, MA 10726-7773
628-644-6364

OutPat Test Sub01 Pharmacy
815 Enos Lock
East Dannie, DE 40254-1274
367-720-5767

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Find Retail Pharmacies

Locate a retail pharmacy certified to dispense TIRF medicines near you.

Philadelphia

Find Retail Pharmacies

OutPat Test Sub02 Pharmacy
22333 Jammie Squares
Philadelphia, PA 19002

XM Test Sub02 Pharmacy
22 Rittenhouse Square
Philadelphia, PA 19002

Locations

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Verify Shipping Address

Generate receipts for proof of shipping destination verification

Wholesaler DEA

Your wholesaler's DEA Number

Destination Organizational NPI

NPI Number

Destination Name, Address

Search Healthcare Settings or Pharmacy...

Find

Certified Shipping Endpoints

NPI	Name	Address	Action
9999999991	Test Pharmacy One, LLC.	111 Somewhere street, Somewhere, 11123	Generate Receipt
9999999992	Test Healthcare Setting Inc.	566 Somewhere Else Drive, Somewhere Else, 13123	Generate Receipt
9999999993	Test Pharmacy Two, LLC.	766 Somewhere Different Street, Somewhere Different, 13123	Generate Receipt

If you cannot find the shipping destination, refine your search criteria and try again. Alternatively, contact the TIRF REMS Call Center 1-866-822-1483.

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

TIRF REMS

Verify Shippi

Generate receipts for pr

Wholesaler DEA

Your wholesaler's DEA Numb

Destination Organizationa

NPI Number

Find

Shipping Verification Receipt

Store this receipt with your shipping records.

Destination:

Test Healthcare Setting Inc
566 Somewhere Else Drive
Somewhere Else, YA nnnnn-nnnn

UTC Date and Time:
9/24/2020 6:58 PM

0f29701d-82a8-4d44-82b3-58fa8add0dc5

Print

NPI	Name		Action
9999999991	Test Pharmacy One, LLC.	111 Somewhere street, Somewhere, 11123	Generate Receipt
9999999992	Test Healthcare Setting Inc.	566 Somewhere Else Drive, Somewhere Else, 13123	Generate Receipt
9999999993	Test Pharmacy Two, LLC.	766 Somewhere Different Street, Somewhere Different, 13123	Generate Receipt

If you cannot find the shipping destination, refine your search criteria and try again. Alternatively, contact the TIRF REMS Call Center 1-866-822-1483.

Prescriber

Prescribers must be certified in the TIRF REMS to prescribe TIRF medicines for outpatient use.

To certify as a prescriber:

1 Review the Prescribing Information

Review each drug's Prescribing Information

- CompanyPI1
- CompanyPI2
- CompanyPI3
- CompanyPI4
- CompanyPI5
- CompanyPI6

2 Review the Prescriber Materials

Review the Prescriber Education.

3 Complete the Prescriber Knowledge Assessment

Successfully complete the Prescriber Knowledge Assessment and submit it to the TIRF REMS.

Online or Print

4 Complete the Prescriber Enrollment Form

Enroll in the TIRF REMS by completing the Prescriber Enrollment Form and submitting it to the TIRF REMS.

Online or Print

Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Counseling Guide
- Patient Status and Opioid Tolerance Form
- Patient Discontinuation Form
- Adverse Events of Special Interest Reporting Form
- Prescriber FAQs

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Pharmacy

Pharmacies must be certified in the TIRF REMS to receive and dispense TIRF medicines.

To certify your pharmacy:

1 Designate an Authorized Representative

Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the TIRF REMS on behalf of the pharmacy.

2 Review the Pharmacy Information

Have the authorized representative review the Pharmacy Education.

3 Complete the Pharmacy Knowledge Assessment

Have the authorized representative successfully complete the Pharmacy Knowledge Assessment and submit it to the TIRF REMS.

Online or Print

4 Enroll Pharmacy

Have the authorized representative enroll in the TIRF REMS by completing the Pharmacy Enrollment Form and submitting it to the TIRF REMS.

Online or Print Inpatient or Print Outpatient

Pharmacy Materials

- Pharmacy Education
- Pharmacy Knowledge Assessment
- Inpatient Pharmacy Enrollment Form
- Outpatient Pharmacy Enrollment Form
- Pharmacy FAQ

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient

To receive treatment, a patient must be enrolled in the TIRF REMS by a certified doctor.

How do patients enroll in the TIRF REMS?

1 Talk with your TIRF REMS Certified doctor

Receive counseling from your doctor on the safe use of TIRF medicines using the Patient Counseling Guide and the appropriate Medication Guide.

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
- Company6MG

2 Make sure you understand

You **must** do the following:

- Take around-the-clock opioid pain medicine when using TIRF medicines
- Do **not** share TIRF medicines
- Properly store and dispose of your TIRF medicines

You **must** inform the doctor of serious adverse events

- Accidental exposure
- Abuse
- Misuse
- Addiction
- Overdose

You **must** receive counseling from the doctor on the safe use of each new TIRF medicine you are prescribed.

3 Enroll

Together with your doctor, complete and sign the Patient Enrollment Form. Your doctor or their staff can assist you in completing the enrollment either online or by using the paper form.

Patient Materials

- Patient Counseling Guide
- Patient Enrollment Form
- Patient FAQs

Important Terms

- What is a REMS?
- What are TIRF medicines?
- What is Opioid Tolerant?
- What is Naloxone?

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

TIRF REMS

What is a REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program. The U.S. Food and Drug Administration (FDA) can require a REMS for certain medications. The purpose of a REMS is to reduce the number or seriousness of injuries related to the use of the medication.

How to say REMS in English

0:00 / 0:00

Patient

To receive treatment, a p

How do pa

1 Talk with your TI

Receive counseling fr
Counseling Guide an

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
- Company6MG

2 Make sure you understand

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- What is Opioid Tolerant?
- What is Naloxone?

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

TIRF REMS

tact Us | Login | Register

Patient

To receive treatment, a p

How do pa

1 Talk with your TI

Receive counseling fr
Counseling Guide an

- Company1MG
- Company2MG

2 Make sure you un

You **must** do the follo

- Take around-the-c medicine when us
- Do **not** share TIRF
- Properly store and medicines

You **must** receive counseling from the doctor on the safe use of each new TIRF medicine you are prescribed.

3 Enroll

Together with your doctor, complete and sign the Patient Enrollment Form. Your doctor or their staff can assist you in completing the enrollment either online or by using the paper form.

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MS?
What are TIRF medicines?
What is Opioid Tolerant?
What is Naloxone?

What are TIRF medicines?

A transmucosal immediate-release fentanyl (TIRF) medicine is a prescription medicine that contains fentanyl, a very strong opioid pain reliever.

TIRF medicines are used to manage breakthrough cancer pain in patients who are already routinely taking another opioid pain medicine around-the-clock.

TIRF medicines are started only after you have been taking other opioid pain medicines and your body has become used to them (meaning you are opioid tolerant).

Brand Name Products	Generic Products
• Product1® • Product2® • Product3® • Product4® • Product5®	• Oral Transmucosal Fentanyl Citrate Lozenge • Oral Transmucosal Fentanyl Citrate Buccal Tablets

TIRF REMS

Patient

To receive treatment, a p

What is Opioid Tolerant?

Patients considered opioid tolerant are those who are taking around-the-clock medicine consisting of at least 60 mg of oral morphine per day, or at least 25 mcg per hour of transdermal fentanyl, or at least 30 mg of oral oxycodone per day, or at least 8 mg of oral hydromorphone per day, or at least 25 mg oral oxymorphone per day, or at least 60 mg oral hydrocodone per day or an equianalgesic dose of another opioid medication daily for a week or longer. Patients must remain on around-the- clock opioids when taking a TIRF medicine.

How do pa

1 Talk with your TI

Receive counseling fr
Counseling Guide an

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
- Company6MG

2 Make sure you understand

You **must** do the following:

- Take around-the-clock opioid pain medicine when using TIRF medicines
- Do **not** share TIRF medicines
- Properly store and dispose of your TIRF medicines

You **must** inform the doctor of serious adverse events

- Accidental exposure
- Abuse
- Misuse
- Addiction
- Overdose

You **must** receive counseling from the doctor on the safe use of each new TIRF medicine you are prescribed.

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atient Materials

- seling Guide
- Patient Enrollment Form
- Patient FAQs

Important Terms

- What is a REMS?
- What are TIRF medicines?
- What is Opioid Tolerant?
- What is Naloxone?

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Patient

To receive treatment, a p

How do pa

What is Naloxone?

Naloxone is a medicine that helps reverse an opioid overdose.
Naloxone is sprayed inside your nose or injected into your body. Some naloxone products are designed for people to use in their home.

Naloxone is never a substitute for emergency medical care. Get emergency help or call 911 right away if you take too much of your TIRF medicine, because you may have had an opioid overdose.
See the Patient Counseling Guide for more information.

1 Talk with your TI

Receive counseling fr
Counseling Guide an

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
- Company6MG

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TIRF REMS

SITE IS UNDER MAINTENANCE

Please check back soon.

Why is the site down?

The site is under maintenance because we are working on improving it.

What is the expected downtime?

We are usually back within 10-15 minutes, but it depends on the issue.

Do you need support?

You may call the TIRF REMS Call Center at 866-822-1483 if you need support.

TIRF REMS

Create Account

User Type Selection

REMS User Types

- (●) **Pharmacy Authorized Representative**
  A pharmacy authorized representative is an individual designated for each pharmacy location to carry out the certification process and oversee implementation and compliance with the TIRF REMS.

- ( ) **Prescriber**
  A prescriber is an individual who may prescribe Transmucosal Immediate-Release Fentanyl medicines in compliance with the TIRF REMS.

Cancel | Next

TIRF REMS

Create Account

Pharmacy Authorized Representative

Username and Password

Username

testr18306@examoto.net

First Name

RxAuth

Last Name

Represenative

Password

••••••••••••

Confirm Password

••••••••••••

Cancel

Next

TIRF REMS

Create Account

Prescriber

Username and Password

Individual National Provider ID (NPI) Number

1310000086

☑ I am Test Prescriber86

If the name above is incorrect, please re-enter your NPI number.

Password

••••••••••••

Confirm Password

••••••••••••

Cancel | Next

TIRF REMS

Create Account

Verify Identity

Choose verification method

We will send you a code to verify your identity. The code may only be used once and is time sensitive.

- (●) ✉ **Email me the code**

  verifytest6726@examoto.net

After logging in, use preferences to add password reset options and/or enable multi-factor authentication.

Cancel | Next

To report any SUSPECTED ADVERSE REACTIONS, contact TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

V0_01

TIRF REMS

Create Account

Verify Identity

Enter Verification Code

Please enter your code.

670194

Cancel Next

TIRF REMS

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To report any SUSPECTED ADVERSE REACTIONS, contact TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

V0_01

Reference ID: 4721752

TIRF REMS

Create Account

Complete

testr18306@examoto.net, your account has been created.

You may now login to perform REMS functions online.

Login

TIRF REMS

Login

Username

Username

Password

Password

Remember my login

Cancel Login

Forgot your password?

Sign in with Examoto Corporate AD

Or

Register

To perform REMS functions online, you must have an account. Creating an account involves creating unique login credentials (username and password). Register to create an account.

Register

TIRF REMS

Reset Password

Username

User ID | NPI number

Cancel Next

TIRF REMS

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V0_01

Reference ID: 4721752

TIRF REMS

Reset Password

Verify Identity

Choose verification method

We will send you a code to verify your identity. The code may only be used once and is time sensitive.

- ○ Email Txxxxxxxxxx@EXAMOTO.NET
- ○ Text (SMS) xxx-xxx-7766
- ○ Call xxx-xxx-7766
- ◉ Approve request on my Authenticator App

After logging in, use preferences to add password reset options and/or enable multi-factor authentication.

Cancel | Next

TIRF REMS

Reset Password

Verify Code

We sent you a code to verify your identity; please enter it here.

Code

367132

Password

••••••••••••

Confirm password

••••••••••••

Cancel Next

TIRF REMS

Reset Password

Completed

Your password has been reset.

Continue

To report any SUSPECTED ADVERSE REACTIONS, contact TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

V0_01

My Account

Preferences

Identity

Username: 1310000000

You may only change your username by calling the coordinating center at 1-866-822-1483.

Password: Change Account Information

Verification Methods

Email: testr56420@examoto.net Change my Email

Phone: 610-248-8636 Change my Phone Number

Authenticator App: Configured Reset my App

Two-Factor Authentication

Two-factor authentication (2FA) improves security. 2FA adds a second level of authentication to an account login. With 2FA enabled, the user is required to enter their username, password and a code. The code can be provided via several methods.

Use Two-Factor Authentication to improve security

Two-Factor Authentication: Disabled Enable

TIRF REMS

Change Account Information

Verify and Update

Current Password

Current Password

New Password

Password

Confirm Password

Password

Cancel | Next

TIRF REMS

Change Account Information

Completed

Your password has been changed.

Continue

TIRF REMS

Change Account Information

Email Address

We will send you a code to verify your identity. The code may only be used once and is time sensitive.

Enter Email

Email

Cancel | Next

TIRF REMS

Change Account Information

Phone Number

We will send you a code to verify your identity. The code may only be used once and is time sensitive.

Phone

nnn-nnn-nnnn

Text (SMS) me with the code Call me with the code

Cancel Next

TIRF REMS

Change Account Information

Verify Email Address

We sent you a code to verify your identity; please enter it here.

Code

301620

I didn't receive the code | Next

To report any SUSPECTED ADVERSE REACTIONS, contact TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

V0_01

TIRF REMS

Change Account Information

Verify Phone Phone Number

We sent you a code to verify your identity; please enter it here.

Code

917381

I didn't receive the code

Next

Account Options

Configure Authenticator App

Follow these steps to use an authenticator app:

1. Download a two-factor authenticator app, like Microsoft Authenticator or Google Authenticator for Android or iOS .
2. Scan the QR Code or enter this key into your two-factor authenticator app:

   YXJ7 FNTY GWRB 45QA OMIC CCKU DRPQ 2XHW

   The spaces are not required, and the code is not case-sensitive.

3. Once you have scanned the QR code or input the key above, your two-factor authentication app will provide you with a unique code. Enter the code in the confirmation box below and select VERIFY.

Code

nnnnnn

Cancel Verify

TIRF REMS

Logged Out

You are now logged out.

Click here to return to the TIRF REMS application.

Enroll Patient

Complete this form to enroll in the TIRF REMS. **A patient must be enrolled in the TIRF REMS** to receive treatment.

Confirm your Date of Birth

Date of Birth

MM/DD/YYYY

Confirm

Patient / Guardian Agreement

TIRF Medicines can cause your breathing to stop – which can lead to death.

Safety Rules for TIRF Medicines

You have agreed to take a TIRF Medicine and follow all the safety rules to make it less likely you or others will experience serious harm.

- My healthcare provider has talked to me about the safe use of TIRF medicines using the **Medication Guide** and **Patient Counseling Guide**.
- I will only use this medicine if I am regularly using another opioid, around-the-clock, for constant pain.
- If I stop taking my around-the-clock-opioid pain medicine, I **MUST** stop taking my TIRF medicine.
- I will never share or give my TIRF medicine to anyone else, even if they have the same symptoms.
  - My TIRF medicine could cause harm to others or even death. A dose that is okay for me could cause an overdose and death for someone else.
- I will store my TIRF medicine in a safe and secure place away from children. I understand that accidental use by a child, or anyone for whom the medicine was not prescribed, can cause death.
- I have been told how to properly dispose of my partially used or unneeded TIRF medicine remaining from my prescription. I will dispose of my TIRF medicine properly as soon as I no longer need it.
- I will contact my healthcare provider if my TIRF medicine does not relieve my pain. I will not change the dose of my TIRF medicine myself or take it more often than my healthcare provider has directed.
- I must enroll in the TIRF REMS and Patient Registry by completing the **Patient Enrollment Form** with my healthcare provider.
- I understand that the TIRF REMS and its agents may use and share my personal information to manage the program, and information all about patients who get TIRF medicines will be stored in a private and secure database. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the TIRF REMS. However, my name will not be shared.
- I give permission for the TIRF REMS and its agents or vendors to contact me by phone, mail, or email to support the administration of the TIRF REMS Program.
- I will tell my healthcare provider if I, or anyone else, experience any adverse event of accidental exposure, abuse, misuse, addiction, and overdose.
- I will re-enroll in the TIRF REMS by completing the **Patient Enrollment Form** with my healthcare provider every two years during treatment.

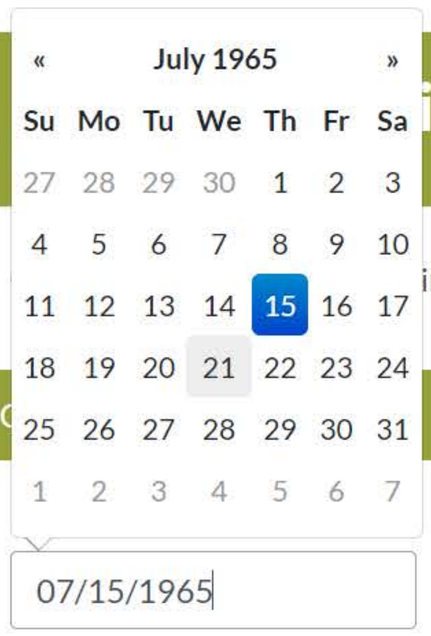
Sign | Type Signature

Clear

Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.



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Enroll Patient

Complete this form to enroll in the TIRF REMS. **A patient must be enrolled in the TIRF REMS** to receive treatment.

Confirm your Date of Birth

Date of Birth

07/15/1965

Confirm

Patient / Guardian Agreement

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Sign and Submit

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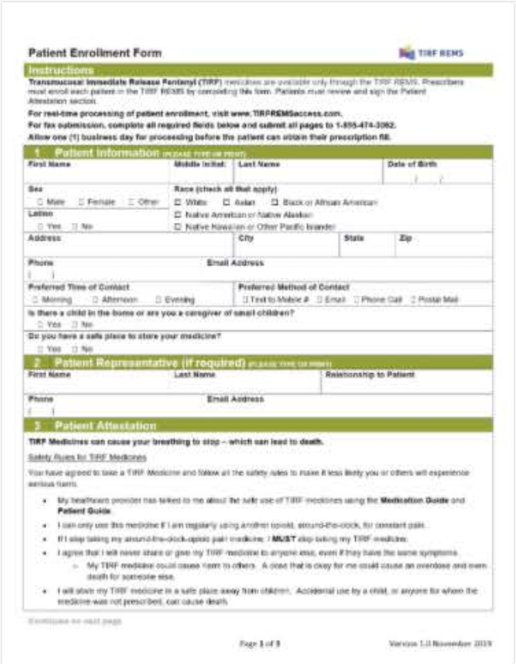
Patient Information Complete

Patient Enrollment Complete

Your enrollment is complete. You may download your copy below.



Patient Enrollment Form

TIRF REMS

Instructions

Transmucosal Immediate Release Fentanyl (TIRF) medicines are available only through the TIRF REMS. Prescribers must enroll each patient in the TIRF REMS by completing this form. Patients must review and sign the Patient Attestation section.

For real-time processing of patient enrollment, visit www.TIRFREMSaccess.com.
For fax submission, complete all required fields below and submit all pages to 1-855-474-3062.
Allow one (1) business day for processing before the patient can obtain their prescription fill.

1 Patient Information (PLEASE PRINT OR WRITE)

First Name | Middle Initial | Last Name | Date of Birth

Sex: ☐ Male ☐ Female ☐ Other
Race (check all that apply): ☐ White ☐ Asian ☐ Black or African American ☐ Native American or Native Alaskan ☐ Native Hawaiian or Other Pacific Islander
Latino: ☐ Yes ☐ No

Address | City | State | Zip

Phone | Email Address

Preferred Time of Contact: ☐ Morning ☐ Afternoon ☐ Evening
Preferred Method of Contact: ☐ Text to Mobile # ☐ Email ☐ Phone Call ☐ Postal Mail

Is there a child in the home or are you a caregiver of small children? ☐ Yes ☐ No

Do you have a safe place to store your medicine? ☐ Yes ☐ No

2 Patient Representative (if required) (PLEASE PRINT OR WRITE)

First Name | Last Name | Relationship to Patient

Phone | Email Address

3 Patient Attestation

TIRF Medicines can cause your breathing to stop – which can lead to death.

Safety Rules for TIRF Medicines

You have agreed to take a TIRF Medicine and follow all the safety rules to make it less likely you or others will experience serious harm.

- My healthcare provider has talked to me about the safe use of TIRF medicines using the **Medication Guide** and **Patient Guide**.
- I can only use this medicine if I am regularly using another opioid, around-the-clock, for constant pain.
- If I stop taking my around-the-clock opioid pain medicine, I **MUST** stop taking my TIRF medicine.
- I agree that I will never share or give my TIRF medicine to anyone else, even if they have the same symptoms.
  - My TIRF medicine could cause harm to others. A dose that is okay for me could cause an overdose and even death for someone else.
- I will store my TIRF medicine in a safe place away from children. Accidental use by a child, or anyone for whom the medicine was not prescribed, can cause death.

Continue on next page

Page 1 of 3 | Version 1.0 November 2019

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____Localization_Version

Prescriber - Knowledge Assessment

TIRF Prescriber KA

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

1 . The patients described are all experiencing breakthrough pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine? Select one option

- 12-year-old sarcoma patient, using transdermal fentanyl for her underlying persistent cancer pain.
- Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
- Adult male with advanced lung cancer, his underlying persistent pain is managed with 25 mcg/hour transdermal fentanyl patches for the past 3 months.
- Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.

2 . The patients described are experiencing breakthrough cancer pain. A TIRF medicine is NOT appropriate for one of them. Which patient should not receive a TIRF medicine? Select one option.

- Adult male with advanced lung cancer; underlying persistent cancer pain managed with 25 mcg/hour transdermal fentanyl patches for the past 2 months.
- Adult female with localized breast cancer; just completed a mastectomy and reconstructive surgery; persistent cancer pain managed with 30 mg oral morphine daily for the past 6 weeks.
- Adult male patient with advanced prostate cancer who, over the last 2 weeks, has been prescribed 100 mg oral morphine daily for pain due to bone metastasis.
- Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

3 . Certain factors may increase the risk of abuse and/or diversion of opioid medications. Which of the following is most accurate?

- A history of alcohol abuse with the patient or close family members.
- The patient has a household member with a street drug abuse problem.
- The patient has a history of prescription drug misuse.
- All of the above.

4 . A patient is already taking a TIRF medicine but wants to change their medicine. His/her doctor decides to prescribe a different TIRF medicine (that is not a bioequivalent generic version of a branded product) in its place. How should the prescriber proceed? Select one option.

- The prescriber can safely convert to the equivalent dosage of the new TIRF medicine as it has the same effect as other TIRF medicines.
- The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.
- Convert from the other TIRF medicine to the new TIRF medicine at half of the dose.
- The prescriber should base the starting dose of the newly prescribed TIRF medicine on the dose of the opioid medicine used for their underlying persistent cancer pain.

5 . A patient is starting titration with a TIRF medicine. What dose must they start with? Select one option.

- An appropriate dose based on the dose of the opioid medicine used for underlying persistent cancer pain.
- The dose that the prescriber believes is appropriate based on their clinical experience.
- The lowest available dose, unless individual product Prescribing Information provides product-specific guidance.
- The median available dose.

6 . A prescriber has started titrating a patient with the lowest dose of a TIRF medicine. However, after 30 minutes, the breakthrough cancer pain has not been sufficiently relieved. What should they advise the patient to do? Select one option.

- Take another (identical) dose of the TIRF medicine immediately.
- Take a dose of an alternative rescue medicine.
- Provide guidance based on the product-specific Prescribing Information because the instructions are not the same for all TIRF medicines.
- Double the dose and take immediately.

7 . A patient is taking a TIRF medicine and the doctor would like to prescribe erythromycin, a CYP3A4 inhibitor. Which of the following statements is TRUE? Select one option.

- The patient can't be prescribed erythromycin, because using it at the same time as a TIRF medicine could be fatal.
- Use of a TIRF medicine with a CYP3A4 inhibitor may require dosage adjustment of the TIRF medicine; carefully monitor the patient for opioid toxicity, otherwise such use may cause serious life threatening, and/or fatal respiratory depression.
- There is no possible drug interaction between CYP3A4 inhibitors and TIRF medicines.
- The dose of the TIRF medicine must be reduced by one half if a CYP3A4 inhibitor is prescribed in the same patient.

8 . Before initiating treatment with a TIRF medicine, prescribers must review the Medication Guide and Patient Counseling Guide with the patient. Which of the following counseling statements is FALSE? Select one option.

- TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.
- Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.
- Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.
- Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

9 . There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate? Select one option.

- TIRF medicines can be fatal if taken by children.
- TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
- TIRF medicines can be fatal if taken by anyone who is not opioid-tolerant.
- All of the above.

10 . Which one of the following statements is most accurate regarding the safe storage and disposal of TIRF medicines? Select one option.

- TIRF medicines should be kept in in a safe and secure place, out of sight and out of reach of all others, especially children.
- TIRF medicines should be protected from theft.
- Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
- All of the above.

11 . Which of the following statements is FALSE? Select one option.

- Educating prescribers, pharmacist and patients that respiratory depression is more common in patients who are not opioid tolerant.
- Requiring that patients remain opioid-tolerant throughout their treatment with TIRF medicines.
- Requiring inpatient pharmacies to verify opioid tolerance in inpatients who require TIRF medicine while hospitalized.
- Requiring documentation of opioid tolerance with only the initial prescription of a TIRF medicine.

Submit KA

Prescriber - Knowledge Assessment

TIRF Prescriber KA

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

Knowledge Assessment Incomplete

10 correct answers out of 11 (Failed)

1. The patients described are all experiencing breakthrough pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine? Select one option ✓

- (●) 12-year-old sarcoma patient, using transdermal fentanyl for her underlying persistent cancer pain.
- ( ) Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
- ( ) Adult male with advanced lung cancer, his underlying persistent pain is managed with 25 mcg/hour transdermal fentanyl patches for the past 3 months.
- ( ) Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.

2. The patients described are experiencing breakthrough cancer pain. A TIRF medicine is NOT appropriate for one of them. Which patient should not receive a TIRF medicine? Select one option. ✓

- ( ) Adult male with advanced lung cancer; underlying persistent cancer pain managed with 25 mcg/hour transdermal fentanyl patches for the past 2 months.
- (●) Adult female with localized breast cancer; just completed a mastectomy and reconstructive surgery; persistent cancer pain managed with 30 mg oral morphine daily for the past 6 weeks.
- ( ) Adult male patient with advanced prostate cancer who, over the last 2 weeks, has been prescribed 100 mg oral morphine daily for pain due to bone metastasis.
- ( ) Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

3. Certain factors may increase the risk of abuse and/or diversion of opioid medications. Which of the following is most accurate? ✓

- ( ) A history of alcohol abuse with the patient or close family members.
- ( ) The patient has a household member with a street drug abuse problem.
- ( ) The patient has a history of prescription drug misuse.
- (●) All of the above.

4. A patient is already taking a TIRF medicine but wants to change their medicine. His/her doctor decides to prescribe a different TIRF medicine (that is not a bioequivalent generic version of a branded product) in its place. How should the prescriber proceed? Select one option. ✓

- ( ) The prescriber can safely convert to the equivalent dosage of the new TIRF medicine as it has the same effect as other TIRF medicines.
- (●) The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.
- ( ) Convert from the other TIRF medicine to the new TIRF medicine at half of the dose.
- ( ) The prescriber should base the starting dose of the newly prescribed TIRF medicine on the dose of the opioid medicine used for their underlying persistent cancer pain.

5. A patient is starting titration with a TIRF medicine. What dose must they start with? Select one option. ✓

- ( ) An appropriate dose based on the dose of the opioid medicine used for underlying persistent cancer pain.
- ( ) The dose that the prescriber believes is appropriate based on their clinical experience.
- (●) The lowest available dose, unless individual product Prescribing Information provides product-specific guidance.
- ( ) The median available dose.

6. A prescriber has started titrating a patient with the lowest dose of a TIRF medicine. However, after 30 minutes, the breakthrough cancer pain has not been sufficiently relieved. What should they advise the patient to do? Select one option. ✓

- ( ) Take another (identical) dose of the TIRF medicine immediately.
- ( ) Take a dose of an alternative rescue medicine.
- (●) Provide guidance based on the product-specific Prescribing Information because the instructions are not the same for all TIRF medicines.
- ( ) Double the dose and take immediately.

7. A patient is taking a TIRF medicine and the doctor would like to prescribe erythromycin, a CYP3A4 inhibitor. Which of the following statements is TRUE? Select one option. ✓

- ( ) The patient can't be prescribed erythromycin, because using it at the same time as a TIRF medicine could be fatal.
- (●) Use of a TIRF medicine with a CYP3A4 inhibitor may require dosage adjustment of the TIRF medicine; carefully monitor the patient for opioid toxicity, otherwise such use may cause serious life threatening, and/or fatal respiratory depression.
- ( ) There is no possible drug interaction between CYP3A4 inhibitors and TIRF medicines.
- ( ) The dose of the TIRF medicine must be reduced by one half if a CYP3A4 inhibitor is prescribed in the same patient.

8. Before initiating treatment with a TIRF medicine, prescribers must review the Medication Guide and Patient Counseling Guide with the patient. Which of the following counseling statements is FALSE? Select one option. ✓

- ( ) TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.
- ( ) Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.
- (●) Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.
- ( ) Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

9. There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate? Select one option. ✓

- ( ) TIRF medicines can be fatal if taken by children.
- ( ) TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
- ( ) TIRF medicines can be fatal if taken by anyone who is not opioid-tolerant.
- (●) All of the above.

10. Which one of the following statements is most accurate regarding the safe storage and disposal of TIRF medicines? Select one option. ✓

- ( ) TIRF medicines should be kept in in a safe and secure place, out of sight and out of reach of all others, especially children.
- ( ) TIRF medicines should be protected from theft.
- ( ) Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
- (●) All of the above.

11. Which of the following statements is FALSE? Select one option. ✗

- ( ) Educating prescribers, pharmacist and patients that respiratory depression is more common in patients who are not opioid tolerant.
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Try Again | Home

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Prescriber - Knowledge Assessment

There are errors, please correct the items below:

- You have exceeded the maximum number of allowed attempts to pass the knowledge assessment
- To reattempt the knowledge assessment you must first review the Prescriber Education and then call the TIRF REMS Call Center at 1-866-822-1483 to reset your account
- You will be denied enrollment into the TIRF REMS after six failed attempts to complete the knowledge assessment

Home

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____Localization_Version

Prescriber - Knowledge Assessment

There are errors, please correct the items below:

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Home

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____Localization_Version

Prescriber - Knowledge Assessment

TIRF Prescriber KA

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

Knowledge Assessment Complete

11 correct answers out of 11 (Passed)

1 . The patients described are all experiencing breakthrough pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine? Select one option ✓

- (●) 12-year-old sarcoma patient, using transdermal fentanyl for her underlying persistent cancer pain.
- ( ) Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
- ( ) Adult male with advanced lung cancer, his underlying persistent pain is managed with 25 mcg/hour transdermal fentanyl patches for the past 3 months.
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- ( ) TIRF medicines should be kept in in a safe and secure place, out of sight and out of reach of all others, especially children.
- ( ) TIRF medicines should be protected from theft.
- ( ) Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
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11 . Which of the following statements is FALSE? Select one option. ✓

- ( ) Educating prescribers, pharmacist and patients that respiratory depression is more common in patients who are not opioid tolerant.
- ( ) Requiring that patients remain opioid-tolerant throughout their treatment with TIRF medicines.
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Home

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Prescriber Enrollment

PRJane PRDoe

To be completed by the prescriber to enroll in the TIRF REMS. Transmucosal Immediate-Release Fentanyl medicines are only available through the TIRF REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and/or receive Transmucosal Immediate-Release Fentanyl medicines

Prescriber Information

Individual NPI Number

Use individual NPI to poplute form: 1310000000

(Select address type to populate form)

(●) Office Address ( ) Mailing Address

First Name* Test

M.I. A

Last Name* Prescriber000000

Specialty* Internal Medicine

Credentials* ( ) MD ( ) NP ( ) PA ( ) DO ( ) Other

Clinic / Practice Name*

Clinic / Practice Name

Address Line 1* 1111 LION ROAD

Address Line 2 Address Line 2

City* SomeWhere

State* Pennsylvania

Zip Code* 11111

Number* 111-111-1111

Extension nnn...

Fax 111-111-1111

Email Address* PR1310000000@examoto.net

Preferred Time of Contact*

( ) Morning ( ) Afternoon ( ) Evening

Preferred Method of Contact*

(●) Email ( ) Text to Mobile# ( ) Phone Call

Office Contact

First Name* PRSally

Last Name* StaffJones

Number* 378-407-4338

Fax Fax

Email Address* PRStaff@examoto.net

Preferred Time of Contact*

( ) Morning ( ) Afternoon ( ) Evening

Preferred Method of Contact*

( ) Email ( ) Text to Mobile# (●) Phone Call

Prescriber Agreement

By signing below, you attest to the following:

I have:

- Reviewed each drug's **Prescribing Information.**
- Reviewed the **Prescriber Education**.
- Successfully completed the **Prescriber Knowledge Assessment** and submitted it to the REMS.

Before treatment initiation, I must:

- Assess the patient for risk factors of opioid addiction, abuse, and misuse including personal and family history of substance abuse or mental illness.
- Counsel the patient on the safe use of TIRF medicines using the **Medication Guide** for the prescribed TIRF medicine and the **Patient Counseling Guide**.
- Provide a copy of the materials to the patient.
- Assess the patient's opioid tolerance.
- Document the patient's opioid tolerance using the **Patient Enrollment Form** and submit to the REMS.
- Enroll the patient by completing and submitting the **Patient Enrollment Form** to the REMS.

During treatment, and before each prescription, I must:

- Assess the patient's health status for opioid tolerance, appropriateness of dose, misuse, abuse, addiction, and overdose.
- Document and submit to the REMS using the **Patient Status and Opioid Tolerance Form.**

During treatment, every 2 years, I must:

- Counsel the patient on the safe use of TIRF medicines using the **Medication Guide** for the prescribed TIRF medicine, and the **Patient Counseling Guide.**
- Provide a copy of the materials to the patient.
- Re-enroll the patient in the REMS by completing the **Patient Enrollment Form** and submitting it to the REMS.

Before treatment re-initiation, after a lapse in treatment of 6 months or longer, I must:

- Counsel the patient on the safe use of TIRF medicines using the **Medication Guide** for the prescribed TIRF medicine and the **Patient Counseling Guide.**
- Provide a copy of the materials to the patient.

At all times, I must:

- Counsel the patient using the **Medication Guide** for any new TIRF medicine not previously prescribed, and provide a copy to the patient.
- Report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose to the REMS using the **Adverse Events of Special Interest Reporting Form.**
- Report treatment discontinuation to the REMS using the **Patient Discontinuation Form**.

To maintain certification to prescribe, every 2 years, I must:

- Review each drug's **Prescribing Information**.
- Review the **Prescriber Education**
- Successfully complete the **Prescriber Knowledge Assessment** and submit it to the REMS.
- Re-enroll in the REMS by completing the **Prescriber Enrollment Form.**

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Prescriber

1310000000

Prescriber Certification

You are currently certified.

PRJane PRDoe

Certified as of 4/20/2020

Edit

Counsel Patient

Before you enroll, counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
- Company6MG

Print Patient Counseling Guide

Enroll Patients in the TIRF REMS

Complete this form with your patient to enroll them in the TIRF REMS. **A patient must be enrolled in the TIRF REMS** to receive treatment.

→ Enroll Patient

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

→ Manage Patients

Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Counseling Guide
- Patient Status and Opioid Tolerance Form
- Patient Discontinuation Form
- Adverse Events of Special Interest Reporting Form
- Prescriber FAQs

Upload Enrollment Form

Uploads must be in PDF format.

Browse

Or drop files here

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Prescriber

1310000001

Prescriber Certification

You must certify in the TIRF REMS to prescribe Transmucosal Immediate-Release Fentanyl medicines. To certify please complete the following:

1 **Review the Prescriber Materials**

Review each drug's Prescribing Information

- CompanyPI1
- CompanyPI2
- CompanyPI3
- CompanyPI4
- CompanyPI5
- CompanyPI6

Review the Prescriber Education.

2 **Complete the Prescriber Knowledge Assessment**

Successfully complete the Prescriber Knowledge Assessment and submit it to the TIRF REMS.

Online or Print

3 **Complete the Prescriber Enrollment Form**

Enroll in the TIRF REMS by completing the Prescriber Enrollment Form and submitting it to the TIRF REMS.

Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Counseling Guide
- Patient Status and Opioid Tolerance Form
- Patient Discontinuation Form
- Adverse Events of Special Interest Reporting Form
- Prescriber FAQs

Upload Enrollment Form

Uploads must be in PDF format.

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PRPat PRDoe

Enrolled as of 4/20/2020

Edit

Counsel Patient

Before you enroll, counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

- Company1MG
- Company2MG
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- Company4MG
- Company5MG
- Company6MG

Print Patient Counseling Guide

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Manage Patients

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- CompanyPI5
- CompanyPI6

Review the Prescriber Education.

2 Complete the Prescriber Knowledge Assessment

Successfully complete the Prescriber Knowledge Assessment and submit it to the TIRF REMS.

3 **Complete the Prescriber Enrollment Form**

Enroll in the TIRF REMS by completing the Prescriber Enrollment Form and submitting it to the TIRF REMS.

Online or Print

Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Counseling Guide
- Patient Status and Opioid Tolerance Form
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Upload Enrollment Form

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PRPat PRDoe

Enrolled as of 4/20/2020

Edit

Counsel Patient

Before you enroll, counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

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Prescriber

1310000000

Re-Certify Notice

Your TIRF REMS certification will soon expire. To dispense Transmucosal Immediate-Release Fentanyl medicines you must:

1 Review the Prescriber Materials

Review each drug's Prescribing Information

- CompanyPI1
- CompanyPI2
- CompanyPI3
- CompanyPI4
- CompanyPI5
- CompanyPI6

Review the Prescriber Education.

2 Complete the Prescriber Knowledge Assessment

Successfully complete the Prescriber Knowledge Assessment and submit it to the TIRF REMS.

Online or Print

3 Complete the Prescriber Enrollment Form

Enroll in the TIRF REMS by completing the Prescriber Enrollment Form and submitting it to the TIRF REMS.

PRJane PRDoe

Certified as of 4/20/2020

Edit

Counsel Patient

Before you enroll, counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

- Company1MG
- Company2MG
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Print Patient Counseling Guide

Enroll Patients in the TIRF REMS

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Manage Patients

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→ Manage Patients

Prescriber Materials

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Upload Enrollment Form

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Prescriber

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Online or Print

PRJane PRDoe

Certified as of 4/20/2020

Edit

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- Company1MG
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Print Patient Counseling Guide

Enroll Patients in the TIRF REMS

Complete this form with your patient to enroll them in the TIRF REMS. **A patient must be enrolled in the TIRF REMS** to receive treatment.

→ Enroll Patient

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

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Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
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- Patient Counseling Guide
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Prescriber

1310000002

Re-Certify Notice

Your TIRF REMS certification has expired. To dispense Transmucosal Immediate-Release Fentanyl medicines you must:

1 Review the Prescriber Materials

Review each drug's Prescribing Information

- CompanyPI1
- CompanyPI2
- CompanyPI3
- CompanyPI4
- CompanyPI5
- CompanyPI6

Review the Prescriber Education.

2 Complete the Prescriber Knowledge Assessment

Successfully complete the Prescriber Knowledge Assessment and submit it to the TIRF REMS.

Online or Print

3 Complete the Prescriber Enrollment Form

Enroll in the TIRF REMS by completing the Prescriber Enrollment Form and submitting it to the TIRF REMS.

PRTom PRSmith

Decertified

Edit

Counsel Patient

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- Company1MG
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→ Enroll Patient

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

→ Manage Patients

Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Counseling Guide
- Patient Status and Opioid Tolerance Form
- Patient Discontinuation Form
- Adverse Events of Special Interest Reporting Form
- Prescriber FAQs

Upload Enrollment Form

Uploads must be in PDF format.

Browse Or drop files here

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Prescriber

1310000002

Re-Certify Notice

Your TIRF REMS certification has expired. To dispense Transmucosal Immediate-Release Fentanyl medicines you must:

1 **Review the Prescriber Materials**

Review each drug's Prescribing Information

- CompanyPI1
- CompanyPI2
- CompanyPI3
- CompanyPI4
- CompanyPI5
- CompanyPI6

Review the Prescriber Education.

2 Complete the Prescriber Knowledge Assessment

Successfully complete the Prescriber Knowledge Assessment and submit it to the TIRF REMS.

3 **Complete the Prescriber Enrollment Form**

Enroll in the TIRF REMS by completing the Prescriber Enrollment Form and submitting it to the TIRF REMS.

Online or Print

Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Counseling Guide
- Patient Status and Opioid Tolerance Form
- Patient Discontinuation Form
- Adverse Events of Special Interest Reporting Form
- Prescriber FAQs

Upload Enrollment Form

Uploads must be in PDF format.

Browse Or drop files here

PRTom PRSmith

Decertified

Edit

Counsel Patient

Before you enroll, counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
- Company6MG

Print Patient Counseling Guide

Enroll Patients in the TIRF REMS

Complete this form with your patient to enroll them in the TIRF REMS. **A patient must be enrolled in the TIRF REMS** to receive treatment.

→ Enroll Patient

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

→ Manage Patients

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Prescriber

1310000001

Prescriber Certification

You must certify in the TIRF REMS to prescribe Transmucosal Immediate-Release Fentanyl medicines. To certify please complete the following:

1 Review the Prescriber Materials

Review each drug's Prescribing Information

- CompanyPI1
- CompanyPI2
- CompanyPI3
- CompanyPI4
- CompanyPI5
- CompanyPI6

Review the Prescriber Education.

2 Complete the Prescriber Knowledge Assessment

Successfully complete the Prescriber Knowledge Assessment and submit it to the TIRF REMS.

Online or Print

3 Complete the Prescriber Enrollment Form

Enroll in the TIRF REMS by completing the Prescriber Enrollment Form and submitting it to the TIRF REMS.

Online or Print

PRPat PRDoe

Enrolled as of 4/20/2020

Edit

Counsel Patient

Before you enroll, counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
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Print Patient Counseling Guide

Enroll Patients in the TIRF REMS

Complete this form with your patient to enroll them in the TIRF REMS. **A patient must be enrolled in the TIRF REMS** to receive treatment.

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Prescriber

PRJane PRDoe

Prescriber

Individual NPI Number*

1310000000

First Name*

PRJane

Middle Initial

Middle Initial

Last Name*

PRDoe

Clinic / Practice Name*

Test Prescriber Practice

Specialty*

Specialty

Credentials*

○ MD ○ NP ○ PA ○ DO ○ Other

Address Line 1*

12 Parker Avenue

Address Line 2

Address Line 2

City*

Chambersburg

State*

Pennsylvania

Zip Code*

17201

Number*

420-689-9443

Extension

nnn...

Fax

209-772-0961

Email Address*

PR1310000000@examoto.net

Preferred Time of Contact*

○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*

◉ Email ○ Text to Mobile# ○ Phone Call

Office Contact

First Name*

PRSally

Last Name*

StaffJones

Number*

378-407-4338

Fax

Fax

Email Address*

PRStaff@examoto.net

Preferred Time of Contact*

○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*

○ Email ○ Text to Mobile# ◉ Phone Call

Cancel | Save

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Manage Patients

PRJane PRDoe
Certified Prescriber
Certified: 15th July, 2014

Find Patient

You can search for a patient already registered in the TIRF REMS and transfer them to your care.

1 **Find a patient by entering the patient's information below:**

First Name	Last Name	Date of Birth
First Name	NotFound	mm/dd/yyyy

Phone Or Email

Phone Or Email

There are errors, please correct the items below:

- Patient cannot be found, please contact the TIRF REMS Call Center or enroll the patient.

Clear | Find

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

Enroll Patient

Show 10 entries

Search My Patient List:

Edit	Name	Date of Birth	Phone	Action
	PatientJulie Williams	6/13/1970		Continuation / Discontinuation / Report AESI
	PatientTerry Smith	9/22/1989		Continuation / Discontinuation / Report AESI
	PatientPat Smith	7/15/1965		Continuation / Discontinuation / Report AESI
	PatientPat Smith	6/27/1954		Continuation / Discontinuation / Report AESI
	PatientAli Smith	4/4/1962		Continuation / Discontinuation / Report AESI

Edit

Showing 1 to 5 of 5 entries

Previous 1 Next

Return

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-888-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Reference ID: 4721752

Manage Patients

PRJane PRDoe
Certified Prescriber
Certified: 15th July, 2014

Find Patient

You can search for a patient already registered in the TIRF REMS and transfer them to your care.

1 **Find a patient by entering the patient's information below:**

First Name	Last Name	Date of Birth
First Name	Miller	mm/dd/yyyy

Phone Or Email

Phone Or Email

Match Found

◉ PatientJenn Miller (DOB:10/31/1985)

2 **You may now add this patient to your Managed Patients. To reset search, hit Clear.** Add Patient | Clear

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

Enroll Patient

Show 10 entries

Search My Patient List:

Edit	Name	Date of Birth	Phone	Action
	PatientJulie Williams	6/13/1970		Continuation / Discontinuation / Report AESI
	PatientTerry Smith	9/22/1989		Continuation / Discontinuation / Report AESI
	PatientPat Smith	7/15/1965		Continuation / Discontinuation / Report AESI
	PatientPat Smith	6/27/1954		Continuation / Discontinuation / Report AESI
	PatientAli Smith	4/4/1962		Continuation / Discontinuation / Report AESI

Edit

Showing 1 to 5 of 5 entries

Previous 1 Next

Return

Manage Patients

PRJane PRDoe
Certified Prescriber
Certified: 15th July, 2014

Find Patient

You can search for a patient already registered in the TIRF REMS and transfer them to your care.

1 **Find a patient by entering the patient's information below:**

First Name: First Name
Last Name: Last Name
Date of Birth: mm/dd/yyyy
Phone Or Email: Phone Or Email

Clear | Find

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

Enroll Patient

Show 10 entries

Search My Patient List:

Edit	Name	Date of Birth	Phone	Action
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	PatientPat Smith	6/27/1954		Continuation / Discontinuation / Report AESI
	PatientAli Smith	4/4/1962		Continuation / Discontinuation / Report AESI
Edit				

Showing 1 to 5 of 5 entries

Previous 1 Next

Return

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Discontinuation Form

Patient Discontinuation Form

This form must be completed and submitted to the TIRF REMS by the prescriber when a patient discontinues treatment with TIRF REMS for any reason.

PatientTerry Smith

Enrolled as of 6/26/2019

Date of Birth:	9/22/1989	Mobile Phone:	920-727-3214
Address:	273 New Saddle Lane Hickory, NC 28601	Home Phone:	

Discontinuation of a TIRF Medicine

Date TIRF medicine was discontinued:

MM/DD/YYYY

Reason for discontinuation (check all that apply):

- ☐ No longer required to manage pain
- ☐ No longer on around-the-clock Opioid
- ☐ Death
  - Date of Death: N/A Cause of Death: N/A
- ☐ Adverse event (if AESI, list below)
- ☐ Other (financial reasons, patient preference, etc.)

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Patient Discontinuation Form

Patient Discontinuation Form

This form must be completed and submitted to the TIRF REMS by the prescriber when a patient discontinues treatment with TIRF REMS for any reason.

PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth:	9/22/1989	Mobile Phone:	920-727-3214
Address:	273 New Saddle Lane Hickory, NC 28601	Home Phone:	

Discontinuation of a TIRF Medicine

Date TIRF medicine was discontinued:

MM/DD/YYYY

Reason for discontinuation (check all that apply):

- [ ] No longer required to manage pain
- [ ] No longer on around-the-clock Opioid
- [ ] Death

  Date of Death: N/A Cause of Death: N/A
- [ ] Adverse event (if AESI, list below)
- [ ] Other (financial reasons, patient preference, etc.)

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

(●) Yes ( ) No

Check all that apply

- [ ] Experienced an overdose of their TIRF medicines medicine (**Overdose** - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)
- [ ] Shown signs or symptoms of addiction to their TIRF medicines medicine (**Addiction** – a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)
- [ ] Misused or been suspected of misusing their TIRF medicines medicine (**Misuse** - the use of a medicinal product without a prescription or in a manner other than as directed by a physician, including use without a prescription of one's own; use in greater amounts to feel euphoria (i.e. to get high), more often, or for a period longer than prescribed; or use in any other way not directed by the prescribing physician)
- [ ] Abused or been suspected of abusing their TIRF medicines medicine (**Abuse** - intentional non-therapeutic use of a medicinal product, even once, for its rewarding psychological or physiological or euphoric effect, and often associated with physical dependence)
- [ ] Someone else has been accidentally exposed to the patient's TIRF medicines medicine (**Accidental exposure** - unintended exposure of a medicinal product to someone other than to whom it was prescribed)
- [ ] Another serious adverse event (**Other serious adverse event** – any adverse event at any dose that results in death, is lifethreatening, requires inpatient hospitalization, or causes prolongation of existing hospitalization)

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Adverse Events of Special Interest Reporting Form

Adverse Events of Special Interest Reporting Form

Adverse events related to accidental exposure, misuse, abuse, addiction, overdose or other serious adverse events must be reported to the TIRF REMS.
This form must be completed to report an adverse event of special interest to the TIRF REMS for any patient taking a TIRF medicine.

PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth:	9/22/1989	Mobile Phone:	920-727-3214
Address:	273 New Saddle Lane Hickory, NC 28601	Home Phone:	

Product Name	Product Strength	Dose*	Frequency*
-- Select Product --		Dose	Frequency

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

◯ Yes ◯ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Patient Status and Opioid Tolerance Form

Patient Status and Opioid Tolerance Form

You must complete and submit this form to the TIRF REMS prior to each subsequent prescription for outpatient use.

Prescriptions will not be authorized for dispensing until this continuation form is on file at the TIRF REMS.

PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Dose

Frequency

Concomitant Medications (check all that apply):*

- [ ] Benzodiazepines
- [ ] Barbiturates
- [ ] Prescription Insomnia Medications
- [ ] Gabapentinoids
- [ ] Antipsychotics
- [ ] Other CNS depressant
- [ ] Sedative Hypnotics
- [ ] Sodium Oxybate
- [ ] None
- [ ] Tranquilizers
- [ ] Alcohol
- [ ] Muscle Relaxants
- [ ] Prescription Cannabinoids

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- [ ] ≥ 60 mg oral morphine/day
- [ ] ≥ 25 micrograms transdermal fentanyl/hour
- [ ] ≥ 30 mg oral oxycodone/day
- [ ] ≥ 8 mg oral hydromorphone/day
- [ ] ≥ 25 mg oral oxymorphone/day
- [ ] ≥ 60 mg oral hydrocodone/day
- [ ] An equianalgesic dose of another opioid

- [ ] I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

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Sign and Submit

Patient Status and Opioid Tolerance Form

Patient Status and Opioid Tolerance Form

You must complete and submit this form to the TIRF REMS prior to each subsequent prescription for outpatient use.

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

- [ ] Benzodiazepines
- [ ] Gabapentinoids
- [ ] Sedative Hypnotics
- [ ] Tranquilizers
- [ ] Muscle Relaxants
- [ ] Barbiturates
- [ ] Antipsychotics
- [ ] Sodium Oxybate
- [ ] Alcohol
- [ ] Prescription Cannabinoids
- [ ] Prescription Insomnia Medications
- [ ] Other CNS depressant
- [ ] None

Medical Information

Type of Pain:*

- ( ) Cancer Pain
- ( ) Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

- (•) Yes
- ( ) No

Check all that apply

- [ ] Experienced an overdose of their TIRF medicines medicine (**Overdose** - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)
- [ ] Shown signs or symptoms of addiction to their TIRF medicines medicine (**Addiction** – a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)
- [ ] Misused or been suspected of misusing their TIRF medicines medicine (**Misuse** - the use of a medicinal product without a prescription or in a manner other than as directed by a physician, including use without a prescription of one's own; use in greater amounts to feel euphoria (i.e. to get high), more often, or for a period longer than prescribed; or use in any other way not directed by the prescribing physician)
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If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- [ ] ≥ 25 micrograms transdermal fentanyl/hour
- [ ] ≥ 8 mg oral hydromorphone/day
- [ ] ≥ 60 mg oral hydrocodone/day

- [ ] I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. **Sign and Submit**

Patient Status and Opioid Tolerance Form

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

- [x] Benzodiazepines
- [ ] Barbiturates
- [ ] Prescription Insomnia Medications
- [ ] Gabapentinoids
- [x] Antipsychotics
- [ ] Other CNS depressant
- [ ] Sedative Hypnotics
- [ ] Sodium Oxybate
- [ ] None
- [ ] Tranquilizers
- [ ] Alcohol
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Medical Information

Type of Pain:*

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To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

(•) Yes ( ) No

Check all that apply

- [ ] Experienced an overdose of their TIRF medicines medicine (**Overdose** - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)
- [ ] Shown signs or symptoms of addiction to their TIRF medicines medicine (**Addiction** – a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)
- [ ] Misused or been suspected of misusing their TIRF medicines medicine (**Misuse** - the use of a medicinal product without a prescription or in a manner other than as directed by a physician, including use without a prescription of one's own; use in greater amounts to feel euphoria (i.e. to get high), more often, or for a period longer than prescribed; or use in any other way not directed by the prescribing physician)
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Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- [ ] I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Patient Status and Opioid Tolerance Form

Patient Status and Opioid Tolerance Form

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

- [x] Benzodiazepines
- [ ] Barbiturates
- [ ] Prescription Insomnia Medications
- [ ] Gabapentinoids
- [x] Antipsychotics
- [ ] Other CNS depressant
- [ ] Sedative Hypnotics
- [ ] Sodium Oxybate
- [ ] None
- [ ] Tranquilizers
- [ ] Alcohol
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Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

◉ Yes ○ No

Check all that apply

- [ ] Experienced an overdose of their TIRF medicines medicine (**Overdose** - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)
- [ ] Shown signs or symptoms of addiction to their TIRF medicines medicine (**Addiction** – a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)
- [ ] Misused or been suspected of misusing their TIRF medicines medicine (**Misuse** - the use of a medicinal product without a prescription or in a manner other than as directed by a physician, including use without a prescription of one's own; use in greater amounts to feel euphoria (i.e. to get high), more often, or for a period longer than prescribed; or use in any other way not directed by the prescribing physician)
- [ ] Abused or been suspected of abusing their TIRF medicines medicine (**Abuse** - intentional non-therapeutic use of a medicinal product, even once, for its rewarding psychological or physiological or euphoric effect, and often associated with physical dependence)
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- [ ] Another serious adverse event (**Other serious adverse event** – any adverse event at any dose that results in death, is lifethreatening, requires inpatient hospitalization, or causes prolongation of existing hospitalization)

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- [ ] ≥ 60 mg oral morphine/day
- [ ] ≥ 25 micrograms transdermal fentanyl/hour
- [ ] ≥ 30 mg oral oxycodone/day
- [ ] ≥ 8 mg oral hydromorphone/day
- [ ] ≥ 25 mg oral oxymorphone/day
- [ ] ≥ 60 mg oral hydrocodone/day
- [ ] An equianalgesic dose of another opioid

- [ ] I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below — Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Status and Opioid Tolerance Form

Patient Status and Opioid Tolerance Form

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

- [x] Benzodiazepines
- [ ] Gabapentinoids
- [ ] Sedative Hypnotics
- [ ] Tranquilizers
- [ ] Muscle Relaxants
- [ ] Barbiturates
- [x] Antipsychotics
- [ ] Sodium Oxybate
- [ ] Alcohol
- [ ] Prescription Cannabinoids
- [ ] Prescription Insomnia Medications
- [ ] Other CNS depressant
- [ ] None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

◉ Yes ○ No

Check all that apply

- [ ] Experienced an overdose of their TIRF medicines medicine (**Overdose** - ingestion of an excessive amount of drug that is considered lethal or toxic, either intentionally or accidentally)
- [ ] Shown signs or symptoms of addiction to their TIRF medicines medicine (**Addiction** – a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance. Signs and symptoms include: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal)
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Verify Opioid Tolerance

Opioid Moiety*

Codeine

Moiety/Strength/Route/Formulation*

--Select--

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

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- [ ] ≥ 8 mg oral hydromorphone/day
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Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- [x] Benzodiazepines
- [ ] Barbiturates
- [ ] Prescription Insomnia Medications
- [ ] Gabapentinoids
- [x] Antipsychotics
- [ ] Other CNS depressant
- [ ] Sedative Hypnotics
- [ ] Sodium Oxybate
- [ ] None
- [ ] Tranquilizers
- [ ] Alcohol
- [ ] Muscle Relaxants
- [ ] Prescription Cannabinoids

Medical Information

Type of Pain:*

( ) Cancer Pain ( ) Non-Cancer Pain

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- Accidental exposure
- Addiction
- Misuse
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- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

(•) Yes ( ) No

Check all that apply

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Verify Opioid Tolerance

Opioid Moiety* Codeine

Moiety/Strength/Route/Formulation* ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET

Quantity* 2
Units* --Select--
Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- [ ] An equianalgesic dose of another opioid

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Patient Status and Opioid Tolerance Form

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Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

- [x] Benzodiazepines
- [ ] Barbiturates
- [ ] Prescription Insomnia Medications
- [ ] Gabapentinoids
- [x] Antipsychotics
- [ ] Other CNS depressant
- [ ] Sedative Hypnotics
- [ ] Sodium Oxybate
- [ ] None
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- [ ] Alcohol
- [ ] Muscle Relaxants
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Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

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- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

◉ Yes ○ No

Check all that apply

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Verify Opioid Tolerance

Opioid Moiety*

Codeine

Moiety/Strength/Route/Formulation*

ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET

Quantity* | Units* | Frequency*

2 | tablet(s) | --Select--

Moiety	Formulation	Strength	Route	Dose	Frequency

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Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

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- [ ] Barbiturates
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- [ ] Gabapentinoids
- [x] Antipsychotics
- [ ] Other CNS depressant
- [ ] Sedative Hypnotics
- [ ] Sodium Oxybate
- [ ] None
- [ ] Tranquilizers
- [ ] Alcohol
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Medical Information

Type of Pain:*

( ) Cancer Pain ( ) Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

(•) Yes ( ) No

Check all that apply

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Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

--Select--	--Select--					

Moiety	Formulation	Strength	Route	Dose	Frequency	
ACETAMINOPHEN/CODEINE ANHYDROUS	TABLET	300 mg/60 mg	ORAL	2 tablet(s)	Three Times a Day	✖

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

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- [ ] ≥ 25 mg oral oxymorphone/day
- [ ] ≥ 60 mg oral hydrocodone/day
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Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

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- Abuse
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○ Yes ○ No

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Verify Opioid Tolerance

Opioid Moiety*

Codeine

Moiety/Strength/Route/Formulation*

ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET

Quantity* | Units* | Frequency*

2 | mg | --Select--

--Select--
Once daily
Every Other Day
Twice a Day
Three Times a Day
Four Times a Day
At Bedtime
Every 4 Hours
Every 6 Hours
Every 8 Hours
Every 12 Hours
Every 48 Hours
Every 72 Hours
Every 7 Days

Moiety	Formulation	Route	Dose	Frequency

Patients must remain on around-the-cl TIRF medicine.

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- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
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- ☐ ≥ 25 micrograms transdermal fentanyl/hour
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- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

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To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

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Verify Opioid Tolerance

Opioid Moiety*

--Moiety--
--Moiety--
Buprenorphine
Codeine
Fentanyl
Hydrocodone
Hydromorphone
Levorphanol
Meperidine
Methadone
Morphine
Oxycodone
Oxymorphone
Pentazocine
Tapentadol
Tramadol

Frequency*

Strength	Route	Dose	Frequency

e-clock opioids while taking a TIRF medicine.

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- ☐ ≥ 60 mg oral morphine/day
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- ☐ ≥ 25 mg oral oxymorphone/day
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○ Yes ○ No

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Verify Opioid Tolerance

Opioid Moiety*

Buprenorphine

Moiety/Strength/Route/Formulation*

--Select--

--Select--
BUPRENORPHINE (75 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (150 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (300 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (450 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (600 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (750 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (900 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (5 ug) TRANSDERMAL PATCH
BUPRENORPHINE (5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (7.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (10 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (15 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (20 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (7.5 ug) TRANSDERMAL PATCH
BUPRENORPHINE (10 ug) TRANSDERMAL PATCH
BUPRENORPHINE (15 ug) TRANSDERMAL PATCH
BUPRENORPHINE (20 ug) TRANSDERMAL PATCH

f the following

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Patient Status and Opioid Tolerance Form

Patient Status and Opioid Tolerance Form

You must complete and submit this form to the TIRF REMS prior to each subsequent prescription for outpatient use.
Prescriptions will not be authorized for dispensing until this continuation form is on file at the TIRF REMS.

Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Codeine

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/15 mg) ORAL TABLET
- ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/30 mg) ORAL TABLET
- ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET
- ACETAMINOPHEN/CODEINE ANHYDROUS (120 mg/12 mg) ORAL LIQUID
- ASPIRIN/ CARISOPRODOL/ CODEINE PHOSPHATE (325mg/200mg/16mg) ORAL TABLET
- BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODEINE ANHYDROUS (50 mg/325 mg/40 mg/30 mg) ORAL CAPSULE
- BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODEINE ANHYDROUS (50 mg/300 mg/40 mg/30 mg) ORAL CAPSULE
- BUTALBITAL/ASPIRIN/CAFFEINE/CODEINE ANHYDROUS (50 mg/325 mg/40 mg/30 mg) ORAL CAPSULE
- CODEINE ANHYDROUS (30 mg) ORAL TABLET
- CODEINE ANHYDROUS (60 mg) ORAL TABLET
- CODEINE ANHYDROUS/GUAIFENESIN (10 mg/100 mg) ORAL LIQUID
- PROMETHAZINE/CODEINE ANHYDROUS (6.25 mg/10 mg) ORAL SOLUTION

f the following

- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

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Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Fentanyl

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- FENTANYL (12 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (25 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (100 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (75 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (37.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (62.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (87.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

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Patient Status and Opioid Tolerance Form

Patient Status and Opioid Tolerance Form

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Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety* Hydrocodone

Moiety/Strength/Route/Formulation* --Select--

--Select--
HYDROCODONE (10 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (15 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (20 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (30 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (40 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (50 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE BITARTRATE (20 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (30 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (40 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (60 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (80 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (100 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (120 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (10 mg/325 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (5 mg/300 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (7.5 mg/300 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL TABLET

f the following

F REMS and
about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

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Patient Status and Opioid Tolerance Form

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Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety* Hydrocodone

Moiety/Strength/Route/Formulation* --Select--

- HYDROCODONE BITARTRATE (60 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROCODONE BITARTRATE (100 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROCODONE BITARTRATE (120 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (10 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (5 mg/300 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/300 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (2.5 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL SYRUP
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL SYRUP
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL SOLUTION
- HYDROCODONE/ACETAMINOPHEN (2.5 mg/108 mg) ORAL SOLUTION
- HYDROCODONE/ACETAMINOPHEN (5 mg/217 mg) ORAL SOLUTION
- HYDROCODONE/CHLORPHENIRAMINE (10 mg/8 mg) ORAL SUSPENSION, EXTENDED RELEASE
- HYDROCODONE/IBUPROFEN (7.5 mg/200 mg) ORAL TABLET, FILM COATED
- HYDROCODONE/IBUPROFEN (5 mg/200 mg) ORAL TABLET
- HYDROCODONE/IBUPROFEN (2.5 mg/200 mg) ORAL TABLET
- HYDROCODONE/IBUPROFEN (10 mg/200 mg) ORAL TABLET

f the following

F REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

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Patient Status and Opioid Tolerance Form

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Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Hydromorphone

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- HYDROMORPHONE (2 mg) ORAL TABLET
- HYDROMORPHONE (4 mg) ORAL TABLET
- HYDROMORPHONE (8 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (12 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (16 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (32 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (8 mg) ORAL TABLET
- HYDROMORPHONE HYDROCHLORIDE (5MG/5ML) ORAL SOLUTION

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

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Sign and Submit

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Patient Status and Opioid Tolerance Form

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Levorphanol

Moiety/Strength/Route/Formulation*

--Select--

--Select--
LEVORPHANOL (2 mg) ORAL TABLET
LEVORPHANOL (3 mg) ORAL TABLET

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* — -- Select Product --
Product Strength*
Dose* — Dose
Frequency* — Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

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Verify Opioid Tolerance

Opioid Moiety*

Meperidine

Moiety/Strength/Route/Formulation*

--Select--
--Select--
MEPERIDINE (50 mg) ORAL TABLET
MEPERIDINE (100 mg) ORAL TABLET
MEPERIDINE (50MG/5ML) ORAL SYRUP

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Methadone

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- METHADONE (10 mg) ORAL TABLET
- METHADONE (5 mg) ORAL TABLET
- METHADONE (5 mg) ORAL SOLUTION
- METHADONE (10 mg) ORAL SOLUTION
- METHADONE HYDROCHLORIDE (40MG) ORAL TABLET, FOR SUSPENSION
- METHADONE HYDROCHLORIDE (10MG/ML) ORAL CONCENTRATE

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below — Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Status and Opioid Tolerance Form

Patient Status and Opioid Tolerance Form

You must complete and submit this form to the TIRF REMS prior to each subsequent prescription for outpatient use.
Prescriptions will not be authorized for dispensing until this continuation form is on file at the TIRF REMS.

Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* — -- Select Product --
Product Strength*
Dose* — Dose
Frequency* — Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety* — Morphine

Moiety/Strength/Route/Formulation* — --Select--

- --Select--
- MORPHINE (30 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (45 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (60 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (75 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (90 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (120 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (15 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (30 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (60 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (100 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (200 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (10 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (20 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (50 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (80 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (100 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (200 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (15 mg) ORAL TABLET
- MORPHINE (40 mg) ORAL CAPSULE, EXTENDED RELEASE

f the following

F REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

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Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Morphine

Moiety/Strength/Route/Formulation*

--Select--

MORPHINE (15 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (30 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (60 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (100 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (200 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (10 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (20 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (50 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (80 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (100 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (200 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (15 mg) ORAL TABLET
MORPHINE (40 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (30 mg) ORAL TABLET
MORPHINE (70 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (130 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (150 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE SULFATE (10MG/5ML) ORAL SOLUTION
MORPHINE SULFATE (20MG/5ML) ORAL SOLUTION
MORPHINE SULFATE (100MG/5ML) ORAL SOLUTION

f the following

F REMS and

about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Oxycodone

Moiety/Strength/Route/Formulation*

--Select--

--Select--
ACETAMINOPHEN/OXYCODONE (325 mg/5 mg) ORAL TABLET
OXYCODONE (5 mg) ORAL SOLUTION
OXYCODONE (10 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (20 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (40 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (80 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (5 mg) ORAL TABLET
OXYCODONE (10 mg) ORAL TABLET
OXYCODONE (15 mg) ORAL TABLET
OXYCODONE (20 mg) ORAL TABLET
OXYCODONE (30 mg) ORAL TABLET
OXYCODONE (100 mg) ORAL SOLUTION
OXYCODONE (7.5 mg) ORAL TABLET
OXYCODONE (9MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (13.5MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (18MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (27MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (36MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE HYDROCHLORIDE (15MG) ORAL TABLET, EXTENDED RELEASE

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Oxycodone

Moiety/Strength/Route/Formulation*

--Select--

OXYCODONE (9MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (13.5MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (18MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (27MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (36MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE HYDROCHLORIDE (15MG) ORAL TABLET, EXTENDED RELEASE
OXYCODONE HYDROCHLORIDE (30MG) ORAL TABLET, EXTENDED RELEASE
OXYCODONE HYDROCHLORIDE (60MG) ORAL TABLET, EXTENDED RELEASE
OXYCODONE/ACETAMINOPHEN (2.5 mg/300 mg) ORAL TABLET
OXYCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL TABLET
OXYCODONE/ACETAMINOPHEN (5 mg/300 mg) ORAL TABLET
OXYCODONE/ACETAMINOPHEN (2.5 mg/325 mg) ORAL TABLET
OXYCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL TABLET
OXYCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL TABLET
OXYCODONE/ACETAMINOPHEN (10 mg/325 mg) ORAL TABLET
OXYCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL SOLUTION
OXYCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL SOLUTION
OXYCODONE/ACETAMINOPHEN (7.5 mg/300 mg) ORAL TABLET
OXYCODONE/ASPIRIN (4.8355 mg/325 mg) ORAL TABLET
OXYCODONE/IBUPROFEN (5 mg/400 mg) ORAL TABLET, FILM COATED

f the following

F REMS and about safe storage and disposal, and to monitor my patients appropriately.

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Clear

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Date of Birth: 9/22/1989
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Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Oxymorphone

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- OXYMORPHONE (5 mg) ORAL TABLET
- OXYMORPHONE (10 mg) ORAL TABLET
- OXYMORPHONE HYDROCHLORIDE (5MG) ORAL TABLET, EXTENDED RELEASE
- OXYMORPHONE HYDROCHLORIDE (7.5MG) ORAL TABLET, EXTENDED RELEASE
- OXYMORPHONE HYDROCHLORIDE (10MG) ORAL TABLET, EXTENDED RELEASE
- OXYMORPHONE HYDROCHLORIDE (15MG) ORAL TABLET, EXTENDED RELEASE
- OXYMORPHONE HYDROCHLORIDE (20MG) ORAL TABLET, EXTENDED RELEASE
- OXYMORPHONE HYDROCHLORIDE (30MG) ORAL TABLET, EXTENDED RELEASE
- OXYMORPHONE HYDROCHLORIDE (40MG) ORAL TABLET, EXTENDED RELEASE

f the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

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Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety* Pentazocine

Moiety/Strength/Route/Formulation* --Select--

- --Select--
- PENTAZOCINE/NALOXONE (50 mg/0.5 mg) ORAL TABLET

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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PatientTerry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Barbiturates
- ☐ Prescription Insomnia Medications
- ☐ Gabapentinoids
- ☐ Antipsychotics
- ☐ Other CNS depressant
- ☐ Sedative Hypnotics
- ☐ Sodium Oxybate
- ☐ None
- ☐ Tranquilizers
- ☐ Alcohol
- ☐ Muscle Relaxants
- ☐ Prescription Cannabinoids

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Addiction
- Misuse
- Overdose
- Abuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety*

Tapentadol

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- Tapentadol (50mg) ORAL TABLET
- Tapentadol (75MG) ORAL TABLET
- Tapentadol (100MG) ORAL TABLET
- Tapentadol (50MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (100MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (150MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (200MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (250MG) ORAL TABLET, EXTENDED RELEASE

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day
- ☐ An equianalgesic dose of another opioid

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

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Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
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- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety* Tramadol

Moiety/Strength/Route/Formulation* --Select--

- --Select--
- ACETAMINOPHEN/TRAMADOL (325 mg/37.5 mg) ORAL TABLET, FILM COATED
- TRAMADOL (50 mg) ORAL TABLET
- TRAMADOL (200 mg) ORAL TABLET, EXTENDED RELEASE
- TRAMADOL (50 mg) ORAL TABLET, FILM COATED
- TRAMADOL (300 mg) ORAL TABLET, EXTENDED RELEASE
- TRAMADOL (100 mg) ORAL TABLET, EXTENDED RELEASE
- TRAMADOL (50 mg) ORAL TABLET, COATED
- TRAMADOL (5 mg) ORAL SOLUTION
- TRAMADOL (100 mg) ORAL TABLET
- TRAMADOL HYDROCHLORIDE (100MG) ORAL CAPSULE, EXTENDED RELEASE
- TRAMADOL HYDROCHLORIDE (200MG) ORAL CAPSULE, EXTENDED RELEASE
- TRAMADOL HYDROCHLORIDE (300MG) ORAL CAPSULE, EXTENDED RELEASE
- TRAMADOL/ACETAMINOPHEN (37.5 mg/325 mg) ORAL TABLET, FILM COATED

f the following

- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below — Clear

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You must complete and submit this form to the TIRF REMS prior to each subsequent prescription for outpatient use.
Prescriptions will not be authorized for dispensing until this continuation form is on file at the TIRF REMS.

Patient Terry Smith — Enrolled as of 6/26/2019

Date of Birth: 9/22/1989
Address: 273 New Saddle Lane Hickory, NC 28601
Mobile Phone: 920-727-3214
Home Phone:

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

Adverse Events of Special Interest (AESI)

Adverse events that MUST be reported to the TIRF medicines REMS:

- Accidental exposure
- Overdose
- Addiction
- Abuse
- Misuse
- Other serious adverse event

To your knowledge, has the patient experienced an adverse event of special interest while they have been using their TIRF medicine?*

○ Yes ○ No

If adverse events of special interest are reported, you will be contacted on behalf of the TIRF REMS for follow-up.

Verify Opioid Tolerance

Opioid Moiety* Codeine

Moiety/Strength/Route/Formulation* ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET

Quantity* 2
Units* --Select
--Select--
film(s)
patch(es)
tablet(s)
capsule(s)
TBSP
mL
mg
mg/mL
Frequency*

Moiety	Strength	Route	Dose	Frequency

Patients must remai e-clock opioids while taking a TIRF medicine.

This patient is opioi use he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens dai prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral mor
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below — Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Patient Enrollment

Patient Information

First Name* | M.I. | Last Name* | Date of Birth*

First Name | Middl | Last Name | mm/dd/yyyy

Sex
- Male
- Female
- Other

Are you Hispanic or Latino?
- Yes
- No

Race (check all that apply)
- White
- Asian
- Black or African American
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Other (please specify)

Address Line 1* | Address Line 2

Address Line 1 | Address Line 2

City* | State* | Zip Code*

City | State | Zip Code

Email Address* | Number*

Email Address | nnn-nnn-nnnn
- Home Phone
- Mobile Phone

Preferred Time of Contact*
- Morning
- Afternoon
- Evening

Preferred Method of Contact*
- Email
- Text to Mobile#
- Phone Call
- Postal Mail

Is there a child in the home or are you a caregiver of small children?*
- Yes
- No

Do you have a safe and secure place to store your medicine?*
- Yes
- No

Patient Representative (if required)

First Name | Last Name | Relationship

First Name | Last Name | Mother, Father...

Number | Email Address

nnn-nnn-nnnn | Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device

Use this option to share your tablet or PC with your patient to sign the agreement.

Sign on My Device

Provide QR Code

Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.

Sign on Patient's Phone

Send Email

Use this option to send your patient an email to sign the agreement at a later time.

Send Email

Print PDF

Use this option to print a paper copy of the agreement for signature.

Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
- Yes
- No

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product -- | | Dose | Frequency

Type of Pain:*
- Cancer Pain
- Non-Cancer Pain

Concomitant Medications (check all that apply):*
- Benzodiazepines
- Gabapentinoids
- Sedative Hypnotics
- Tranquilizers
- Muscle Relaxants
- Barbiturates
- Antipsychotics
- Sodium Oxybate
- Alcohol
- Prescription Cannabinoids
- Prescription Insomnia Medications
- Other CNS depressant
- None

Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*
- ≥ 60 mg oral morphine/day
- ≥ 30 mg oral oxycodone/day
- ≥ 25 mg oral oxymorphone/day
- An equianalgesic dose of another opioid
- ≥ 25 micrograms transdermal fentanyl/hour
- ≥ 8 mg oral hydromorphone/day
- ≥ 60 mg oral hydrocodone/day

- I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Enrollment

Patient Information

First Name* Megan
M.I. Middl
Last Name* Brown
Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
Number* nnn-nnn-nnnn
○ Home Phone ○ Mobile Phone

Preferred Time of Contact*
○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name
Last Name Last Name
Relationship Mother, Father...

Number nnn-nnn-nnnn
Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* --Moiety--

Moiety/Strength/Route/Formulation*

Quantity* Units* Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Patient Enrollment

Patient Information

First Name* Megan
M.I. Middl
Last Name* Brown
Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
Number* nnn-nnn-nnnn
○ Home Phone ○ Mobile Phone

Preferred Time of Contact*
○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name
Last Name Last Name
Relationship Mother, Father...

Number nnn-nnn-nnnn
Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☑ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* Units* Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

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- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

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Reference ID: 4721762

Patient Enrollment

Patient Information

First Name* Megan
M.I. Middl
Last Name* Brown
Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
Number* nnn-nnn-nnnn
○ Home Phone ○ Mobile Phone

Preferred Time of Contact*
○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name
Last Name Last Name
Relationship Mother, Father...

Number nnn-nnn-nnnn
Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☑ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* Units* Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

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Cancel

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Patient Enrollment

Patient Information

First Name* Megan

M.I. Middl

Last Name* Brown

Date of Birth* 07/14/2000

Sex
- Male
- Female
- Other

Are you Hispanic or Latino?
- Yes
- No

Race (check all that apply)
- White
- Asian
- Black or African American
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn
- Home Phone
- Mobile Phone

Preferred Time of Contact*
- Morning
- Afternoon
- Evening

Preferred Method of Contact*
- Email
- Text to Mobile#
- Phone Call
- Postal Mail

Is there a child in the home or are you a caregiver of small children?*
- Yes
- No

Do you have a safe and secure place to store your medicine?*
- Yes
- No

Patient Representative (if required)

First Name First Name

Last Name Last Name

Relationship Mother, Father...

Number nnn-nnn-nnnn

Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device

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Sign on My Device

Provide QR Code

Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.

Sign on Patient's Phone

Send Email

Use this option to send your patient an email to sign the agreement at a later time.

Send Email

Print PDF

Use this option to print a paper copy of the agreement for signature.

Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
- Yes
- No

Product Name* -- Select Product --

Product Strength*

Dose* Dose

Frequency* Frequency

Type of Pain:*
- Cancer Pain
- Non-Cancer Pain

Concomitant Medications (check all that apply):*
- [ ] Benzodiazepines
- [ ] Gabapentinoids
- [ ] Sedative Hypnotics
- [ ] Tranquilizers
- [ ] Muscle Relaxants
- [ ] Barbiturates
- [x] Antipsychotics
- [ ] Sodium Oxybate
- [ ] Alcohol
- [ ] Prescription Cannabinoids
- [ ] Prescription Insomnia Medications
- [ ] Other CNS depressant
- [ ] None

Verify Opioid Tolerance

Opioid Moiety* Codeine

Moiety/Strength/Route/Formulation* --Select--

Quantity*

Units*

Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*
- [ ] ≥ 60 mg oral morphine/day
- [ ] ≥ 30 mg oral oxycodone/day
- [ ] ≥ 25 mg oral oxymorphone/day
- [ ] An equianalgesic dose of another opioid
- [ ] ≥ 25 micrograms transdermal fentanyl/hour
- [ ] ≥ 8 mg oral hydromorphone/day
- [ ] ≥ 60 mg oral hydrocodone/day

- [ ] I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

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Patient Enrollment

Patient Information

First Name* Megan
M.I. Middl
Last Name* Brown
Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
Number* nnn-nnn-nnnn
○ Home Phone ○ Mobile Phone

Preferred Time of Contact*
○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name
Last Name Last Name
Relationship Mother, Father...

Number nnn-nnn-nnnn
Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device
Use this option to share your tablet or PC with your patient to sign the agreement.
Sign on My Device

Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☑ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Codeine

Moiety/Strength/Route/Formulation* ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET

Quantity* 2
Units* --Select--
Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

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- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Patient Enrollment

Patient Information

First Name* Megan
M.I. Middl
Last Name* Brown
Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
Number* nnn-nnn-nnnn
○ Home Phone ○ Mobile Phone

Preferred Time of Contact*
○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name
Last Name Last Name
Relationship Mother, Father...

Number nnn-nnn-nnnn
Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device
Use this option to share your tablet or PC with your patient to sign the agreement.
Sign on My Device

Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☑ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Codeine

Moiety/Strength/Route/Formulation* ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET

Quantity* 2
Units* tablet(s)
Frequency* --Select--

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Enrollment

Patient Information

First Name* Megan
M.I. Middl
Last Name* Brown
Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)
- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
Number* nnn-nnn-nnnn
○ Home Phone ○ Mobile Phone

Preferred Time of Contact*
○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name
Last Name Last Name
Relationship Mother, Father...

Number nnn-nnn-nnnn
Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device
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Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*
- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☑ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Codeine

Moiety/Strength/Route/Formulation* ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET

Quantity* 2
Units* tablet(s)
Frequency* Three Times a Day
Add

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*
- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

Clear

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Cancel

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Patient Enrollment

Patient Information

First Name* Megan
M.I. Middl
Last Name* Brown
Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
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Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name
Last Name Last Name
Relationship Mother, Father...

Number nnn-nnn-nnnn
Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on My Device

Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Product --
Product Strength*
Dose* Dose
Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☑ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* --Moiety--

Moiety/Strength/Route/Formulation*

Quantity* Units* --Select-- Frequency* --Select--

Moiety	Formulation	Strength	Route	Dose	Frequency	
ACETAMINOPHEN/CODEINE ANHYDROUS	TABLET	300 mg/60 mg	ORAL	2 tablet(s)	Three Times a Day	✖

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

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Patient Enrollment

Patient Information

First Name* Megan

M.I. Middl

Last Name* Brown

Date of Birth* 07/14/2000

Sex
- Male
- Female
- Other

Are you Hispanic or Latino?
- Yes
- No

Race (check all that apply)
- White
- Asian
- Black or African American
- American Indian or Alaska Native
- Native Hawaiian or Other Pacific Islander
- Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn
- Home Phone
- Mobile Phone

Preferred Time of Contact*
- Morning
- Afternoon
- Evening

Preferred Method of Contact*
- Email
- Text to Mobile#
- Phone Call
- Postal Mail

Is there a child in the home or are you a caregiver of small children?*
- Yes
- No

Do you have a safe and secure place to store your medicine?*
- Yes
- No

Patient Representative (if required)

First Name First Name

Last Name Last Name

Relationship Mother, Father...

Number nnn-nnn-nnnn

Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device

Use this option to share your tablet or PC with your patient to sign the agreement.

Sign on My Device

Provide QR Code

Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.

Sign on Patient's Phone

Send Email

Use this option to send your patient an email to sign the agreement at a later time.

Send Email

Print PDF

Use this option to print a paper copy of the agreement for signature.

Print PDF

Cancel

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Reference ID: 4721752

TI

PRDoe

Pa

Patient Inf

First Name

Megan

Sex

Male

Race (chec

White

Asian

Black or

Address Li

Address Li

City*

City

Email Addr

Megan.Bro

Preferred

Morni

Is there a c

Yes

Patient Re

First Name

First Name

Number

nnn-nnn-n

Patient / G

You have n to sign the agree complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Patient / Guardian Agreement

TIRF Medicines can cause your breathing to stop – which can lead to death.

Safety Rules for TIRF Medicines

You have agreed to take a TIRF Medicine and follow all the safety rules to make it less likely you or others will experience serious harm.

- My healthcare provider has talked to me about the safe use of TIRF medicines using the **Medication Guide** and **Patient Counseling Guide**.
- I will only use this medicine if I am regularly using another opioid, around-the-clock, for constant pain.
- If I stop taking my around-the-clock-opioid pain medicine, I **MUST** stop taking my TIRF medicine.
- I will never share or give my TIRF medicine to anyone else, even if they have the same symptoms.
  - My TIRF medicine could cause harm to others or even death. A dose that is okay for me could cause an overdose and death for someone else.
- I will store my TIRF medicine in a safe and secure place away from children. I understand that accidental use by a child, or anyone for whom the medicine was not prescribed, can cause death.
- I have been told how to properly dispose of my partially used or unneeded TIRF medicine remaining from my prescription. I will dispose of my TIRF medicine properly as soon as I no longer need it.
- I will contact my healthcare provider if my TIRF medicine does not relieve my pain. I will not change the dose of my TIRF medicine myself or take it more often than my healthcare provider has directed.
- I must enroll in the TIRF REMS and Patient Registry by completing the **Patient Enrollment Form** with my healthcare provider.
- I understand that the TIRF REMS and its agents may use and share my personal information to manage the program, and information all about patients who get TIRF medicines will be stored in a private and secure database. My health information may be shared with the U.S. Food and Drug Administration (FDA) to evaluate the TIRF REMS. However, my name will not be shared.
- I give permission for the TIRF REMS and its agents or vendors to contact me by phone, mail, or email to support the administration of the TIRF REMS Program.
- I will tell my healthcare provider if I, or anyone else, experience any adverse event of accidental exposure, abuse, misuse, addiction, and overdose.
- I will re-enroll in the TIRF REMS by completing the **Patient Enrollment Form** with my healthcare provider every two years during treatment.

Sign | Type Signature

Clear

Megan Brown: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*

Yes No

Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

Dose

Frequency

Type of Pain:*

Cancer Pain Non-Cancer Pain

Concomitant Medications (check all that apply):*

- Benzodiazepines
- Gabapentinoids
- Sedative Hypnotics
- Tranquilizers
- Muscle Relaxants
- Barbiturates
- Antipsychotics
- Sodium Oxybate
- Alcohol
- Prescription Cannabinoids
- Prescription Insomnia Medications
- Other CNS depressant
- None

Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ≥ 60 mg oral morphine/day
- ≥ 30 mg oral oxycodone/day
- ≥ 25 mg oral oxymorphone/day
- An equianalgesic dose of another opioid
- ≥ 25 micrograms transdermal fentanyl/hour
- ≥ 8 mg oral hydromorphone/day
- ≥ 60 mg oral hydrocodone/day

I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

TIRF REMS

Contact Us | PRJane PRDoe

Patient Enro

Patient Information

First Name*: Megan

Date of Birth*: 7/14/2000

Sex: Male | Female | O

Race (check all that apply): White | Asian | Black or African American

Address Line 1*: Address Line 1

City*: City

Email Address*: Megan.Brown@examoto.net

Preferred Time of Contact*: Morning | Afternoon | ... | Mail | Postal Mail

Is there a child in the home or ... store your medicine?*: Yes | No

Patient Representative (if requir

First Name: First Name

Number: nnn-nnn-nnnn

Email: Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on Patient's Phone

Send Email

Use this option to send your patient an email to sign the agreement at a later time.

Send Email

Print PDF

Use this option to print a paper copy of the agreement for signature.

Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*: Yes | No

Product Name*: -- Select Product --

Product Strength*:

Dose*: Dose

Frequency*: Frequency

Type of Pain:*: Cancer Pain | Non-Cancer Pain

Concomitant Medications (check all that apply):*

- Benzodiazepines
- Gabapentinoids
- Sedative Hypnotics
- Tranquilizers
- Muscle Relaxants
- Barbiturates
- Antipsychotics
- Sodium Oxybate
- Alcohol
- Prescription Cannabinoids
- Prescription Insomnia Medications
- Other CNS depressant
- None

Verify Opioid Tolerance

Opioid Moiety*: --Moiety--

Moiety/Strength/Route/Formulation*:

Quantity*: | Units*: | Frequency*:

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- ≥ 60 mg oral morphine/day
- ≥ 30 mg oral oxycodone/day
- ≥ 25 mg oral oxymorphone/day
- An equianalgesic dose of another opioid
- ≥ 25 micrograms transdermal fentanyl/hour
- ≥ 8 mg oral hydromorphone/day
- ≥ 60 mg oral hydrocodone/day

I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature.

Sign and Submit

Cancel

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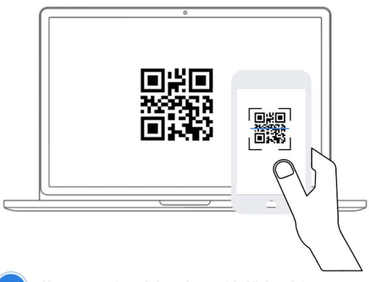
Reference ID: 4751752

Provide QR Code

Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.

Directions

1. Have your patient point their modern phone camera at the personalized QR Code. Older phones may require an App.



2. Have your patient click on the provided link and sign.

Click the button below to generate a QR code for this patient. This will create a custom invite link that the patient can scan to complete the enrollment.

Send Email

Patient Enro

Send Email

Use this option to send your patient an email to sign the agreement at a later time.

Confirm Email

Megan.Brown@examoto.net

HIPAA Acknowledgement

☐ I understand this email may contain Personally Identifiable Information and confirm that I have the appropriate HIPAA agreements in place with this patient.

Send Email

Patient Information

First Name*: Megan

Date of Birth*: 7/14/2000

Sex: ○ Male ○ Female ○ O

Race (check all that apply):
- ☐ White
- ☐ Asian
- ☐ Black or African American

Address Line 1*: Address Line 1

Address Line 2: Address Line 2

City*: City

State*: State

Zip Code*: Zip Code

Email Address*: Megan.Brown@examoto.net

Number*: nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact*: ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*: ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*: ○ Yes ○ No

Do you have a safe and secure place to store your medicine?*: ○ Yes ○ No

Patient Representative (if required)

First Name: First Name

Last Name: Last Name

Relationship: Mother, Father...

Number: nnn-nnn-nnnn

Email Address: Email Address

Patient / Guardian Agreement

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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*: ○ Yes ○ No

Product Name*: -- Select Product --

Product Strength*:

Dose*: Dose

Frequency*: Frequency

Type of Pain:*: ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*
- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*: --Moiety--

Moiety/Strength/Route/Formulation*:

Quantity*: Units*: Frequency*:

Moiety	Formulation	Strength	Route	Dose	Frequency

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- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Reference ID: 4721752

Patient Enro

Print PDF

Use this option to print a paper copy of the agreement for signature.

Print

Patient Information

First Name*: Megan

Date of Birth*: 7/14/2000

Sex: ○ Male ○ Female ○ O

Race (check all that apply):
- ☐ White
- ☐ Asian
- ☐ Black or African American

Address Line 1*: Address Line 1

City*: City

State: State

Zip Code: Zip Code

Email Address*: Megan.Brown@examoto.net

Number*: nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact*: ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*: ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*: ○ Yes ○ No

Do you have a safe and secure place to store your medicine?*: ○ Yes ○ No

Patient Representative (if required)

First Name: First Name

Last Name: Last Name

Relationship: Mother, Father...

Number: nnn-nnn-nnnn

Email Address: Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name*: -- Select Product --

Product Strength*:

Dose*: Dose

Frequency*: Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*
- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*: --Moiety--

Moiety/Strength/Route/Formulation*:

Quantity*: Units*: Frequency*:

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*
- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

Clear

PRJane PRDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

TIRF REMS

Counsel Patient

Remember to counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

Prescriber

1310000000

Prescriber Certif

You are currently cer

PRJane PRDoe

Certified as of 4/20/2020

Edit

Counsel Patient

Before you enroll, counsel the patient on the safe use of TIRF medicines using the Medication Guide for the prescribed TIRF medicine and the Patient Counseling Guide. Remember to provide a copy of these materials to the patient.

- Company1MG
- Company2MG
- Company3MG
- Company4MG
- Company5MG
- Company6MG

Print Patient Counseling Guide

Enroll Patients in the TIRF REMS

Complete this form with your patient to enroll them in the TIRF REMS. **A patient must be enrolled in the TIRF REMS** to receive treatment.

→ Enroll Patient

Manage Patients

Manage your patients. Enter Patient Status and Opioid Tolerance, Discontinuation, and Adverse Events of Special Interest Reporting Forms.

→ Manage Patients

Prescriber Materials

- Prescriber Education
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Counseling Guide
- Patient Status and Opioid Tolerance Form
- Patient Discontinuation Form
- Adverse Events of Special Interest Reporting Form
- Prescriber FAQs

Upload Enrollment Form

Uploads must be in PDF format.

Browse

Or drop files here

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Codeine

Moiety/Strength/Route/Formulation* ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/30 mg) ORAL TABLET

Quantity* 2 | Units* mg | Frequency* --Select--

--Select--
Once daily
Every Other Day
Twice a Day
Three Times a Day
Four Times a Day
At Bedtime
Every 4 Hours
Every 6 Hours
Every 8 Hours
Every 12 Hours
Every 48 Hours
Every 72 Hours
Every 7 Days

Moiety	Formulation	Route	Dose	Frequency

Patients must remain on around-the-clock c… edicine.

This patient is opioid tolerant because he/sl… xclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this… longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below. Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex
O Male O Female O Other

Are you Hispanic or Latino?
O Yes O No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn O Home Phone O Mobile Phone

Preferred Time of Contact*
O Morning O Afternoon O Evening

Preferred Method of Contact*
O Email O Text to Mobile# O Phone Call O Postal Mail

Is there a child in the home or are you a caregiver of small children?*
O Yes O No

Do you have a safe and secure place to store your medicine?*
O Yes O No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device
Use this option to share your tablet or PC with your patient to sign the agreement.
Sign on My Device

Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
O Yes O No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:*
O Cancer Pain O Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
--Moiety--
--Moiety--
Buprenorphine
Codeine
Fentanyl
Hydrocodone
Hydromorphone
Levorphanol
Meperidine
Methadone
Morphine
Oxycodone
Oxymorphone
Pentazocine
Tapentadol
Tramadol

Frequency*

Strength	Route	Dose	Frequency

ock opioids while taking a TIRF medicine.

ne/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
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- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact*: ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*: ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Buprenorphine

Moiety/Strength/Route/Formulation* --Select--

--Select--
BUPRENORPHINE (75 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (150 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (300 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (450 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (600 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (750 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (900 ug) BUCCAL FILM, SOLUBLE
BUPRENORPHINE (5 ug) TRANSDERMAL PATCH
BUPRENORPHINE (5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (7.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (10 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (15 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (20 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
BUPRENORPHINE (7.5 ug) TRANSDERMAL PATCH
BUPRENORPHINE (10 ug) TRANSDERMAL PATCH
BUPRENORPHINE (15 ug) TRANSDERMAL PATCH
BUPRENORPHINE (20 ug) TRANSDERMAL PATCH

ng opioid

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex
O Male O Female O Other

Are you Hispanic or Latino?
O Yes O No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn O Home Phone O Mobile Phone

Preferred Time of Contact*
O Morning O Afternoon O Evening

Preferred Method of Contact*
O Email O Text to Mobile# O Phone Call O Postal Mail

Is there a child in the home or are you a caregiver of small children?*
O Yes O No

Do you have a safe and secure place to store your medicine?*
O Yes O No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device
Use this option to share your tablet or PC with your patient to sign the agreement.
Sign on My Device

Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
O Yes O No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:*
O Cancer Pain O Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
Codeine

Moiety/Strength/Route/Formulation*
--Select--

--Select--
ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/15 mg) ORAL TABLET
ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/30 mg) ORAL TABLET
ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/60 mg) ORAL TABLET
ACETAMINOPHEN/CODEINE ANHYDROUS (120 mg/12 mg) ORAL LIQUID
ASPIRIN/ CARISOPRODOL/ CODEINE PHOSPHATE (325mg/200mg/16mg) ORAL TABLET
BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODEINE ANHYDROUS (50 mg/325 mg/40 mg/30 mg) ORAL CAPSULE
BUTALBITAL/ACETAMINOPHEN/CAFFEINE/CODEINE ANHYDROUS (50 mg/300 mg/40 mg/30 mg) ORAL CAPSULE
BUTALBITAL/ASPIRIN/CAFFEINE/CODEINE ANHYDROUS (50 mg/325 mg/40 mg/30 mg) ORAL CAPSULE
CODEINE ANHYDROUS (30 mg) ORAL TABLET
CODEINE ANHYDROUS (60 mg) ORAL TABLET
CODEINE ANHYDROUS/GUAIFENESIN (10 mg/100 mg) ORAL LIQUID
PROMETHAZINE/CODEINE ANHYDROUS (6.25 mg/10 mg) ORAL SOLUTION

ng opioid

- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Fentanyl

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- FENTANYL (12 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (25 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (100 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (75 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (37.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (62.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE
- FENTANYL (87.5 ug) TRANSDERMAL PATCH, EXTENDED RELEASE

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Hydrocodone

Moiety/Strength/Route/Formulation* --Select--

--Select--
HYDROCODONE (10 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (15 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (20 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (30 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (40 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE (50 mg) ORAL CAPSULE, EXTENDED RELEASE
HYDROCODONE BITARTRATE (20 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (30 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (40 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (60 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (80 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (100 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE BITARTRATE (120 mg) ORAL TABLET, EXTENDED RELEASE
HYDROCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (10 mg/325 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (5 mg/300 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (7.5 mg/300 mg) ORAL TABLET
HYDROCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL TABLET

ng opioid

and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex
O Male O Female O Other

Are you Hispanic or Latino?
O Yes O No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn

O Home Phone O Mobile Phone

Preferred Time of Contact*
O Morning O Afternoon O Evening

Preferred Method of Contact*
O Email O Text to Mobile# O Phone Call O Postal Mail

Is there a child in the home or are you a caregiver of small children?*
O Yes O No

Do you have a safe and secure place to store your medicine?*
O Yes O No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
O Yes O No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:*
O Cancer Pain O Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
Hydrocodone

Moiety/Strength/Route/Formulation*
--Select--

- HYDROCODONE BITARTRATE (80 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROCODONE BITARTRATE (100 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROCODONE BITARTRATE (120 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (10 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (5 mg/300 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/300 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (2.5 mg/325 mg) ORAL TABLET
- HYDROCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL SYRUP
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL SYRUP
- HYDROCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL SOLUTION
- HYDROCODONE/ACETAMINOPHEN (2.5 mg/108 mg) ORAL SOLUTION
- HYDROCODONE/ACETAMINOPHEN (5 mg/217 mg) ORAL SOLUTION
- HYDROCODONE/CHLORPHENIRAMINE (10 mg/8 mg) ORAL SUSPENSION, EXTENDED RELEASE
- HYDROCODONE/IBUPROFEN (7.5 mg/200 mg) ORAL TABLET, FILM COATED
- HYDROCODONE/IBUPROFEN (5 mg/200 mg) ORAL TABLET
- HYDROCODONE/IBUPROFEN (2.5 mg/200 mg) ORAL TABLET
- HYDROCODONE/IBUPROFEN (10 mg/200 mg) ORAL TABLET

ng opioid

and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 5472217 52

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Hydromorphone

Moiety/Strength/Route/Formulation* --Select--

- --Select--
- HYDROMORPHONE (2 mg) ORAL TABLET
- HYDROMORPHONE (4 mg) ORAL TABLET
- HYDROMORPHONE (8 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (12 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (16 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (32 mg) ORAL TABLET, EXTENDED RELEASE
- HYDROMORPHONE (8 mg) ORAL TABLET
- HYDROMORPHONE HYDROCHLORIDE (5MG/5ML) ORAL SOLUTION

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

ERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Levorphanol

Moiety/Strength/Route/Formulation*

--Select--
- --Select--
- LEVORPHANOL (2 mg) ORAL TABLET
- LEVORPHANOL (3 mg) ORAL TABLET

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

To report ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact*: ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*: ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Meperidine

Moiety/Strength/Route/Formulation*

--Select--
- --Select--
- MEPERIDINE (50 mg) ORAL TABLET
- MEPERIDINE (100 mg) ORAL TABLET
- MEPERIDINE (50MG/5ML) ORAL SYRUP

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex
O Male O Female O Other

Are you Hispanic or Latino?
O Yes O No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
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Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn O Home Phone O Mobile Phone

Preferred Time of Contact*
O Morning O Afternoon O Evening

Preferred Method of Contact*
O Email O Text to Mobile# O Phone Call O Postal Mail

Is there a child in the home or are you a caregiver of small children?*
O Yes O No

Do you have a safe and secure place to store your medicine?*
O Yes O No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

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Share My Device
Use this option to share your tablet or PC with your patient to sign the agreement.
Sign on My Device

Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
O Yes O No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:*
O Cancer Pain O Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
Methadone

Moiety/Strength/Route/Formulation*
--Select--

- --Select--
- METHADONE (10 mg) ORAL TABLET
- METHADONE (5 mg) ORAL TABLET
- METHADONE (5 mg) ORAL SOLUTION
- METHADONE (10 mg) ORAL SOLUTION
- METHADONE HYDROCHLORIDE (40MG) ORAL TABLET, FOR SUSPENSION
- METHADONE HYDROCHLORIDE (10MG/ML) ORAL CONCENTRATE

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

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- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
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- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

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Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

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Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Morphine

Moiety/Strength/Route/Formulation* --Select--

--Select--
MORPHINE (30 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (45 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (60 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (75 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (90 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (120 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (15 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (30 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (60 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (100 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (200 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
MORPHINE (10 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (20 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (50 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (80 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (100 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (200 mg) ORAL CAPSULE, EXTENDED RELEASE
MORPHINE (15 mg) ORAL TABLET
MORPHINE (40 mg) ORAL CAPSULE, EXTENDED RELEASE

ng opioid

and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below. Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

To report SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex
O Male O Female O Other

Are you Hispanic or Latino?
O Yes O No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn O Home Phone O Mobile Phone

Preferred Time of Contact*
O Morning O Afternoon O Evening

Preferred Method of Contact*
O Email O Text to Mobile# O Phone Call O Postal Mail

Is there a child in the home or are you a caregiver of small children?*
O Yes O No

Do you have a safe and secure place to store your medicine?*
O Yes O No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device
Use this option to share your tablet or PC with your patient to sign the agreement.
Sign on My Device

Provide QR Code
Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
O Yes O No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:*
O Cancer Pain O Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Morphine

Moiety/Strength/Route/Formulation* --Select--

- MORPHINE (15 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (30 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (60 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (100 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (200 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
- MORPHINE (10 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (20 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (50 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (80 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (100 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (200 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (15 mg) ORAL TABLET
- MORPHINE (40 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (30 mg) ORAL TABLET
- MORPHINE (70 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (130 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE (150 mg) ORAL CAPSULE, EXTENDED RELEASE
- MORPHINE SULFATE (10MG/5ML) ORAL SOLUTION
- MORPHINE SULFATE (20MG/5ML) ORAL SOLUTION
- MORPHINE SULFATE (100MG/5ML) ORAL SOLUTION

ng opioid

and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Oxycodone

Moiety/Strength/Route/Formulation* --Select--

--Select--
ACETAMINOPHEN/OXYCODONE (325 mg/5 mg) ORAL TABLET
OXYCODONE (5 mg) ORAL SOLUTION
OXYCODONE (10 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (20 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (40 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (80 mg) ORAL TABLET, FILM COATED, EXTENDED RELEASE
OXYCODONE (5 mg) ORAL TABLET
OXYCODONE (10 mg) ORAL TABLET
OXYCODONE (15 mg) ORAL TABLET
OXYCODONE (20 mg) ORAL TABLET
OXYCODONE (30 mg) ORAL TABLET
OXYCODONE (100 mg) ORAL SOLUTION
OXYCODONE (7.5 mg) ORAL TABLET
OXYCODONE (9MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (13.5MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (18MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (27MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE (36MG) ORAL CAPSULE, EXTENDED RELEASE
OXYCODONE HYDROCHLORIDE (15MG) ORAL TABLET, EXTENDED RELEASE

ng opioid

and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below. Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Oxycodone

Moiety/Strength/Route/Formulation* --Select--

- OXYCODONE (9MG) ORAL CAPSULE, EXTENDED RELEASE
- OXYCODONE (13.5MG) ORAL CAPSULE, EXTENDED RELEASE
- OXYCODONE (18MG) ORAL CAPSULE, EXTENDED RELEASE
- OXYCODONE (27MG) ORAL CAPSULE, EXTENDED RELEASE
- OXYCODONE (36MG) ORAL CAPSULE, EXTENDED RELEASE
- OXYCODONE HYDROCHLORIDE (15MG) ORAL TABLET, EXTENDED RELEASE
- OXYCODONE HYDROCHLORIDE (30MG) ORAL TABLET, EXTENDED RELEASE
- OXYCODONE HYDROCHLORIDE (60MG) ORAL TABLET, EXTENDED RELEASE
- OXYCODONE/ACETAMINOPHEN (2.5 mg/300 mg) ORAL TABLET
- OXYCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL TABLET
- OXYCODONE/ACETAMINOPHEN (5 mg/300 mg) ORAL TABLET
- OXYCODONE/ACETAMINOPHEN (2.5 mg/325 mg) ORAL TABLET
- OXYCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL TABLET
- OXYCODONE/ACETAMINOPHEN (7.5 mg/325 mg) ORAL TABLET
- OXYCODONE/ACETAMINOPHEN (10 mg/325 mg) ORAL TABLET
- OXYCODONE/ACETAMINOPHEN (5 mg/325 mg) ORAL SOLUTION
- OXYCODONE/ACETAMINOPHEN (10 mg/300 mg) ORAL SOLUTION
- OXYCODONE/ACETAMINOPHEN (7.5 mg/300 mg) ORAL TABLET
- OXYCODONE/ASPIRIN (4.8355 mg/325 mg) ORAL TABLET
- OXYCODONE/IBUPROFEN (5 mg/400 mg) ORAL TABLET, FILM COATED

ng opioid

and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Oxymorphone

Moiety/Strength/Route/Formulation* --Select--

--Select--
OXYMORPHONE (5 mg) ORAL TABLET
OXYMORPHONE (10 mg) ORAL TABLET
OXYMORPHONE HYDROCHLORIDE (5MG) ORAL TABLET, EXTENDED RELEASE
OXYMORPHONE HYDROCHLORIDE (7.5MG) ORAL TABLET, EXTENDED RELEASE
OXYMORPHONE HYDROCHLORIDE (10MG) ORAL TABLET, EXTENDED RELEASE
OXYMORPHONE HYDROCHLORIDE (15MG) ORAL TABLET, EXTENDED RELEASE
OXYMORPHONE HYDROCHLORIDE (20MG) ORAL TABLET, EXTENDED RELEASE
OXYMORPHONE HYDROCHLORIDE (30MG) ORAL TABLET, EXTENDED RELEASE
OXYMORPHONE HYDROCHLORIDE (40MG) ORAL TABLET, EXTENDED RELEASE

ng opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact* ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact* ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Pentazocine

Moiety/Strength/Route/Formulation* --Select--

--Select--
PENTAZOCINE/NALOXONE (50 mg/0.5 mg) ORAL TABLET

Moiety	Formulation	Strength	Route	Dose	Frequency

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact*
○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*
○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?*
○ Yes ○ No

Do you have a safe and secure place to store your medicine?*
○ Yes ○ No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device	Provide QR Code	Send Email	Print PDF
Use this option to share your tablet or PC with your patient to sign the agreement.	Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.	Use this option to send your patient an email to sign the agreement at a later time.	Use this option to print a paper copy of the agreement for signature.
Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:*
○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
Tapentadol

Moiety/Strength/Route/Formulation*
--Select--

- --Select--
- Tapentadol (50mg) ORAL TABLET
- Tapentadol (75MG) ORAL TABLET
- Tapentadol (100MG) ORAL TABLET
- Tapentadol (50MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (100MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (150MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (200MG) ORAL TABLET, EXTENDED RELEASE
- Tapentadol (250MG) ORAL TABLET, EXTENDED RELEASE

This patient is opioid tolerant because he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been prescribed this regimen(s) for one week or longer (check all that apply):*

- ☐ ≥ 60 mg oral morphine/day
- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equianalgesic dose of another opioid
- ☐ ≥ 25 micrograms transdermal fentanyl/hour
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

☐ I understand the risks of TIRF medicines and my obligations as a TIRF medicines prescriber to educate my patients about the TIRF REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below

Clear

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Cancel

Reference ID: 4721752

Patient Enrollment

Patient Information

First Name* Megan | M.I. Midd | Last Name* Brown | Date of Birth* 07/14/2000

Sex: ○ Male ○ Female ○ Other

Are you Hispanic or Latino? ○ Yes ○ No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1 | Address Line 2 Address Line 2

City* City | State* State | Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net | Number* nnn-nnn-nnnn ○ Home Phone ○ Mobile Phone

Preferred Time of Contact*: ○ Morning ○ Afternoon ○ Evening

Preferred Method of Contact*: ○ Email ○ Text to Mobile# ○ Phone Call ○ Postal Mail

Is there a child in the home or are you a caregiver of small children?* ○ Yes ○ No

Do you have a safe and secure place to store your medicine?* ○ Yes ○ No

Patient Representative (if required)

First Name | Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

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Sign on My Device	Sign on Patient's Phone	Send Email	Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:* ○ Yes ○ No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:* ○ Cancer Pain ○ Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
- ☐ Tranquilizers
- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety* Tramadol

Moiety/Strength/Route/Formulation*

--Select--

- --Select--
- ACETAMINOPHEN/TRAMADOL (325 mg/37.5 mg) ORAL TABLET, FILM COATED
- TRAMADOL (50 mg) ORAL TABLET
- TRAMADOL (200 mg) ORAL TABLET, EXTENDED RELEASE
- TRAMADOL (50 mg) ORAL TABLET, FILM COATED
- TRAMADOL (300 mg) ORAL TABLET, EXTENDED RELEASE
- TRAMADOL (100 mg) ORAL TABLET, EXTENDED RELEASE
- TRAMADOL (50 mg) ORAL TABLET, COATED
- TRAMADOL (5 mg) ORAL SOLUTION
- TRAMADOL (100 mg) ORAL TABLET
- TRAMADOL HYDROCHLORIDE (100MG) ORAL CAPSULE, EXTENDED RELEASE
- TRAMADOL HYDROCHLORIDE (200MG) ORAL CAPSULE, EXTENDED RELEASE
- TRAMADOL HYDROCHLORIDE (300MG) ORAL CAPSULE, EXTENDED RELEASE
- TRAMADOL/ACETAMINOPHEN (37.5 mg/325 mg) ORAL TABLET, FILM COATED

ng opioid

- ☐ ≥ 30 mg oral oxycodone/day
- ☐ ≥ 25 mg oral oxymorphone/day
- ☐ An equi analgesic dose of another opioid
- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Sign | Type Signature

PRJane PRDoe: Please use your mouse or stylus to sign below | Clear

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Cancel

References ID: 4721752

SE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Patient Enrollment

Patient Information

First Name* Megan | M.I. Middl | Last Name* Brown | Date of Birth* 07/14/2000

Sex
O Male O Female O Other

Are you Hispanic or Latino?
O Yes O No

Race (check all that apply)

- ☐ White
- ☐ Asian
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1

Address Line 2 Address Line 2

City* City

State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

Number* nnn-nnn-nnnn

O Home Phone O Mobile Phone

Preferred Time of Contact*
O Morning O Afternoon O Evening

Preferred Method of Contact*
O Email O Text to Mobile# O Phone Call O Postal Mail

Is there a child in the home or are you a caregiver of small children?*
O Yes O No

Do you have a safe and secure place to store your medicine?*
O Yes O No

Patient Representative (if required)

First Name First Name | Last Name Last Name | Relationship Mother, Father...

Number nnn-nnn-nnnn | Email Address Email Address

Patient / Guardian Agreement

You have four options to obtain the patient's signature. Sharing your device or providing the patient a QR Code will allow for them to sign the agreement in your office. It may take more time for a patient to receive an email. To use a printed form, you will need to print, complete, sign and either upload or fax the form to the call center. The call center will then process the form. The processing may take up to two (2) business days from receipt.

Share My Device
Use this option to share your tablet or PC with your patient to sign the agreement.
Sign on My Device

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Use this option to present a QR Code to your patient. Your patient can scan the QR Code with their phone and sign the patient agreement.
Sign on Patient's Phone

Send Email
Use this option to send your patient an email to sign the agreement at a later time.
Send Email

Print PDF
Use this option to print a paper copy of the agreement for signature.
Print PDF

The following sections to be completed by the prescriber

Medical Information

Prior TIRF Use within the last 6 months:*
O Yes O No

Product Name* -- Select Produc | Product Strength* | Dose* Dose | Frequency* Frequency

Type of Pain:*
O Cancer Pain O Non-Cancer Pain

Concomitant Medications (check all that apply):*

- ☐ Benzodiazepines
- ☐ Gabapentinoids
- ☐ Sedative Hypnotics
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- ☐ Muscle Relaxants
- ☐ Barbiturates
- ☐ Antipsychotics
- ☐ Sodium Oxybate
- ☐ Alcohol
- ☐ Prescription Cannabinoids
- ☐ Prescription Insomnia Medications
- ☐ Other CNS depressant
- ☐ None

Verify Opioid Tolerance

Opioid Moiety*
Codeine

Moiety/Strength/Route/Formulation*
ACETAMINOPHEN/CODEINE ANHYDROUS (300 mg/30 mg) ORAL TABLET

Quantity* 2 | Units* --Select-- | Frequency*

--Select--
film(s)
patch(es)
tablet(s)
capsule(s)
TBSP
mL
mg
mg/mL

Moiety	Strength	Route	Dose	Frequency

Patients must remain ock opioids while taking a TIRF medicine.

This patient is opioid he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and ha this regimen(s) for one week or longer (check all that apply):*

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- ☐ ≥ 30 mg oral oxycodone/day
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Clear

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Cancel

Reference ID: 4721752

Pharmacy

Inpatient Pharmacy Group

To certify your pharmacy:

Your pharmacy is currently certified.

Pharmacy Personnel

A pharmacy can have multiple personnel with online accounts. You may invite personnel, reset their passwords, or remove them.

→ Manage Personnel

Pharmacies

A pharmacy can have multiple pharmacies grouped together under the responsibility of a Pharmacy Authorized Representative.

→ Manage Pharmacies

Pharmacy Materials

- Pharmacy Education
- Pharmacy Knowledge Assessment
- Inpatient Pharmacy Enrollment Form
- Outpatient Pharmacy Enrollment Form
- Pharmacy FAQ

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Pharmacy

Outpatient Pharmacy Group

To certify your pharmacy:

Your pharmacy is currently certified.

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the TIRF REMS signifying that the REMS requirements to dispense for this patient are currently met.

→ Obtain Patient RDA

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Pharmacy

Outpatient Pharmacy Group

Site Biennial Confirmation Notice

Your pharmacy's TIRF REMS biennial confirmation is expiring soon. To dispense Transmucosal Immediate-Release Fentanyl medicines you must:

1 Authorized Representative Biennial Confirmation

For your Pharmacy or Pharmacies to remain certified, you must confirm that you are the Authorized Representative every two years.

☐ I, RxOutPatJane AuthRepDoe, am the REMS Authorized Representative for Outpatient Pharmacy Group

Complete

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the TIRF REMS signifying that the REMS requirements to dispense for this patient are currently met.

→ Obtain Patient RDA

Pharmacy Personnel

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Pharmacy

Examoto Pharmacy Group

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Complete

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Pharmacy - Knowledge Assessment

TIRF Pharmacy KA

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

0 of 11 questions in progress

1 . The patients described are all experiencing breakthrough cancer pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine? Select one option

- 12-year-old sarcoma patient, using 25 mcg/hour transdermal fentanyl patches for her underlying persistent cancer pain.
- Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
- Adult male with advanced lung cancer, his underlying persistent pain is managed with transdermal fentanyl patches for the past 3 months.
- Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.
- Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

2 . Pharmacists can assist in prevention of diversion or accidental exposure of TIRF medicines by people for whom they are not prescribed. Which of the following statements is TRUE?

- Pharmacists should counsel TIRF medicine users to keep their TIRF medicine out of reach of children and pets.
- Pharmacists should counsel TIRF medicine users to refer to safe disposal guidelines in the TIRF product-specific Medication Guide.
- Pharmacists should counsel patients not to share their TIRF medicine with anyone else even if their symptoms are the same as it could result in serious life threatening and/or fatal respiratory depression.
- Remind patients to call their prescriber if they have questions about usage of their TIRF medicine.
- All of the above.

3 . A patient's prescriber has ordered a new TIRF medicine for the patient. What dose must they start with?

- An appropriate dose based on the dose of the opioid medicine used for underlying persistent cancer pain.
- The dose the prescriber believes is appropriate based on the previous clinical history of TIRF medicine use.
- The lowest available dose, unless individual product Prescribing Information provides product-specific guidance.
- The median available dose.
- The dose the prescriber believes is appropriate based on their clinical experience.

4 . Select the following statement which is FALSE.

- Before dispensing, the pharmacy must check the patient's medication use for a change in opioid tolerance. This could include reviewing data from various sources (e.g. -available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)
- When a patient's breakthrough cancer pain is not relieved by their TIRF medicine, he/she may repeat their dose of TIRF medicine every 20 minutes until they achieve pain relief.
- TIRF medicines are not interchangeable on a microgram-per-microgram basis.
- The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.

5 . Which of the following is not a pharmacy requirement in the TIRF REMS?

- The authorized representative must train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the TIRF REMS using the Pharmacy Education.
- The authorized representative must re-enroll in the TIRF REMS by completing the Outpatient Pharmacy Enrollment Form.
- Before dispensing, the pharmacy must check the patient's medication use for a change in opioid tolerance. This could include reviewing data from various sources (e.g. - available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)
- The pharmacy may dispense the first prescription to the patient before the patient is enrolled in the TIRF REMS as long as the patient is enrolled before the next dispensing.

6 . A patient is taking a TIRF medicine and the doctor would like to prescribe erythromycin, a CYP3A4 inhibitor. Which of the following statements is TRUE?

- The patient cannot be prescribed erythromycin, because using it at the same time as a TIRF medicine could be fatal.
- Use of a TIRF medicine with a CYP3A4 inhibitor may require dosage adjustment of the TIRF medicine; carefully monitor the patient for opioid toxicity, otherwise such use may cause potentially fatal respiratory depression.
- There is no possible drug interaction between CYP3A4 inhibitors and TIRF medicines.
- The dose of the TIRF medicine must be reduced by one half if a CYP3A4 inhibitor is prescribed in the same patient.

7 . Before dispensing a TIRF medicine, pharmacists must provide a patient with the Medication Guide. Which of the following counseling statements is FALSE?

- TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.
- Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.
- Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.
- Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

8 . There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate?

- TIRF medicines can be fatal if taken by children.
- TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
- TIRF medicines can be fatal if taken by anyone who is not opioid-tolerant.
- All of the above.

9 . Which of the following statements is FALSE?

- A REMS Dispense Authorization is required before dispensing TIRF medicines at all outpatient pharmacies.
- A REMS Dispense Authorization is not required when the patient is paying by cash rather than submitting a traditional pharmacy benefit claim.
- A REMS Dispense Authorization is not required prior to dispensing TIRF medicines to hospital inpatients.
- A REMS Dispense Authorization at an outpatient pharmacy confirms that the required opioid tolerance verification is on file with the TIRF REMS prior to dispensing.

10 . Which one of the following statements is most accurate regarding the safe storage and disposal of TIRF medicines?

- TIRF medicines should be stored in a safe and secure place, out of sight and out of reach of all others, especially children.
- TIRF medicines should be protected from theft.
- Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
- All of the above.

11 . As an authorized representative for my pharmacy, which of the following is not my responsibility?

- Make sure that my staff and I confirm pharmacy, patient and prescriber enrollment in the TIRF REMS and patient opioid tolerance by obtaining a REMS Dispense Authorization prior to every outpatient dispensing of a TIRF medicine.
- Enroll and train all sub-stores if my pharmacy acts as a chain headquarters pharmacy in the TIRF REMS.
- Provide a Patient Status and Opioid Tolerance Form to the TIRF REMS for every prescription prior to dispensing.
- My pharmacy must not sell, loan or transfer TIRF medicine inventory to any other pharmacy, institution, distributor, or prescriber.

Submit KA

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Pharmacy - Knowledge Assessment

TIRF Pharmacy KA

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

Knowledge Assessment Incomplete

9 correct answers out of 11 (Failed)

1. The patients described are all experiencing breakthrough cancer pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine? Select one option ✓

- (●) 12-year-old sarcoma patient, using 25 mcg/hour transdermal fentanyl patches for her underlying persistent cancer pain.
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2. Pharmacists can assist in prevention of diversion or accidental exposure of TIRF medicines by people for whom they are not prescribed. Which of the following statements is TRUE? ✓

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- ( ) An appropriate dose based on the dose of the opioid medicine used for underlying persistent cancer pain.
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4. Select the following statement which is FALSE. ✓

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- ( ) TIRF medicines are not interchangeable on a microgram-per-microgram basis.
- ( ) The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.

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- ( ) Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.
- (●) Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

8. There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate? ✓

- ( ) TIRF medicines can be fatal if taken by children.
- ( ) TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
- ( ) TIRF medicines can be fatal if taken by anyone who is not opioid-tolerant.
- (●) All of the above.

9. Which of the following statements is FALSE? ✓

- ( ) A REMS Dispense Authorization is required before dispensing TIRF medicines at all outpatient pharmacies.
- (●) A REMS Dispense Authorization is not required when the patient is paying by cash rather than submitting a traditional pharmacy benefit claim.
- ( ) A REMS Dispense Authorization is not required prior to dispensing TIRF medicines to hospital inpatients.
- ( ) A REMS Dispense Authorization at an outpatient pharmacy confirms that the required opioid tolerance verification is on file with the TIRF REMS prior to dispensing.

10. Which one of the following statements is most accurate regarding the safe storage and disposal of TIRF medicines? ✓

- ( ) TIRF medicines should be stored in a safe and secure place, out of sight and out of reach of all others, especially children.
- ( ) TIRF medicines should be protected from theft.
- ( ) Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
- (●) All of the above.

11. As an authorized representative for my pharmacy, which of the following is not my responsibility? ✗

- (●) Make sure that my staff and I confirm pharmacy, patient and prescriber enrollment in the TIRF REMS and patient opioid tolerance by obtaining a REMS Dispense Authorization prior to every outpatient dispensing of a TIRF medicine.
- ( ) Enroll and train all sub-stores if my pharmacy acts as a chain headquarters pharmacy in the TIRF REMS.
- ( ) Provide a Patient Status and Opioid Tolerance Form to the TIRF REMS for every prescription prior to dispensing.
- ( ) My pharmacy must not sell, loan or transfer TIRF medicine inventory to any other pharmacy, institution, distributor, or prescriber.

Try Again | Home

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Pharmacy - Knowledge Assessment

There are errors, please correct the items below:

- You have exceeded the maximum number of allowed attempts to pass the knowledge assessment
- To reattempt the knowledge assessment you must first review the Pharmacy Education and then call the TIRF REMS Call Center at 1-866-822-1483 to reset your account
- You will be denied enrollment into the TIRF REMS after six failed attempts to complete the knowledge assessment

Home

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Pharmacy - Knowledge Assessment

There are errors, please correct the items below:

- You have exceeded the maximum number of allowed attempts to pass the knowledge assessment and have been denied enrollment into the TIRF REMS

Home

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Pharmacy - Knowledge Assessment

TIRF Pharmacy KA

You may leave and return to the Knowledge Assessment at any time, your progress will be saved.

Knowledge Assessment Complete

11 correct answers out of 11 (Passed)

1. The patients described are all experiencing breakthrough cancer pain, but ONE is not an appropriate patient for a TIRF medicine. Which patient should not receive a TIRF medicine? Select one option ✓

- (●) 12-year-old sarcoma patient, using 25 mcg/hour transdermal fentanyl patches for her underlying persistent cancer pain.
- ( ) Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
- ( ) Adult male with advanced lung cancer, his underlying persistent pain is managed with transdermal fentanyl patches for the past 3 months.
- ( ) Adult male with multiple myeloma who has bone pain currently managed with 50 mg oral oxymorphone daily for the last 2 weeks.
- ( ) Adult female with advanced sarcoma who has been taking a daily dose of 12 mg oral hydromorphone for the last 3 weeks.

2. Pharmacists can assist in prevention of diversion or accidental exposure of TIRF medicines by people for whom they are not prescribed. Which of the following statements is TRUE? ✓

- ( ) Pharmacists should counsel TIRF medicine users to keep their TIRF medicine out of reach of children and pets.
- ( ) Pharmacists should counsel TIRF medicine users to refer to safe disposal guidelines in the TIRF product-specific Medication Guide.
- ( ) Pharmacists should counsel patients not to share their TIRF medicine with anyone else even if their symptoms are the same as it could result in serious life threatening and/or fatal respiratory depression.
- ( ) Remind patients to call their prescriber if they have questions about usage of their TIRF medicine.
- (●) All of the above.

3. A patient's prescriber has ordered a new TIRF medicine for the patient. What dose must they start with? ✓

- ( ) An appropriate dose based on the dose of the opioid medicine used for underlying persistent cancer pain.
- ( ) The dose the prescriber believes is appropriate based on the previous clinical history of TIRF medicine use.
- (●) The lowest available dose, unless individual product Prescribing Information provides product-specific guidance.
- ( ) The median available dose.
- ( ) The dose the prescriber believes is appropriate based on their clinical experience.

4. Select the following statement which is FALSE. ✓

- ( ) Before dispensing, the pharmacy must check the patient's medication use for a change in opioid tolerance. This could include reviewing data from various sources (e.g. -available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)
- (●) When a patient's breakthrough cancer pain is not relieved by their TIRF medicine, he/she may repeat their dose of TIRF medicine every 20 minutes until they achieve pain relief.
- ( ) TIRF medicines are not interchangeable on a microgram-per-microgram basis.
- ( ) The prescriber must not convert from the first TIRF medicine dose to another TIRF medicine at the equivalent dose. The different TIRF medicines have different absorption and bioavailability profiles, and conversion to an equivalent dose of a second TIRF product could result in a fentanyl overdose.

5. Which of the following is not a pharmacy requirement in the TIRF REMS? ✓

- ( ) The authorized representative must train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the TIRF REMS using the Pharmacy Education.
- ( ) The authorized representative must re-enroll in the TIRF REMS by completing the Outpatient Pharmacy Enrollment Form.
- ( ) Before dispensing, the pharmacy must check the patient's medication use for a change in opioid tolerance. This could include reviewing data from various sources (e.g. - available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.)
- (●) The pharmacy may dispense the first prescription to the patient before the patient is enrolled in the TIRF REMS as long as the patient is enrolled before the next dispensing.

6. A patient is taking a TIRF medicine and the doctor would like to prescribe erythromycin, a CYP3A4 inhibitor. Which of the following statements is TRUE? ✓

- ( ) The patient cannot be prescribed erythromycin, because using it at the same time as a TIRF medicine could be fatal.
- (●) Use of a TIRF medicine with a CYP3A4 inhibitor may require dosage adjustment of the TIRF medicine; carefully monitor the patient for opioid toxicity, otherwise such use may cause potentially fatal respiratory depression.
- ( ) There is no possible drug interaction between CYP3A4 inhibitors and TIRF medicines.
- ( ) The dose of the TIRF medicine must be reduced by one half if a CYP3A4 inhibitor is prescribed in the same patient.

7. Before dispensing a TIRF medicine, pharmacists must provide a patient with the Medication Guide. Which of the following counseling statements is FALSE? ✓

- ( ) TIRF medicines contain fentanyl in an amount that could be fatal to children of all ages, in individuals for whom they were not prescribed, and in those who are not opioid tolerant.
- ( ) Inform patients that TIRF medicines must not be used to treat acute or postoperative pain, including headache/migraine, dental pain or acute pain in the emergency department.
- (●) Instruct patients that, if they stop taking their around-the-clock opioid medicine, they can continue to take their TIRF medicine.
- ( ) Instruct patients to never share their TIRF medicine with anyone else, even if that person has the same symptoms.

8. There is a risk of fatal overdose with inappropriate use of TIRF medicines. Which one of the following answers is most accurate? ✓

- ( ) TIRF medicines can be fatal if taken by children.
- ( ) TIRF medicines can be fatal if taken by anyone for whom it is not prescribed.
- ( ) TIRF medicines can be fatal if taken by anyone who is not opioid-tolerant.
- (●) All of the above.

9. Which of the following statements is FALSE? ✓

- ( ) A REMS Dispense Authorization is required before dispensing TIRF medicines at all outpatient pharmacies.
- (●) A REMS Dispense Authorization is not required when the patient is paying by cash rather than submitting a traditional pharmacy benefit claim.
- ( ) A REMS Dispense Authorization is not required prior to dispensing TIRF medicines to hospital inpatients.
- ( ) A REMS Dispense Authorization at an outpatient pharmacy confirms that the required opioid tolerance verification is on file with the TIRF REMS prior to dispensing.

10. Which one of the following statements is most accurate regarding the safe storage and disposal of TIRF medicines? ✓

- ( ) TIRF medicines should be stored in a safe and secure place, out of sight and out of reach of all others, especially children.
- ( ) TIRF medicines should be protected from theft.
- ( ) Dispose of partially used or unneeded TIRF medicine by following the TIRF medicine-specific procedure specified in the Medication Guide.
- (●) All of the above.

11. As an authorized representative for my pharmacy, which of the following is not my responsibility? ✓

- ( ) Make sure that my staff and I confirm pharmacy, patient and prescriber enrollment in the TIRF REMS and patient opioid tolerance by obtaining a REMS Dispense Authorization prior to every outpatient dispensing of a TIRF medicine.
- ( ) Enroll and train all sub-stores if my pharmacy acts as a chain headquarters pharmacy in the TIRF REMS.
- (●) Provide a Patient Status and Opioid Tolerance Form to the TIRF REMS for every prescription prior to dispensing.
- ( ) My pharmacy must not sell, loan or transfer TIRF medicine inventory to any other pharmacy, institution, distributor, or prescriber.

Home

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Pharmacy

Outpatient Pharmacy Group

Additional Pharmacy

Organizational NPI Number*

Use organizational NPI to populate form: Organizational NPI Number

(Select address type to populate form)

○ Office Address ○ Mailing Address

Pharmacy Name*

Pharmacy Name

Address Line 1*

Address Line 1

Address Line 2

Address Line 2

City*

City

State*

State

Zip Code*

Zip Code

Phone*

nnn-nnn-nnnn

Extension

nnn...

Fax*

nnn-nnn-nnnn

Chain ID

Chain ID

You may assign this pharmacy to one or more staff members below:

Show 10 entries Search:

	Name
☑	RxOutPatJane AuthRepDoe
☐	RxOutPatJohn StaffSmith
☐	RxOutPatMike StaffGreen
☐	RxOutPatSally StaffJones

Authorized Representative | Staff

Cancel | Save

Pharmacy

Outpatient Pharmacy Group

Pharmacies

A pharmacy can have multiple pharmacies grouped together under the responsibility of a Pharmacy Authorized Representative.
You may add, remove, or edit the pharmacies in this pharmacy group.

Add Pharmacy

Show 10 entries

Search:

Action	NPI	Name	Pharmacy Type	Consumer Type	Status
	2110000000	OutPat Test Pharmacy	Outpatient Pharmacy	Mail Order	Certified as of 4/20/2020
	2110000002	OutPat Test Sub02 Pharmacy	Inpatient Pharmacy	Walk-in	Certified as of 4/20/2020
	2110000001	OutPat Test Sub01 Pharmacy	Inpatient Pharmacy	Mail Order	Certified as of 4/20/2020
Delete Edit					

Showing 1 to 3 of 3 entries

Previous 1 Next

Return

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Pharmacy

Outpatient Pharmacy Group

RxOutPatJane AuthRepDoe
Authorized Representative
Certified as of 4/20/2020

Edit | View Enrollment PDF

Pharmacy Personnel

A pharmacy can have multiple personnel with online accounts. You may invite personnel, reset their passwords, or remove them. You may add an authorized representative or staff to your pharmacy.

Add Authorized Representative or Staff

Show 10 entries

Search:

Action	Role	Name	Email Address	Status	Added	Days Inactive
		RxOutPatJane AuthRepDoe	RxAuthRepOutPat@examoto.net	Certified as of 4/20/2020	4/20/2020	0
		RxOutPatJohn StaffSmith	RxStaffOutPat@examoto.net	Authorized	4/20/2020	191
		RxOutPatMike StaffGreen	RxStaffOutPat02@examoto.net	Authorized	4/20/2020	191
		RxOutPatSally StaffJones	RxStaffOutPat01@examoto.net	Authorized	4/20/2020	191

Delete | Edit | Authorized Representative | Staff

Showing 1 to 4 of 4 entries

Previous 1 Next

Return

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Pharmacy

Outpatient Pharmacy Group

Additional Staff

Personnel Type:

- (●) Authorized Representative
- ( ) Pharmacy Staff

Authorized Representative Information

First Name: First Name

Last Name: Last Name

Title: Title

Credentials: ( ) RPh ( ) PharmD ( ) BCPS ( ) Other

Phone: Phone

Fax: Fax

Email Address: Email Address

Preferred Method of Contact: ( ) Email ( ) Text to Mobile# ( ) Phone Call

You are the Authorized Representative for the following:

Show 10 entries Search:

	Name	Zip Code
☑	OutPat Test Pharmacy: 2110000000	10726-7773
☑	OutPat Test Sub02 Pharmacy: 2110000002	19002
☑	OutPat Test Sub01 Pharmacy: 2110000001	40254-1274

Showing 1 to 3 of 3 entries Previous 1 Next

Cancel Send Invite

Pharmacy

Outpatient Pharmacy Group

Additional Staff

Personnel Type:

- ○ Authorized Representative
- ◉ Pharmacy Staff

Pharmacy Staff Information

First Name: First Name

Last Name: Last Name

Title: Title

Credentials: ○ RPh ○ PharmD ○ BCPS ○ Other

Phone: Phone

Fax: Fax

Email Address: Email Address

Preferred Method of Contact: ○ Email ○ Text to Mobile# ○ Phone Call

You may assign this staff member to one or more pharmacies below:

Show 10 entries Search:

	Name	Zip Code
☐	OutPat Test Pharmacy: 2110000000	10726-7773
☐	OutPat Test Sub02 Pharmacy: 2110000002	19002
☐	OutPat Test Sub01 Pharmacy: 2110000001	40254-1274

Showing 1 to 3 of 3 entries Previous 1 Next

Cancel Send Invite

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

Pharmacy Enrollment

To become certified in the TIRF REMS and dispense TIRF medicines, a pharmacy must designate an Authorized Representative to:

1. Review the **Pharmacy Education**
2. Complete and submit the **Pharmacy Knowledge Assessment** to the TIRF REMS
3. Complete and submit this **Pharmacy Enrollment Form** to the TIRF REMS

Pharmacy Type (Please pick a Pharmacy Type. Different pharmacies have different REMS requirements.)

○ Inpatient Pharmacy ○ Outpatient Pharmacy

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

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Pharmacy Enrollment

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3. Complete and submit this **Pharmacy Enrollment Form** to the TIRF REMS

Pharmacy Type (Please pick a Pharmacy Type. Different pharmacies have different REMS requirements.)

○ Inpatient Pharmacy ◉ Outpatient Pharmacy

Pharmacy Information

Organizational NPI Number*

Use organizational NPI to populate form: Organizational NPI Number

(Select address type to populate form)

○ Office Address ○ Mailing Address

Pharmacy Name*

Pharmacy Name

Address Line 1*

Address Line 1

Address Line 2

Address Line 2

City*

City

State*

State

Zip Code*

Zip Code

Phone*

nnn-nnn-nnnn

Extension

nnn...

Fax*

nnn-nnn-nnnn

Chain ID

Chain ID

The name, location, and phone number of your pharmacy will be publicly available on TIRFREMSaccess.com. If you do not want your information available, please call the TIRF REMS Call Center at 1-866-822-1483.

Authorized Representative Information

First Name*

RxOutPatJane

Last Name*

AuthRepDoe

Credentials*

○ RPh ○ PharmD ○ BCPS ○ Other

Title or Position*

Title or Position

Phone*

nnn-nnn-nnnn

Fax*

nnn-nnn-nnnn

Email Address

RxAuthRepOutPat@examoto.net

Preferred Method of Contact*

○ Email ○ Text to Mobile# ○ Phone Call

Pharmacy Authorized Representative Responsibilities

As the Authorized Representative, I must:

- Review the **Pharmacy Education**.
- Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS.
- Establish processes and procedures to check the patient's medication use for a change in opioid tolerance.
- Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS using the **Pharmacy Education**.

Before dispensing, all pharmacy staff must:

- Provide the patient with the product-specific **Medication Guide**.
- Assess the patient's medication use for a change in opioid tolerant status. Document and submit the results to the REMS.
- Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber and the patient are enrolled, and the patient is opioid tolerant.

All pharmacy staff must:

- Not distribute, transfer, loan, or sell TIRF medicines.
- Maintain records of staff training.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.
- Report serious adverse events of accidental exposure, misuse, abuse, addiction, and overdose associated with the TIRF medicine to the REMS using the **Adverse Events of Special Interest Reporting Form**.

To maintain certification to dispense, any new authorized representative must:

- Review the **Pharmacy Education**.
- Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS.
- Enroll in the REMS by completing the **Outpatient Pharmacy Enrollment Form**.

Sign | Type Signature

Clear

RxOutPatJane AuthRepDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. Sign and Submit

Pharmacy Enrollment

To become certified in the TIRF REMS and dispense TIRF medicines, a pharmacy must designate an Authorized Representative to:

1. Review the **Pharmacy Education**
2. Complete and submit the **Pharmacy Knowledge Assessment** to the TIRF REMS
3. Complete and submit this **Pharmacy Enrollment Form** to the TIRF REMS

Pharmacy Type (Please pick a Pharmacy Type. Different pharmacies have different REMS requirements.)

(●) Inpatient Pharmacy ( ) Outpatient Pharmacy

Pharmacy Information

Organizational NPI Number*

Use organizational NPI to populate form: Organizational NPI Number

(Select address type to populate form)

( ) Office Address ( ) Mailing Address

Pharmacy Name*

Pharmacy Name

Address Line 1*

Address Line 1

Address Line 2

Address Line 2

City*

City

State*

State

Zip Code*

Zip Code

Phone*

nnn-nnn-nnnn

Extension

nnn...

Fax*

nnn-nnn-nnnn

The name, location, and phone number of your pharmacy will be publicly available on TIRFREMSaccess.com. If you do not want your information available, please call the TIRF REMS Call Center at 1-866-822-1483.

Authorized Representative Information

First Name*

RxInPatJane

Last Name*

AuthRepDoe

Credentials*

( ) RPh ( ) PharmD ( ) BCPS ( ) Other

Title or Position*

Title or Position

Phone*

nnn-nnn-nnnn

Fax*

nnn-nnn-nnnn

Email Address

RxAuthRepInPat@examoto.net

Preferred Method of Contact*

( ) Email ( ) Text to Mobile# ( ) Phone Call

Pharmacy Authorized Representative Responsibilities

As the Authorized Representative, I must:

- Review the **Pharmacy Education**.
- Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS.
- Train all relevant staff involved in dispensing of TIRF medicines on the risks associated with TIRF medicines and the requirements of the REMS using the **Pharmacy Education**.
- Establish processes and procedures to verify that the patient is opioid tolerant.

All pharmacy staff must:

- Verify the patient is opioid tolerant through the processes and procedures established as a requirement of the REMS.

All pharmacy staff must:

- Not distribute, transfer, loan, or sell TIRF medicines.
- Maintain records of staff training.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.
- Not dispense TIRF medicines for outpatient use.

To maintain certification to dispense, any new authorized representative must:

- Review the **Pharmacy Education**.
- Successfully complete the **Pharmacy Knowledge Assessment** and submit it to the REMS.
- Enroll in the REMS by completing the **Inpatient Pharmacy Enrollment Form**.

Sign | Type Signature

Clear

RxInPatJane AuthRepDoe: Please use your mouse or stylus to sign below

I authorize the above signature to be the legally binding equivalent of my handwritten signature. **Sign and Submit**

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the TIRF REMS signifying that the REMS requirements to dispense for this patient are currently met.
Find an enrolled patient below:

1 Find a patient by entering the patient's information below:

First Name: First Name

Last Name: wil

Date of Birth: mm/dd/yyyy

Phone Or Email: Phone Or Email

Match Found

- (selected) PatientJulie Williams (DOB:6/13/1970)

Cancel | Continue

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

____Localization_Version

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the TIRF REMS signifying that the REMS requirements to dispense for this patient are currently met.

Patient

Enrolled as of 4/20/2020

Name:	PatientJulie Williams	Zip Code:	30180
Date of Birth:	6/13/1970	Phone:	204-896-4439
		Email Address:	Patient@examoto.net

Prescriber

Certified as of 4/20/2020

Prescriber:	PRJane PRDoe	NPI:	1310000000
Address:	12 Parker Avenue Chambersburg, PA 17201		

Pharmacy Verification

I provided the patient with the product-specific Medication Guide and I:

- ◯ Checked the patient's opioid tolerance by reviewing data from available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

— Or —

- ◯ Do not have access to Prescription Drug Monitoring Program data for this patient. I have reviewed the opioid tolerance data provided by the prescriber for this patient, the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

☐ Reviewed the following REMS data:

Prescriber Reported:
≥ 8 mg oral hydromorphone/day

Adverse Events of Special Interest Reported	
Abused or been suspected of abusing their TIRF medicine	9/11/2020

☐ Followed my pharmacy's procedures for TIRF medicines.

Based on the information provided, is the medication appropriate for the patient? [Opioid Tolerance Criteria]

- ◯ Yes, the medication is appropriate for the patient
- ◯ No

[Verify]

REMS Dispense Authorization (RDA)

A REMS Dispense Authorization is a receipt from the TIRF REMS indicating that the safe use conditions managed by the REMS are currently in place. Store this receipt with your records. This verifies that all requirements have been satisfied and that a REMS Dispense Authorization (RDA) has been issued.

[Obtain RDA]

[Cancel]

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the TIRF REMS signifying that the REMS requirements to dispense for this patient are currently met.

Patient

Enrolled as of 4/20/2020

Name:	PatientJulie Williams	Zip Code:	30180
Date of Birth:	6/13/1970	Phone:	204-896-4439
		Email Address:	Patient@examoto.net

Prescriber

Certified as of 4/20/2020

Prescriber:	PRJane PRDoe	NPI:	1310000000
Address:	12 Parker Avenue Chambersburg, PA 17201		

Pharmacy Verification

I provided the patient with the product-specific Medication Guide and I:

- (●) Checked the patient's opioid tolerance by reviewing data from available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

— Or —

- ( ) Do not have access to Prescription Drug Monitoring Program data for this patient. I have reviewed the opioid tolerance data provided by the prescriber for this patient, the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

[x] Reviewed the following REMS data:

Prescriber Reported:
≥ 8 mg oral hydromorphone/day

Adverse Events of Special Interest Reported	
Abused or been suspected of abusing their TIRF medicine	9/11/2020

[x] Followed my pharmacy's procedures for TIRF medicines.

Based on the information provided, is the medication appropriate for the patient? [Opioid Tolerance Criteria]

- (●) Yes, the medication is appropriate for the patient
- ( ) No

[Verify]

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[Obtain RDA]

[Cancel]

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the TIRF REMS signifying that the REMS requirements to dispense for this patient are currently met.

Patient

Enrolled as of 4/20/2020

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Date of Birth:	6/13/1970	Phone:	204-896-4439
		Email Address:	Patient@examoto.net

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Certified as of 4/20/2020

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Address:	12 Parker Avenue Chambersburg, PA 17201		

Pharmacy Verification

I provided the patient with the product-specific Medication Guide and I:

- ○ Checked the patient's opioid tolerance by reviewing data from available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

— Or —

- ◉ Do not have access to Prescription Drug Monitoring Program data for this patient. I have reviewed the opioid tolerance data provided by the prescriber for this patient, the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

☑ Reviewed the following REMS data:

Prescriber Reported:
≥ 8 mg oral hydromorphone/day

Adverse Events of Special Interest Reported	
Abused or been suspected of abusing their TIRF medicine	9/11/2020

☑ Followed my pharmacy's procedures for TIRF medicines.

Based on the information provided, is the medication appropriate for the patient? [Opioid Tolerance Criteria]

- ◉ Yes, the medication is appropriate for the patient
- ○ No

[Verify]

REMS Dispense Authorization (RDA)

A REMS Dispense Authorization is a receipt from the TIRF REMS indicating that the safe use conditions managed by the REMS are currently in place. Store this receipt with your records. This verifies that all requirements have been satisfied and that a REMS Dispense Authorization (RDA) has been issued.

[Obtain RDA]

[Cancel]

TIRF REMS

OutPatJane AuthRepDoe

Pharmacy

Outpatient Pharmacy Gr

Patients must remain on around-the-clock opioids while taking a TIRF medicine.

To be opioid tolerant, a patient must be currently prescribed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and have been prescribed this regimen(s) for one week or longer:

- ≥ 60 mg oral morphine/day
- ≥ 30 mg oral oxycodone/day
- ≥ 25 mg oral oxymorphone/day
- An equianalgesic dose of another opioid
- ≥ 25 micrograms transdermal fentanyl/hour
- ≥ 8 mg oral hydromorphone/day
- ≥ 60 mg oral hydrocodone/day

Obtain a Patient'

An RDA is a receipt fr ... ntly met.

Patient

Enrolled as of 4/20/2020

Name: PatientJulie W

Date of Birth: 6/13/1970

-4439

Email Address: Patient@examoto.net

Prescriber

Certified as of 4/20/2020

Prescriber: PRJane PRDoe

Address: 12 Parker Avenue
Chambersburg, PA 17201

NPI: 1310000000

Pharmacy Verification

I provided the patient with the product-specific Medication Guide and I:

(●) Checked the patient's opioid tolerance by reviewing data from available state Prescription Drug Monitoring Programs (PDMPs), the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

— Or —

( ) Do not have access to Prescription Drug Monitoring Program data for this patient. I have reviewed the opioid tolerance data provided by the prescriber for this patient, the patient's records in the pharmacy's management system, and information provided by the TIRF REMS.

[x] Reviewed the following REMS data:

Prescriber Reported:
≥ 8 mg oral hydromorphone/day

Adverse Events of Special Interest Reported	
Abused or been suspected of abusing their TIRF medicine	9/11/2020

[x] Followed my pharmacy's procedures for TIRF medicines.

Based on the information provided, is the medication appropriate for the patient? Opioid Tolerance Criteria

(●) Yes, the medication is appropriate for the patient

( ) No

Verify

REMS Dispense Authorization (RDA)

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Obtain RDA

Cancel

SUCCESS

Rx Verification Recorded

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

An RDA is a receipt from the TIRF REMS signifying that the REMS requirements to dispense for this patient are currently met.

Patient

Enrolled as of 4/20/2020

Name:	PatientJulie Williams	Zip Code:	30180
Date of Birth:	6/13/1970	Phone:	204-896-4439
		Email Address:	Patient@examoto.net

Prescriber

Certified as of 4/20/2020

Prescriber:	PRJane PRDoe	NPI:	1310000000
Address:	12 Parker Avenue Chambersburg, PA 17201		

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RDA: d5fbbe14 Copy Print

Reverse

Obtained by RxOutPatJane AuthRepDoe on 10/28/2020 at 6:12 PM Coordinated Universal Time

Detail

Safe Use Conditions:

- Patient is Enrolled: PatientJulie Williams
- To PRJane PRDoe's knowledge, Patient, PatientJulie Williams, is Opioid Tolerant
- Pharmacy Personnel is Certified: RxOutPatJane AuthRepDoe
- Pharmacy is Certified
- Pharmacy Personnel, RxOutPatJane AuthRepDoe, verified Opioid Tolerance for Patient, PatientJulie Williams
- Prescriber is Certified: PRJane PRDoe

Dispensation Information

Date	Manufacturer	NDC Code	Days Supply	Quantity
mm/dd/yyyy	Manufacturers			

Save

To report any SUSPECTED ADVERSE REACTIONS, contact the TIRF REMS Call Center at 1-866-822-1483 or FDA at 800-FDA-1088 or http://www.fda.gov/medwatch.

SUCCESS

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Date	Manufacturer	NDC Code	Days Supply	Quantity
10/28/2020	Company4	05640-0407-45	30	30

Save

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SUCCESS
RDA Dispensation information saved.

Pharmacy

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Prescription dispense recorded for this RDA.

Return

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____Localization_Version

Pharmacy

Outpatient Pharmacy Group

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- ○ Yes, the medication is appropriate for the patient
- ◉ No

Please describe the reason for discrepancy below

reason for discrepancy gets added here

[Verify]

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[Obtain RDA]

[Cancel]

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Please describe the reason for discrepancy below

reason for discrepancy gets added here

Verify

STOP! Do Not Dispense

Please contact the patient's prescriber to discuss the discrepancy in the opioid tolerance information. After the discussion with the prescriber, if you agree that the medication is appropriate for the patient, please attempt to obtain the RDA again. Based on this discussion, the prescriber may need to submit a new Patient Status and Opioid Tolerance Form to update the opioid tolerance information for this patient.

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Obtain RDA

Cancel

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MARK A LIBERATORE
12/23/2020 04:12:25 PM