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?

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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

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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

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- ment Form
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TIRF REMS

tact Us | Login | Register

Patient

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Receive counseling fr
Counseling Guide an

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- Company2MG

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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
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- 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
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- 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

Non-Compliance Policy | Privacy Policy | Terms of Use | Contact Us

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

Non-Compliance Policy | Privacy Policy | Terms of Use | Contact Us

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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.

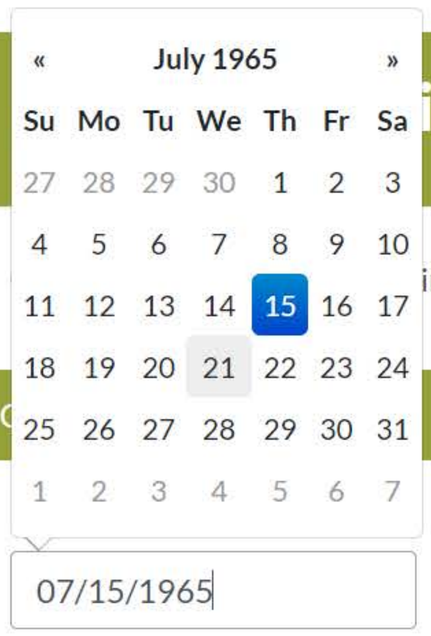
Sign | Type Signature

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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- 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

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

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.
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Clear

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Sign and Submit

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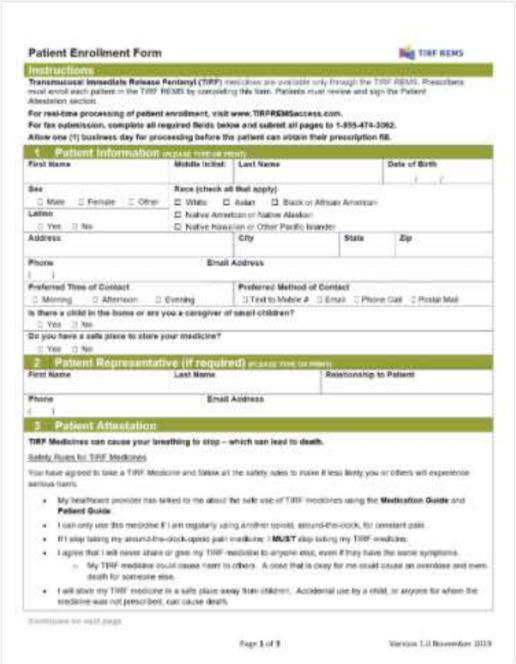
Patient Information Complete

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.
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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.
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- ( ) 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.
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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.
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- ( ) 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.
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Try Again | Home

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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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Prescriber - Knowledge Assessment

TIRF Prescriber KA

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Knowledge Assessment Complete

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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
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Upload Enrollment Form

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Browse Or drop files here

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
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- Company3MG
- Company4MG
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- Company6MG

Print Patient Counseling Guide

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Manage Patients

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

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Online or Print

Prescriber Materials

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PRPat PRDoe

Enrolled as of 4/20/2020

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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:

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Review each drug's Prescribing Information

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- CompanyPI3
- CompanyPI4
- CompanyPI5
- CompanyPI6

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

Online or Print

3 Complete the Prescriber Enrollment Form

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PRJane PRDoe

Certified as of 4/20/2020

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Certified as of 4/20/2020

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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

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
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Prescriber

1310000002

Re-Certify Notice

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PRTom PRSmith

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Prescriber

1310000001

Prescriber Certification

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PRPat PRDoe

Enrolled as of 4/20/2020

Edit

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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
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Manage Patients

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Certified Prescriber
Certified: 15th July, 2014

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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

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Edit				

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Return

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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.

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Date of Birth:	9/22/1989	Mobile Phone:	920-727-3214
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- Accidental exposure
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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

- [ ] 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

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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

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

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PatientTerry Smith — Enrolled as of 6/26/2019

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

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

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

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Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

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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

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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
- [ ] 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

Check all that apply

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Verify Opioid Tolerance

Opioid Moiety*

--Moiety--

Moiety/Strength/Route/Formulation*

Quantity* | Units* | Frequency*

Moiety	Formulation	Strength	Route	Dose	Frequency

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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

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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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Sign | Type Signature

Clear

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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):*

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

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

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

- [x] Benzodiazepines
- [ ] Barbiturates
- [ ] Prescription Insomnia Medications
- [ ] Gabapentinoids
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Medical Information

Type of Pain:*

○ Cancer Pain ○ Non-Cancer Pain

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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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Address:	273 New Saddle Lane Hickory, NC 28601	Home Phone:	

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

-- Select Product -- | | Dose | Frequency

Concomitant Medications (check all that apply):*

- [x] Benzodiazepines
- [ ] Barbiturates
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- [ ] 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

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.

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):*

- [ ] ≥ 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

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 --

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* | 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.

This patient is opioid tolerant because ibed (exclusive of a TIRF medicine) one or more of the following opioid regimens daily and has been pre 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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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

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PatientTerry Smith — Enrolled as of 6/26/2019

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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*

--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.

use he/she is currently prescribed (exclusive of a TIRF medicine) one or more of the following 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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Product Name* | Product Strength* | Dose* | Frequency*

-- Select Product --

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- ☐ 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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- 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*

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

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Sign | Type Signature

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

Clear

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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
- 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

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Sign | Type Signature

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Patient Status and Opioid Tolerance Form

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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
- 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

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

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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

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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

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

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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* 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

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F REMS and about safe storage and disposal, and to monitor my patients appropriately.

Sign | Type Signature

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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

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

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.

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

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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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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)

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- 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*

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

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- ☐ ≥ 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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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* — 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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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*

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

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

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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

f the following

F 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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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:

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- 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*

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

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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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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

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○ Cancer Pain ○ Non-Cancer Pain

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- 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.

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* 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

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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 --

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.

Sign | Type Signature

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

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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* 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

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* 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.

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

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.

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.

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

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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:*
○ 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

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

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Print PDF

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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

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- [ ] 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 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
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Address Line 1* Address Line 1
Address Line 2 Address Line 2

City* City
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Email Address* Megan.Brown@examoto.net
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Do you have a safe and secure place to store your medicine?*
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Last Name Last Name
Relationship Mother, Father...

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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

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

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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
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- ☐ Native Hawaiian or Other Pacific Islander
- ☐ Other (please specify)

Address Line 1* Address Line 1
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City* City
State* State
Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net
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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

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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
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Relationship Mother, Father...

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Medical Information

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○ 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

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Patient Enrollment

Patient Information

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Last Name* Brown
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Sex
○ Male ○ Female ○ Other

Are you Hispanic or Latino?
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○ Yes ○ No

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

Type of Pain:*
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- ☐ Sedative Hypnotics
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- ☑ 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	✖

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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
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Address Line 2 Address Line 2

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State* State

Zip Code* Zip Code

Email Address* Megan.Brown@examoto.net

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Last Name Last Name

Relationship Mother, Father...

Number nnn-nnn-nnnn

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Print PDF

Cancel

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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.

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*: --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):*

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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

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

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.

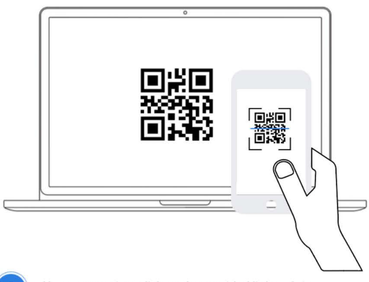
Reference ID: 4751752

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

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

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
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- ☐ ≥ 25 mg oral oxymorphone/day
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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

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.

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* 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

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.

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:*
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.

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* 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.

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* 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

☐ 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

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.

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* 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

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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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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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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

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- ☐ ≥ 25 mg oral oxymorphone/day
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- ☐ ≥ 8 mg oral hydromorphone/day
- ☐ ≥ 60 mg oral hydrocodone/day

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Clear

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Cancel

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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

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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* 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

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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.

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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--

--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.

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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.

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* 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

☐ 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

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

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*
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):*

- ☐ ≥ 60 mg oral morph
- ☐ ≥ 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

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

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.

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

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.

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

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.

Pharmacy

Examoto Pharmacy Group

Site Biennial Confirmation Notice

Your pharmacy's TIRF REMS biennial confirmation has expired. 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, RxScreenPatJane AuthRepDoe, am the REMS Authorized Representative for Examoto 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

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

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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

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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.
- ( ) Adult female with advanced breast cancer; on 60 mg of oral morphine daily for the past 4 weeks.
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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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- ( ) 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.
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- (●) 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.
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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.
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11. As an authorized representative for my pharmacy, which of the following is not my responsibility? ✗

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Try Again | Home

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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

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____Localization_Version

Pharmacy - Knowledge Assessment

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Home

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____Localization_Version

Pharmacy - Knowledge Assessment

TIRF Pharmacy KA

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Knowledge Assessment Complete

11 correct answers out of 11 (Passed)

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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

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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

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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

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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

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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

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— Or —

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[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

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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

Prescriber

Certified as of 4/20/2020

Prescriber:	PRJane PRDoe	NPI:	1310000000
Address:	12 Parker Avenue Chambersburg, PA 17201		

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— 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)

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[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

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Obtain RDA

Cancel

SUCCESS

Rx Verification Recorded

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

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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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- ( ) 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.

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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.

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Verify

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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

Rx Verification Recorded

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

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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

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Prescriber Reported:
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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
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Verify

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Reverse

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Detail

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- 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
10/28/2020	Company4	05640-0407-45	30	30

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
RDA Dispensation information saved.

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
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Prescriber

Certified as of 4/20/2020

Prescriber:	PRJane PRDoe	NPI:	1310000000
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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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RDA: d5fbbe14 Copy Print

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- Pharmacy is Certified
- Pharmacy Personnel, RxOutPatJane AuthRepDoe, verified Opioid Tolerance for Patient, PatientJulie Williams
- Prescriber is Certified: PRJane PRDoe

Prescription dispense recorded for this RDA.

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

Obtain a Patient's REMS Dispense Authorization (RDA)

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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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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

Please describe the reason for discrepancy below

reason for discrepancy gets added here

[Verify]

REMS Dispense Authorization (RDA)

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[Obtain RDA]

[Cancel]

Pharmacy

Outpatient Pharmacy Group

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[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
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reason for discrepancy gets added here

Verify

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Obtain RDA

Cancel

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SUCCESS
Rx Verification Recorded

Pharmacy

Outpatient Pharmacy Group

Obtain a Patient's REMS Dispense Authorization (RDA)

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Patient

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Date of Birth:	6/13/1970	Phone:	204-896-4439
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Adverse Events of Special Interest Reported	
Abused or been suspected of abusing their TIRF medicine	9/11/2020

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Based on the information provided, is the medication appropriate for the patient? Opioid Tolerance Criteria

- ( ) Yes, the medication is appropriate for the patient
- (●) No

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.

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

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