

The TIRF REMS Privacy Policy

Last Revised Date: March 29, 2021

Descriptive. The term TRIG or 'us' or 'we' refers to the Transmucosal Immediate-Release Fentanyl ("TIRF") REMS (Risk Evaluation and Mitigation Strategy) Industry Group or its authorized representatives, the owner of the TIRF REMS website. The term 'you' refers to the user or viewer of our website.

Under the TIRF REMS, only prescribers, pharmacies, wholesalers-distributors and patients enrolled in the program are able to prescribe, dispense, distribute, and receive transmucosal immediate release fentanyl (TIRF) medicines. In order for you to meet the requirements of the program, TIRF REMS must obtain certain Personal Information from you. The TIRF REMS Industry Group ("TRIG") and its authorized representatives are committed to respecting your privacy. Please read the following to learn more about our Privacy Policy regarding Personal Information that is collected on the website (www.TIRFREMSAccess.com).

What This Privacy Policy Covers

- This policy covers how the TIRF REMS treats personal information that the TIRF REMS collects and receives through its website, including patients' health information and the personally identifiable information of anyone that creates a website account (credentials), completes a knowledge assessment or enrolls/registers in the TIRF REMS.
- This policy does not apply to the practices of companies that TRIG does not own or control, or to people that TRIG companies do not employ or manage. This policy does not apply to any third-party websites which may be accessed via links on the website.

Your Consent

By using the TIRF REMS website you agree to the terms of this REMS Website Privacy Policy. Whenever you submit information to us through the TIRF REMS website, you consent to the collection, use, and disclosure of that information in accordance with this REMS Website Privacy Policy, including agreeing that we may contact you through a variety of means such as email, postal mail, phone, or fax. By submitting information to TIRF REMS related to the REMS program, you are consenting to TIRF REMS using and sharing this information for any purpose consistent with the goals of the REMS program and to effectuate operation and administration of the REMS program.

Information Collection and General Use

- The TIRF REMS collects personal information when you voluntarily choose to contact us with comments or inquiries through the website or choose to use certain areas of the website, including: creating a website account (credentials), completing a Knowledge Assessment (healthcare professionals only); enrolling/registering in the TIRF REMS; requesting information from the TIRF REMS; and visiting www.TIRFREMSAccess.com.
 - When you create a website account (credentials), (healthcare professionals only) we ask for information such as your name, NPI number, email address and phone number. Once you create a website account with the TIRF REMS, you are not anonymous to us.
 - When you enroll in the TIRF REMS as a Prescriber, we ask for information such as your name, address, email address, Individual NPI number, phone and fax number and credentials. Once you enroll with the TIRF REMS, you are not anonymous to us.
 - When you enroll in the TIRF REMS Access program as a Pharmacy, we ask for information such as your name, pharmacy name and address, email address, NPI number, credentials, position/title, and phone and fax number. Once you enroll with the TIRF REMS, you are not anonymous to us.
 - When a prescriber enrolls a patient in the TIRF REMS we will ask the prescriber for patient information such as their name, birth date, sex, race, ethnicity, address, city, state, zip code, phone number, email address, if there is a child in the home or you are a caregiver of small children, if you have a safe and secure place to store your medicine, medical information, representative's name, phone number, email address, and relationship to patient if applicable. The collection, use and handling of all patient information, including any Protected Health Information (PHI), will be consistent with the HIPAA (Health Insurance Portability and Accountability Act) Authorization forms signed by the patient prior to enrolling in the TIRF REMS.
 - When a prescriber submits a Patient Status and Opioid Tolerance Form for the patient, we will ask the prescriber for patient information such as their name, birth

date, and medical information. The collection, use and handling of all patient information, including any Protected Health Information (PHI), will be consistent with the HIPAA (Health Insurance Portability and Accountability Act) Authorization forms signed by the patient prior to enrolling in the TIRF REMS.

- The TIRF REMS also collects information about your transactions within the TIRF REMS.
- When you interact with us through the website, the TIRF REMS automatically receives and records personally non-identifiable information on our server logs from your computer, including your IP (Internet Provider) address, TIRF REMS cookie information, the pages you visit, and other anonymous statistical data involving your use of the website and/or the Services, but only in regard to your interactions with the TIRF REMS.
 - An IP address is a number assigned to your computer for access to the Internet. All computer identification on the Internet is conducted with IP addresses, which allow computers and servers to recognize and communicate with each other.
 - The TIRF REMS may set and access TIRF REMS cookies on your computer. A cookie is a piece of information that is placed on your computer when you access certain Web sites. The cookie uniquely identifies your computer to the TIRF REMS server. Cookies allow us to store information on the server to help make the Web experience better for you and to conduct site analysis and Web site performance review. Most Web browsers are set up to accept cookies, although you can reset your browser to refuse all cookies or to indicate when a cookie is being sent. Note, however, that some portions of our site may not work properly if you refuse cookies. Check the “Help” menu of your browser to learn how to change your cookie preferences. To find out more about cookies, visit www.aboutcookies.org.
 - We may embed tracking pixels within various pages of the Site to enable use of site analytics. The site analytics enable us to determine the usage frequency of various areas of the Site and identify areas of the Site for enhancement. While you are visiting and after you leave the Site, we may use web beacons to notify you of areas of the Site and other aspects of our organization and its affiliated companies in which you may be interested. Certain tracking pixels and web beacons may be cleared or reset through configuration of your web browser such as by clearing your cache.

- The Site does not track users over time and across the third party site to provide targeted advertising, and therefore does not respond to Do Not Track (DNT) signals. However, some third party sites do keep track of your browsing activities when they serve you content, which enables them to tailor what they present to you. If you are visiting such sites and do not want to be tracked, please adjust your web browser settings so third parties know you do not want to be tracked.
- The TIRF REMS uses your Personal Information to fulfill your requests for information; to verify your enrollment in the TIRF REMS; conduct research related to the program; to assess compliance with the TIRF REMS; and to contact you on TIRF REMS related matters. We use aggregated (non-personally identifiable) information to help us understand trends, website performance and patient needs. For example, we may analyze the gender or age of visitors to the TIRF REMS site, and we may use that analysis of aggregate data internally or share it with others such as companies that sponsor and/or support TIRF REMS (i.e., the manufacturers and their trusted partners) and the US Food and Drug Administration (FDA).

Information Sharing and Disclosure

- The TIRF REMS does not sell personal information about you to other people or nonaffiliated companies for any reason. Furthermore, we do not share personal information about you with other people or affiliated or nonaffiliated companies except to provide information or services you've requested, when we have your permission, or under the following circumstances:
 - We provide information to trusted business partners who work on behalf of or with the TIRF REMS under confidentiality agreements. These companies may use your information to help facilitate the TIRF REMS and to enable TIRF REMS to communicate with you about matters regarding the TIRF REMS. These companies do not have any independent right to share or use this information.
 - We respond to subpoenas, court orders, or legal process, requests for cooperation from law enforcement or other government agencies, to establish or exercise our legal rights or defend against legal claims. In such cases, we may raise or waive any legal objection or right available to us.

- When we believe disclosure is appropriate in connection with efforts to investigate, prevent, or take other action regarding illegal activities, suspected fraud, situations involving potential threats to the physical safety of any person, violations of the TIRF REMS Terms of Use, or as otherwise required by law;
- We may transfer information about you if TIRF REMS, TRIG companies, or the business(es) that support the TIRF REMS is acquired by or merged with another company and you hereby consent to such transfer.
- We may disclose your personal information to fulfill regulatory requirements. For example, if an adverse event of special interest related to you is reported to the TIRF REMS, we may use the information provided about you in submitting reports to the U.S. Food and Drug Administration. We may also use the information to contact you or your healthcare provider to perform follow-up regarding this event.

Information from Children

- The Program and the Site are not intended for any user under the age of 13 and we do not knowingly collect Personal Information from children under the age of 13. We request that children under the age of 13 not submit any Personal Information through the Site. If we determine that such information has been inadvertently collected on anyone under the age of 13, we will take the necessary steps to ensure that such information is deleted from our systems. If you are a parent or guardian and become aware that your child has provided us with information, please contact us using one of the methods specified below.

Notices and Bulletins.

- Periodically, we may choose to send news, bulletins, educational materials, marketing materials, or other information to you, and will use Personal Information to send such communications.

Information Collected on this website that is NOT Covered by this Privacy Policy.

- We may allow you to communicate with other users of the website and post information using message boards, Short Message Service (SMS), email, and other similar features available through the website. NONE of the information that you provide using these

features is protected by this Privacy Policy. THIS PRIVACY POLICY DOES NOT APPLY TO ANY INFORMATION (INCLUDING PERSONAL INFORMATION) THAT YOU PROVIDE USING MESSAGE BOARDS OR OTHER SIMILAR FEATURES THAT MAY BE AVAILABLE THROUGH THE SITE. ALL SUCH INFORMATION IS PUBLIC INFORMATION AND MAY BE SEEN, COLLECTED OR USED BY ANYONE, INCLUDING THIRD PARTIES, NOT AFFILIATED WITH US.

Confidentiality and Security

- We take commercially reasonable steps, including physical, electronic, and procedural safeguards, to protect Personal Information and to protect such information from loss, misuse, and unauthorized access, disclosure, alteration, or destruction. However, no internet, SMS, or email transmission is ever fully secure or error-free. In particular, email sent to or from the website may not be secure, and you should therefore take special care in deciding what information you send to us via email. Please keep this in mind when disclosing Personal Information to us or to any other party via the internet.
- We limit access to personal information to employees who we believe reasonably need to come into contact with that information in order to do their jobs and to operate the TIRF REMS.
- If you have a specific question or need to update or correct your personal information, please contact us at 1-866-822-1483.
- We will notify you if a breach occurs.

Information Retention

- We retain information collected through the Site for as long as it is necessary to provide you with the Services and comply with applicable laws, regulations, and court orders. For ease of use, the Site temporarily stores some user provided information, such as username and password, until the browser is closed.

Your Rights – California Residents

Access to Specific Information and Personal Information Portability Rights

You have the right, subject to certain exceptions defined in the CCPA and other applicable laws and regulations, to request that companies disclose certain information to you about their collection and use of your Personal Information over the past 12 months. This right of access includes information about:

- The categories of Personal Information we collected about you.
- The categories of sources for the Personal Information we collected about you.
- Our business or commercial purpose for collecting that Personal Information.
- The categories of third parties with whom we share that Personal Information.
- The categories of Personal Information that each recipient received.
- The specific pieces of Personal Information we collected about you.

Deletion Request Rights

You have the right, subject to certain exceptions defined in the CCPA and other applicable laws and regulations, to request that a company delete any of your Personal Information that it has collected from you and retained, subject to certain exceptions.

Non-Discrimination

California consumers also have the right not to receive discriminatory treatment if they exercise the rights list above.

Exercising Access, Personal Information Portability, and Deletion Rights

When you make a request, we may require that you provide information and follow procedures so that we can verify the request and your jurisdiction before responding to it. The verification steps we take may differ depending on the request you make. We will match the information that you provide in your request to information we already have on file to verify your identity. If we are able to verify your request, we will process it. If we cannot verify your request, we may ask you for additional information to help us verify your request.

Consumers will be required to submit their first and last name and email address and may also be asked to provide their telephone number or address so that we can verify the request. Please provide as much of the requested information as possible to help us verify the request. We will only use the information received in a request for the purposes of responding to the request.

We are not required to respond to a consumer's requests for access or disclosure of Personal Information more than twice in a 12-month period.

Authorized Agent

The CCPA permits California consumers to use an authorized agent to make privacy rights requests. We require the authorized agent to provide us with proof of the California consumer's written permission (for example, a power of attorney) that shows the authorized agent has the authority to submit a request for the California consumer. An authorized agent must follow the process described above to make a request. The authorized agent must also verify his/her own identity. We will confirm the agent's authority with the California consumer about whom the request was made.

No Sale of Personal Information

We are not currently selling your Personal Information.

Information Exempt from the CCPA

Note that certain information that is governed by the California Confidentiality of Medical Information Act (CMIA), HIPAA, or is subject to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule, pursuant to good clinical practice guidelines issued by the International Council for Harmonisation or pursuant to human subject protection requirements of the FDA, is not considered Personal Information with respect to the rights of California residents noted above. However, additional rights might be available under those laws and standards.

Your Rights – How to Exercise

To exercise any of the rights described above, you can get in touch with us by contacting the TIRF REMS at 1-866-822-1483 or by emailing at info@apcerls.com.

Visiting our website from outside the United States

- The use and content of our website is intended for US residents. This Privacy Policy is intended to apply to collection of information from residents of the United States. If you

are not a resident of the United States, please be aware that your information may be transferred to, stored and processed in the United States.

Changes to this Privacy Policy

- TIRF REMS may update or modify this policy at any time. We will notify you about significant changes in the way we treat personal information by sending a notice to the primary email address specified in your TIRF REMS enrollment or by placing a prominent notice on our site.

Questions and Suggestions

If you have questions or suggestions, please contact us at 1-866-822-1483.

For assistance, please call the TIRF REMS program at 1-866-822-1483.