

## The Clozapine REMS Privacy Policy

Effective Date: 08/15/2021

Last Updated: August 15, 2021

CPMG and its authorized representatives are committed to protecting your Personal Information. This Privacy Policy governs any Personal Information that may be processed as a result of your use of this website.

### Descriptive

The term 'CPMG' or 'us', 'our' or 'we' refers to the Clozapine Product Manufacturers Group or its agents, affiliates, and authorized representatives, who are the owner of this Clozapine REMS 'website' ([www.newclozapinerems.com](http://www.newclozapinerems.com)). The term 'you' or 'your' refers to the viewer or user of this website.

Under the Clozapine REMS or 'REMS', only prescribers and pharmacies certified in the REMS are able to prescribe and dispense clozapine medicines. Only distributors enrolled in the REMS are able to distribute clozapine medicines. Only patients enrolled in the REMS by a certified prescriber are able to receive Clozapine medicines.

The purpose of this website is to provide (i) a public, searchable list of certified pharmacies and distributors currently enrolled in the REMS for 'viewers,' and (ii) a central place to manage non-public information about the REMS for 'users.'

Patients may view the list referenced above but will not be authorized to modify or enter information. Authorized prescribers and pharmacies may enter information (which may include information regarding patients enrolled in the REMS) but this information cannot be viewed by the public.

### What This Privacy Policy Covers

- This Privacy Policy covers how the REMS treats personally identifiable information that the REMS collects and receives through this website (including patients' health information) associated with patients, prescribers, pharmacies, prescriber designees, pharmacy staff, and distributors ('Personal Information').
- This website may provide links to various third-party websites. However, even if a third-party affiliation exists between the REMS, this website, and the destination site, the REMS exercises no authority over linked destination sites, each of which maintains independent privacy and data collection policies and procedures. The REMS assumes no responsibility or liability for the independent privacy practices of destination sites. Similarly, the REMS cannot take responsibility for the content of such destination sites. These destination links are provided only for your convenience, and as such, you access them at your own risk.

### Your Consent

By using this website, you agree to the terms of this Privacy Policy. Whenever you submit Personal Information to us through this website, you consent to the collection, use, analysis, disclosure, storage, and deletion of that information in accordance with this Privacy Policy, including agreeing that we may contact you through a variety of means such as email, postal mail, phone, or fax, unless you opt out of these communications by contacting us. By submitting information to the REMS through this website, you are consenting to the REMS using and sharing this information (in accordance with applicable law) for any purpose consistent with the goals of the REMS and to effectuate operation and administration of the REMS.

### Information Collection and General Use

- This website collects Personal Information when you voluntarily choose to contact us with comments or inquiries, enroll in the REMS, complete a knowledge assessment, or enter ANC lab results.
- When you certify in the REMS as a Pharmacy, we ask for information such as your name, pharmacy name and address, pharmacy type, email address, NPI and DEA numbers, phone and fax numbers, and contact preference. Once you certify with the REMS and sign into this website, you are not anonymous to us.

- When you certify in the REMS as a Prescriber, we ask for information such as your name, address, email address, NPI and DEA numbers, phone and fax numbers, contact preference, and practice name and credentials. Once you certify with the REMS and sign into this website, you are not anonymous to us.
- When you enroll in the REMS as a Designee of a certified Prescriber, we ask for information such as your name, email address, phone and fax numbers, and contact preference. Once you enroll with the REMS and sign into this website, you are not anonymous to us.
- When you enroll in the REMS as a staff of a Pharmacy, we ask for information such as your name, email address, phone and fax numbers, and contact preference. Once you provide the information to the REMS and sign into this website, you are not anonymous to us.
- When a Prescriber or the Prescriber's Designee enrolls a patient or enters a patient's lab results in the REMS, we will ask the Prescriber or Designee for patient Personal Information, such as the patient's name, birth date, phone number, email address, gender, race, ethnicity, zip code, ANC lab values, and blood draw date. Patient written authorization is not required for the REMS to receive this information because this is an FDA mandated REMS (per 45 CFR 164.512 (b)(1)(iii)).
- When a Pharmacy or the Pharmacy staff requests a dispense authorization from the REMS, we will ask the pharmacist or staff for patient and clozapine prescription information such as the patient's name, birth date, and the prescription dispense date and National Drug Code (NDC).
- We also collect information about your transactions within the REMS. Certain visitors to this website interact with the site in ways that require the REMS to collect Personal Information and other information. The amount and type of information gathered depends on the nature of the interaction. For example, we ask Prescribers and Pharmacies to register by providing a username and email address. Those who engage in transactions with the REMS – by enrolling patients, entering lab values, or requesting REMS dispense authorizations, for example – are asked to provide additional information, including as necessary the Personal Information required to process those transactions. In each case, we collect such information only insofar as is necessary or appropriate to fulfill the purpose of the visitor's interaction with the REMS. We do not disclose Personal Information other than as described in this Privacy Policy. Visitors to this website can always refuse to supply Personal Information, with the caveat that it may prevent them from engaging in certain website-related activities.
- When you interact with us through this website, we gather information automatically and store it in log files. This information may include IP addresses, browser type, internet service provider, referring/exit pages, operating system, date/time stamp and/or clickstream data. We do not link this automatically collected Personal Information to other information we collect about you. 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.
- This website may set and access non-persistent cookies on your computer. A cookie is a piece of information that is placed on your computer when you access certain websites. The cookie uniquely identifies your computer to the 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 website 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 this website may not work properly if you refuse cookies.

We use your Personal Information to fulfill your requests for information; to verify your enrollment and/or certification in the REMS; to conduct research related to the REMS; to assess compliance with the REMS; to contact you on REMS-related matters; and, to the extent applicable, to provide consumers and enrolled distributors with information regarding pharmacies certified with the REMS. 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 this website, and we may use that analysis of aggregated data internally or share aggregated data with others such as companies that sponsor and/or support the REMS (i.e., a CPMG company and their trusted partners) and the U.S. Food and Drug Administration (FDA). Any third party that receives aggregated data will agree not to attempt to re-identify the persons to whom it belongs. This website does not track users over time and across third-party websites 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.

## **Information Sharing and Disclosure**

- We do not sell Personal Information to third parties. We may share your Personal Information with third parties that perform services on our behalf in connection with the REMS, or under the following circumstances:
  - 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 REMS Terms of Use, or as otherwise required by law.
  - We may transfer information about you if the REMS, a CPMG company, or a business(es) that supports the REMS is acquired by or merged with another company, and you hereby consent to such transfer.

## **Information From Children**

- The REMS is 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 this website.

## **Notices and Bulletins**

- Periodically, we may choose to send news, bulletins, educational materials, or other information to you that is associated with the REMS; and we 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 this website and post information using message boards and other similar features available through this website. NONE of the information users provide using these features is protected by this Privacy Policy. THIS PRIVACY POLICY DOES NOT APPLY TO ANY INFORMATION (INCLUDING PERSONAL INFORMATION) PROVIDED USING MESSAGE BOARDS OR OTHER SIMILAR FEATURES THAT MAY BE AVAILABLE THROUGH THIS WEBSITE. 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 appropriate physical, electronic, and administrative safeguards, to protect Personal Information from loss, misuse, and unauthorized access, disclosure, alteration, or destruction. However, no internet or email transmission is ever fully secure or error-free. In particular, email sent to or from this 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, contractors, and agents with whom we believe reasonably need to come into contact with that information in order to do their jobs and to operate the REMS.

## **Information Retention**

- The REMS retains information collected through this website for as long as it is necessary to comply with applicable laws, regulations and court orders.
- For ease of use, this website temporarily stores some user provided information, such as username and password, until the browser is closed.

- Information transmitted to your facility through this website may be stored according to your facility's privacy policies and procedures. Your facility, not the REMS, determines how long that information is retained.

## **Your Rights – California Residents**

### Access to Specific Information and Personal Information Portability Rights

- You have the right, subject to certain exceptions defined in the California Consumer Privacy Act (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 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 Clozapine REMS at 888-586-0758.

### **Visiting Our Website From Outside the United States**

- The use and content of this website is intended for U.S. residents only. 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**

- The REMS may update or modify this Privacy 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 REMS enrollment or by placing a prominent notice on this website.

### **Contact Us**

- If you have questions regarding this Privacy Policy, please contact us at 888-586-0758.