The Clozapine REMS Program Privacy Policy

Effective Date: 08/31/15

Descriptive

The term ‘CPMG’ or ‘us’ or ‘we’ refers to the Clozapine Product Manufacturers Group or its agents, affiliates, and authorized representatives, the owner of the Clozapine REMS Program website (www.clozapinerems.com). The term ‘you’ refers to the user or viewer of our website.

Under the Clozapine REMS Program or ‘Program’, only prescribers, pharmacies, and distributors enrolled in the Program are able to prescribe, dispense and distribute, clozapine medicines. The website is targeted for their use, access, and entering information for the Program. Only patients enrolled by their prescriber are able to receive Clozapine medicines. Patients may visit the website but will not be entering information into the website. In order to meet the requirements of the Program, the Program must obtain certain Personal Information from you. CPMG and its authorized representatives are committed to protecting your Personal Information.

Please read the following to learn more about our Privacy Policy regarding Personal Information that is collected, used, and shared by the Program and how that information is protected.

What This Privacy Policy Covers

- This Privacy Policy covers how the Program treats personally identifiable information that the Program collects and receives through the Program website, including patients’ health information and the personally identifiable information of patients, prescribers, pharmacies, prescriber or pharmacy designees, and distributors that enroll for the training and knowledge assessment, and certify in the Program (“Personal Information”).

- The Program may provide links to various third party websites within the Program website. However, even if a third party affiliation exists between the Program and the destination site, the Program exercises no authority over linked destination sites, each of which maintains independent privacy and data collection policies and procedures. The Program assumes no responsibility or liability for the independent privacy practices of destination sites. Similarly, the Program 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 the Program website, you agree to the terms of this Privacy Policy. Whenever you submit Personal Information to us through the Program website, you consent to the collection, use, 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 Program, you are consenting to the Program using and sharing this information for any purpose consistent with the goals of the Program and to effectuate operation and administration of the Program.

Information Collection and General Use

- The Program 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: enrolling in the Program, entering ANC lab results, and visiting www.clozapinerems.com.

  o When you enroll in the Program 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 Program and sign into our website, you are not anonymous to us.

  o When you certify in the Program as a Pharmacy, we ask for information such as your name, pharmacy name and address, pharmacy type, email address, NCPDP, NPI and DEA numbers, phone and fax numbers, and contact preference. Once you certify with the Program and sign into our website, you are not anonymous to us.
o When you certify in the Program as a Designee of a Prescriber, we ask for information such as your name, email address, Prescriber you wish to be associated with, phone and fax numbers, and contact preference. Once you certify with the Program and sign into our website, you are not anonymous to us.

o When you certify in the Program as a Designee of a Pharmacy, we ask for information such as your name, email address, Pharmacy you wish to be associated with, phone and fax numbers, and contact preference. Once you provide the information to the Program and sign into our website, you are not anonymous to us.

o When a Prescriber or the Prescriber's Designee enrolls a patient or enters a patient's lab results in the Program, we will ask the Prescriber or Designee for patient Personal Information such as the patient's name, birth date, state, zip code, ANC lab values, and blood draw date. Patient written authorization is not required for REMS program to receive this information because this is a FDA mandated program (per 45 CFR 164.512 (b)(1)(iii)).

- The Program also collects information about your transactions within the Program. Certain visitors to the Program’s website interact with the site in ways that require the Program to collect Personal Information and other information. The amount and type of information that the Program gathers 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 Program – by enrolling patients, entering lab values, or requesting pre-dispense authorizations, for example – are asked to provide additional information, including as necessary the Personal Information required to process those transactions. In each case, the Program collects such information only insofar as is necessary or appropriate to fulfill the purpose of the visitor’s interaction with the Program. The Program does not disclose Personal Information other than as described in this Privacy Policy. Visitors to the Program 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 the Program 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.

o The Program 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 Program 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 our site may not work properly if you refuse cookies.

- The Program uses your Personal Information to fulfill your requests for information; to verify your enrollment and/or certification in the Program; to conduct research related to the Program; to assess compliance with the Program; and to contact you on Program-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 Program 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 Program (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

- The Program does 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 Program, or under the following circumstances:
  
  o 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.

  o 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 Program’s Terms of Use, or as otherwise required by law.

  o We may transfer information about you if the Program, a CPMG company, or a business(es) that supports the Program is acquired by or merged with another company and you hereby consent to such transfer.

Information From Children

- The Program 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, 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 Program website and post information using message boards and other similar features available through the Program 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 PROGRAM 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 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, contractors, and agents who we believe reasonably need to come into contact with that information to in order to do their jobs and to operate the Program.

Information Retention

- The Program retains information collected through the Program website for as long as it is necessary to comply with applicable laws, regulations and court orders.

- For ease of use, the Program website temporarily stores some user provided information, such as username and password, until the browser is closed.
• Information transmitted to your facility through the Program website may be stored according to your facility's privacy policies and procedures. Your facility, not the Program, determines how long that information is retained.

Visiting Our Website From Outside the United States

• The use and content of our 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 Program 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 Program enrollment or by placing a prominent notice on the Program website.

Contact Us

• If you have questions regarding this Privacy Policy, please contact us at 844-267-8678 or mail inquiry to the Clozapine REMS Program, P.O. Box 29058, Phoenix, Arizona 85038-9058.