



Subject: Clozapine REMS Update

Date: October 16, 2015

CPNP Members:

Below are some clarifications on the Clozapine REMS including important information on the importance of continued patient care and public health. CPNP will continue to post updates as we become aware of them and share the issues/concerns with our contacts. Members should continue to contact the ClozapineREMS call center for individual issues and concerns.

1. **Website Update:** The ClozapineREMS website now contains a red “Important Program Update >>” button. Clicking this button offers several clarifications as result of the problems experienced during the initial release of the website.
2. **Important Note:** Patient care and public health come first. During this transition, the last thing all parties want is for patients to not receive their clozapine from known prescribers and known pharmacies. The transition period established by the Clozapine REMS Program is October 12<sup>th</sup> through December 14<sup>th</sup>. This transition window is intended to allow for continuity of care while the enrollment process and any issues associated with it are resolved. Issues that pharmacies and prescribers are encountering with the web site should not be allowed to interrupt the continuity of clozapine care. CPNP strongly recommended this information be shared on the website. In fact, this morning’s update specifically notes the following
  - Pharmacies can presently still order and receive drug from their distributors
  - Pharmacies are not required to certify in the REMS in order to dispense clozapine to patients with an ANC within acceptable ranges
  - Prescribers may continue to prescribe clozapine to patients with an ANC within acceptable ranges without being enrolled in the REMS
3. **Communication:** The ClozapineREMS and FDA are very aware of the issues that users are encountering with the online system and hear your frustration. They have issued more communications by messages on their phone line and web site regarding these issues. Please click the “Important Program Update >>” button to access these communications.
4. **Technical Issues:** The contractor responsible for the ClozapineREMS system has addressed the technical issue that was preventing online enrollment. This was attributed to conflicting roles between the data imported from the legacy registries and the new registry.
5. **Confirmation:** If you have gotten to the confirmation page, but received no notification of confirmation, you can consider yourself confirmed.

6. **Enhancements to the System/Process:** CPNP has been invited to continue to submit information regarding needed enhancements to the system and the process. Though the most immediate concerns are the technical glitches, the Clozapine REMS will consider additional enhancements as the process matures. Feel free to submit such items through the call center or to [info@cpnp.org](mailto:info@cpnp.org).
7. **Multiple Roles:** There was some clarification about a few questions regarding users being allowed to hold multiple roles within the system. There will be no limitation, once the system is running properly that will prevent a user from holding multiple roles. For example, a pharmacist can be an authorized representative and a prescriber designee, etc. Also, while pharmacies cannot view a list of all of their enrolled patients, a prescriber designee in the pharmacy can view a list of all patients enrolled to all of the prescribers for which they are a designee. There was some question about whether or not the multiple roles would require multiple user names and login information and that is not resolved. CPNP will continue to request that the ability of pharmacies to view a full list of their enrolled patients be added to the capabilities of the software.

CPNP thanks you for your communication and contributions related to the ClozapineREMS and is proud of your commitment to your clozapine patients. We are pleased we can serve as a source of information during this transition.