

**FDA REQUIRED
UPDATED REMS
SAFETY
INFORMATION**

Switch System will be removed November 15, 2021; Re-certification required

Dear Authorized Representative,

The Clozapine REMS requirements are changing due to a recently approved modification. New Clozapine requirements will be implemented on November 15, 2021.

Starting November 15, 2021

- The current “switch” pharmacy management system is being removed. A REMS dispense authorization will only be provided by accessing either the modified Clozapine REMS website platform or the Clozapine REMS Call Center by phone.
- Only pharmacies with Authorized Representatives re-certified in the Clozapine REMS will be able to dispense clozapine.
- New processes and procedures may need to be put in place for your pharmacy to be able to continue dispensing clozapine.

Authorized Representatives must **re-certify** for your pharmacy to continue to dispense clozapine. You may re-certify beginning August 16, 2021. In order for an individual pharmacist to re-enroll in the Clozapine REMS, the certified Authorized Representative will need to invite the pharmacist to enroll in the program using a valid email address.

- Large chain pharmacies may call the Clozapine REMS Contact Center at 1-888-586-0758 to arrange for a bulk upload of stores and staff.

Starting August 16, 2021

- **Re-certification will open August 16th at the new Clozapine REMS Website.** To reach this new clozapine REMS website:
 - o Go to www.clozapinerems.com.
 - o Click on the link in the **Important Program Update**. You will be taken to the new Clozapine REMS website.

- o Authorized Representatives must create new log-in credentials.
- o Click on **Log-in | Register** tab. These credentials will only work on the modified Clozapine REMS website.
- o Authorized Representatives must first review the Pharmacy Training, complete and submit the Knowledge Assessment and Pharmacy Enrollment Form to become re-certified.
- Additionally, the Clozapine REMS Transition Call Center will be available on August 2, 2021 to help guide you through the re-certification process at 1-888-586-0758.
- Authorized Representatives must also train pharmacy staff using new materials and send staff an invitation to re-enroll after they are trained.
- See [Fact Sheet: What's Changed in the Clozapine REMS for Pharmacies](#) for more details on these and other changes to the program.

Re-certify prior to November 15th to avoid delays in patient treatment!

Questions?

The [Clozapine REMS Transition Call Center](#) at **1-888-586-0758** can answer any questions you may have beginning August 2nd.

Signed,

CPMG