

NC Pharmacists- New Clozapine REMS System Coming November 15, 2021

To help manage the risk of neutropenia, clozapine has a Risk Evaluation and Mitigation Strategy (REMS) mandated by the FDA. On July 29, 2021, [FDA approved](#) a modification to the Clozapine REMS, in conjunction with the Clozapine Product Manufacturers Group (CPMG).

The modification to the Clozapine REMS will go into effect on November 15, 2021. Important changes include:

- All prescribers and pharmacies must be re-certified by November 15, 2021, or they will no longer be able to prescribe/dispense clozapine.
- Prescribers must re-enroll their patients who will continue clozapine by November 15, 2021. Patients who are not re-enrolled by that day will no longer be able to receive clozapine.
- Pharmacies will no longer be able to use the telecommunication verification (also known as the switch system) to verify safe use conditions. The authorization to dispense RDA will be obtained either through the contact center or online via the REMS website.
- A new Patient Status Form (PSF) must be submitted monthly by the prescriber. Patient ANC monitoring must continue per the Prescribing Information, however this is provider driven in the new system. After enrolling the patient, the REMS system requires a detailed Patient Status Form (PSF) monthly. Currently there is no electronic PSF to use. The PSF will document
 - absolute neutrophil count (ANC) monitoring for all outpatient
 - monitoring frequency
 - appropriateness for continuing treatment.
- continuation of therapy if one or more ANC results are missing for the month . Provider or pharmacy failure to re-enroll or re-certify may lead to clozapine interruption, which could result in significant consequences and negative outcomes for individuals stabilized on clozapine.
- Designee assignment- Providers must initiate the designee process. Further, pharmacists in the past have been in a position to be named provider designee for more than one provider. This is currently not the case in the new REMS system, although the REMS officials are addressing this gap and it may be corrected prior to REMS launch. Also, nurses may not be designees for more than 1 provider-there must be a 1:1 relationship between the provider and the designees in the new REMS.
- The ANC monitoring frequency will not be determined by REMS. The prescriber will have to keep note of when they switch to q-2 week or q-monthly because the program will not notify you like it used to.
- Dispense Rationale (Pharmacist Medication Dispense Over-ride)- pharmacists may override system three times per year with a “Dispense Rationale” if to avoid disruption in patient care if no PSF submitted within 37 days

- No carryover of historical patient data to new REMS system and also no carryover of National Non-Rechallenge Master File also called the “Do Not Rechallenge List”

New REMS vendor: Syneos Health®

- Syneos phone number: 888-586-0758
- Syneos fax number: 800-878-5927
- Transition website: NewClozapineREMS.com

The New REMS – Changes for Pharmacists

- Wholesalers requested to avoid selling to non-registered pharmacies

- A pharmacy can have two authorized representatives- cannot be both a representative and a designee
- Physician must assign/initiate designee status (formerly initiated by pharmacist)
 - A pharmacy doesn't need to recertify every two years, however needs to confirm authorized representative hasn't changed.
 - Pharmacy doesn't need to see labs to dispense
 - Individual pharmacists do not need to complete Knowledge Assessment Quiz, only the authorized representative is required to do so.

Pharmacists/Dispensing Pharmacies – What You Need To Do

- Must recertify
- Must obtain a REMS Dispense Authorization (RDA) to dispense each prescription
- RDA is only available from REMS website or by calling REMS Contact Center; RDA is no longer available via SWITCH (pharmacy management system)
- Can submit ANCs via ANC Lab Reporting Form
- Pharmacies must re-enroll!
 - Create an account with authorized representative
 - Review Clozapine and the Risk of Neutropenia: A Guide for Pharmacists.
 - Authorized representative must complete the Knowledge Assessment for Pharmacies.
 - Submit enrollment form as inpatient or outpatient pharmacy
 - Contact prescribers to have them submit a pharmacist as designee if desired
 - Train staff
 - Add staff online in “manage personnel” section
 - Individual staff are emailed to establish own credentials

On 10/21/21, the College of Psychiatric and Neurologic Pharmacists (CPNP), the National Alliance on Mental Illness (NAMI), the American Psychiatric Association (APA), the American Pharmacists Association (APhA), the American Psychiatric Nurses Association (APNA), the National Association of State Mental Health Program Directors (NASMHPD) and the National Council for Mental Wellbeing met with numerous representatives from various divisions of the FDA and the Clozapine Product Manufacturers Group. This meeting was a follow up to the shared organizational concerns about the new clozapine REMS. The agenda addressed the concerns that have emerged as the health providers have attempted to use or plan for the new clozapine REMS. The meeting was characterized as an "FDA Listening Session."

While no resolution was reached, Clozapine Product Manufacturers Group (CPMG) noted they were working on a new 90-day transition plan to reduce the risk of patients not getting their clozapine. However, they did not supply specifics, state when enhancements would be implemented.

Below are links taking you to information regarding the new clozapine REMS. The CPNP webinar is member protected (slides attached) but SMI Adviser information is free and open access.

- Resources regarding new Clozapine REMS
 - [Keeping Up with Clozapine REMS: A Guide to Navigating the November 15 Changes](#) (1.0 AMA PRA Category 1 Credits™) is a one hour free CME program (medical, not pharmacy CE) from SMI Adviser, a collaboration of SAMHSA and APA. The slides are attached.
 - [CPNP -New Clozapine REMS CPNP Webinar](#) Covers questions on the REMS test, after a review done by the College of Psychiatric & Neurologic Pharmacists (who also were part of the SMI Adviser CE program above . The accompanying *New Clozapine REMS FAQs CPNP 2021* are also a good resource (MEMBERSHIP REQUIRED)
 - [HTTP://NewClozapineREMS.com](http://NewClozapineREMS.com)
 - [FDA Press Release-Announcement of New Clozapine REMS 7/29/2021.](#)