FDA has eliminated clozapine REMS requirements. Now what?

On Feb. 25, the U.S. Food and Drug Administration announced that it is removing the REMS requirements for clozapine, an atypical antipsychotic medication indicated for treatment-resistant schizophrenia.

The purpose of this letter is to seek your assistance in alerting pharmacies to removal of this barrier to clozapine use for patients for whom it is indicated.

About the REMS Discontinuation

- The FDA REMS decision is being hailed by the schizophrenia community – including providers, patients and their caregivers – as it greatly improves access to clozapine and reduces the risk of the dangerous treatment interruptions that have resulted in many patients relapsing into psychosis, suicidality, hospitalization and even death.
- Many of these treatment interruptions occurred during pharmacy dispensing, due to payer enforcement of REMS elements as well as corporate policies regarding clozapine. In fact, many pharmacies elected not to fill clozapine prescriptions due to the burden imposed by both FDA and non-FDA requirements.
- Although the REMS removal eliminates many of the burdensome administrative requirements pharmacies and prescribers have faced, it has resulted in a flurry of questions and confusion about the practical execution of this removal. This includes how quickly pharmacies will move to eliminate the REMS requirements from their systems, and how pharmacies should operate in the face of corporate and payer requirements that may continue even without the REMS.
- It is critical that we work together in the coming months to ensure a smooth transition, so that we are all equipped to help patients and their caregivers navigate this momentous change.

What Should Pharmacies Do Now?

To expedite these urgently needed actions, we ask that you communicate the need for these changes to your membership as quickly as possible. **Any delay in removing REMS requirements from pharmacy systems perpetuates the obstacles to treatment that FDA is seeking to eliminate.**

As a result of the REMS removal, pharmacies:

- **Do not** need to register with the REMS program.
- **Do not** need special dispensing authorization to fill clozapine prescriptions.

An important part of FDA's decision was based on the significant and potentially dangerous barriers patients encounter when attempting to fill their clozapine prescriptions at the pharmacy. We urge:

- **Clinics, hospitals and mail order and community pharmacies to immediately change their operating procedures to remove all requirements related to clozapine dispensing and audit criteria that were part of the now-defunct REMS elements.** These elements include quantity limits, copies of lab results and REMS Dispensing Authorizations.
- **Pharmacies to resume dispensing clozapine if they had previously stopped dispensing it.** FDA's removal of the clozapine REMS makes this medicine newly accessible for the 1 million+ people who suffer from treatment-resistant schizophrenia and suicidal behavior associated with schizophrenia. This is an opportunity for your members to demonstrate their commitment to the communities they serve by making clozapine available for their patients. For many, clozapine is the only medicine that allows them to manage this severe disease and begin a path to recovery.

The Clozapine REMS Working Group:

- American Association for Community Psychiatry
- American Association of Psychiatric Pharmacists
- American Psychiatric Association
- CURESZ Foundation
- National Alliance on Mental Illness
- National Association of State Mental Health Program Directors
- Schizophrenia & Psychosis Action Alliance
- Team Daniel Running for Recovery from Mental Illness
- The Angry Moms
- Treatment Advocacy Center