

NOTICE: Clozapine REMS Program Update

March 25, 2025

Dear Providers,

FDA Ends Clozapine REMS Program Requirements: **Effective February 24, 2025**, the FDA has eliminated the mandatory requirements of the Clozapine REMS Program. Prescribers, pharmacies, and patients are no longer required to participate in the program or report absolute neutrophil count (ANC) results before dispensing clozapine.

Key Updates:

- REMS Reporting No Longer Required: FDA no longer expects prescribers or pharmacies to submit patient data, registration, or ANC lab results to the REMS program.
 - ANC Monitoring Still Recommended: Despite the REMS program ending, prescribers should continue to monitor ANC levels per prescribing guidelines.
 - Improved Access to Clozapine: Eliminating the REMS program is intended to reduce healthcare system burdens and improve patient access to clozapine.
 - Pharmacy Variability: Some individual pharmacies may still follow REMS requirements. Continue existing workflows to prevent treatment disruptions.
- The Arizona State Board of Pharmacy will post the FDA notice on their website and include this update in their quarterly newsletter.

Action Required: Please inform your relevant stakeholders, including but not limited to:

- Members & Network Pharmacies
- Prescribing Clinicians & Clinic Facilities
- Behavioral Health Organizations
- Hospitals

For additional information:

- Visit the Clozapine REMS website: <https://www.newclozapinerems.com/Public/home/Contact>
 - Contact Clozapine REMS: 1-888-586-0758
- <https://www.azahcccs.gov/shared/News/GeneralNews/ClozapineProgramUpdate.html>

If you have any questions, please contact:

- General Pharmacy Mailbox: AHCCCSPharmacyDept@azahcccs.gov

Thank you for your attention to this important update

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