

KATHY HOCHUL
Governor

ANN MARIE T. SULLIVAN, M.D.
Commissioner

THOMAS E. SMITH, M.D.
Chief Medical Officer

MEMORANDUM

To: NYS Public Mental Health Programs

From: Dr. Thomas Smith, Chief Medical Officer
Christopher Smith, PhD, Acting Associate Commissioner, Division of Adult
Community Care Group
Dr. Flavio Casoy, Medical Director, Adult Community Care and Managed Care

Date: September 29, 2021

RE: **Clozapine Risk Evaluation and Mitigation Strategy Requires Providers and Pharmacies to Re-certify and Re-enroll Patients by November 15, 2021**

Clozapine is FDA-approved for treatment-resistant schizophrenia and to reduce the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder. Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L), and as part of the REMS, the patient's absolute neutrophil count (ANC) must be submitted monthly via the Patient Status form. Modifications to the Clozapine REMS were approved on July 29, 2021 by the [Food and Drug Administration](#).¹ The Clozapine REMS now incorporates the prescribing, dispensing, and receiving of clozapine into a single-shared program.

All providers and pharmacies that prescribe or dispense clozapine must re-certify in the Clozapine Risk Evaluation and Mitigation Strategy (REMS) program by November 15, 2021. Prescribers and pharmacies that fail to re-certify cannot prescribe or dispense clozapine. For prescribers, re-certification is required regardless of practice setting (e.g., outpatient, inpatient). To avoid disruption in care, prescribers must also re-enroll their patients in the Clozapine REMS program by November 15, 2021. Patients who are not re-enrolled by their provider into the Clozapine REMS program cannot receive clozapine. Providers and pharmacies can re-certify or re-enroll patients into the program at the [Clozapine REMS Home](#).²

OMH Licensed Article 31 Providers should contact their local Field Office with questions and concerns.

¹ U.S. Food and Drug Administration. Clozapine Risk Evaluation and Mitigation Strategy (REMS) requirements will change on November 15, 2021. Accessed at <https://www.fda.gov/drugs/drug-safety-and-availability/clozapine-risk-evaluation-and-mitigation-strategy-rems-requirements-will-change-november-15-2021>. September 2021.

² Clozapine REMS: The single shared system for clozapine. Accessed at <https://www.clozapinerems.com/CpmgClozapineUI/home.u>. September 2021.