December 14, 2021

Dear State Medical and Pharmacy Boards,

On November 15, 2021, the modified Risk Evaluation and Mitigation (REMS) program for clozapine launched for health care professionals and patients. Shortly thereafter, FDA began receiving reports from stakeholders across the country about serious difficulties interacting with the program impeding patient access to the drug.

FDA takes these concerns very seriously. On November 19, 2021, to help address these challenges and avoid sudden interruptions in patient care, FDA announced that it would temporarily exercise enforcement discretion for certain requirements of the Clozapine REMS. During this period, **FDA does not intend to enforce certain provisions** of the Clozapine REMS:

Temporary Enforcement Discretion for Certain Clozapine REMS Requirements

REMS Stakeholder Role	REMS Requirement	Does enforcement discretion apply?	What does this mean for stakeholders
Pharmacies	Obtain a Request to Dispense Authorization (RDA) through the Clozapine Call Center	Yes	FDA does not intend to object if pharmacists dispense clozapine without obtaining an RDA.
Wholesalers	Confirm pharmacies and health care settings are enrolled in the REMS	Yes	FDA does not intend to object if wholesalers ship clozapine to pharmacies and health care settings without confirming enrollment in the REMS.

FDA believes that the decision not to enforce specific elements of the REMS on a temporary basis should alleviate any barriers for patient access to treatment resulting from call center wait times. Abrupt discontinuation of clozapine can result in significant complications for patients, and patient safety is our top priority.

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Silver Spring, MD 20993
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We encourage pharmacists and prescribers to continue working with the Clozapine REMS to complete certification and patient enrollment. Prescribers and pharmacists should continue to monitor their patients' absolute neutrophil count (ANC) according to the FDA-approved labeling and report those values using the Patient Status Form when feasible to the Clozapine REMS program.

FDA is also aware of reports that some clozapine insurance claims have been rejected when RDAs are not provided during claim adjudication or submission. FDA is reaching out to payer groups to clarify that RDAs may not be consistently issued during this period of enforcement discretion, and encouraging insurance providers to develop an override code, if necessary, for rejected claims.

We will continue to provide updates on the status of the Clozapine REMS modification implementation as issues resolve with the program. If you have questions or concerns about the Clozapine REMS Program or its website, please contact FDA at druginfo@fda.hhs.gov, 1-855-543-3784 or 301-796-3400.

We hope this information is helpful. Please feel free to contact FDA's Intergovernmental Affairs Staff at IGA@fda.hhs.gov if you have any questions. Thank you.

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