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Food and Drug Administration

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We appreciate the continued dialogue and responses to our concerns about the implementation of the New Clozapine REMS (NCR). As stakeholders, we are greatly concerned by the reports from our members that we have received in the past few days. As we near the end of the first week of the NCR implementation, it is evident that things are not going smoothly. We are aware of the following issues:

1. Despite enrolling as a pharmacy system, one entire hospital system is unable to order clozapine from its wholesaler as the wholesaler does not have them listed as enrolled. They are down to a four-day supply of clozapine. They are trying to work with their wholesaler, but this is obviously unacceptable.
2. The 90-day transition to allow RDAs without the patient being enrolled is not working. It appears that one has to call NCR to invoke this. We are aware of no one who has been able to do this, because they have not been able to get through to NCR.
3. We have reports of facsimile lines being busy all day and thus facilities cannot send in anything by fax.
4. We have numerous reports of telephone wait times of 4 to 7.5 hours, individuals not being called back until after their working hours, and individuals not receiving return calls. This means that any problem with enrollment, correcting errors or obtaining an RDA cannot be resolved.
5. The lack of education by CPMG despite offers by the stakeholders to assist them means that many pharmacies are unaware that the switch is no longer in place. This is resulting in difficulties with patients having prescriptions filled.
6. We are aware of community pharmacies who have chosen not to enroll and not to dispense clozapine because their initial attempt to get through to NCR was time consuming and unsuccessful.
7. The ability to switch providers or remove a patient from a provider is proving difficult. This makes it difficult for the new prescriber or their designee to submit the required data to NCR. For example, as a patient is discharged from inpatient, the outpatient provider can assume the patient. Additionally, if one provider enrolled the patient, but the patient is being transferred to a new provider, the new provider cannot assume the patient in the system.
8. We have one report that clinicians were told they had to resubmit paperwork that was faxed to NCR for multiple patients before November 15.

In order to remove this burden to patient access and alleviate the excessive burden on healthcare providers and vulnerable patients, we urge to postpone the further implementation of this program immediately. Alternately, it is imperative that you eliminate the wholesaler restriction on providing REMS to non-enrolled pharmacies immediately and the RDA requirement entirely.

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