National Alliance on Mental Illness

New Clozapine REMS Update: Impact Survey

NAMI believes that all people with mental health conditions deserve access to effective medication and treatment options. NAMI created a brief survey to determine if recent updates to the clozapine REMS program created barriers to treatment for NAMI members who are using clozapine to manage a mental health condition.

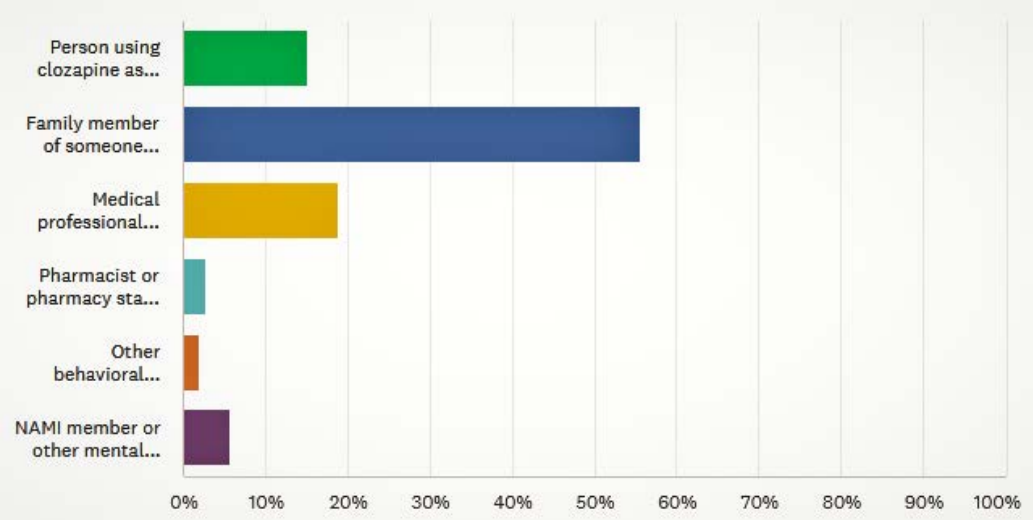
The survey link was first shared with an internal NAMI advocacy listserv on March 10th, which included 150 NAMI State Policy and Advocacy leaders who were encouraged to share the survey with peers, family members, pharmacists, and prescribers. It was then made publicly available during the March 24th presentation of NAMI's Ask the Expert webinar.

The eight question survey closed on May 12th with a total of 106 responses, representing a 77% completion rate.

Summary of Results

Question 1 identified the role of the respondent:

- 75 respondents were individuals or family members
- 23 respondents were prescribers, pharmacists or staff members
- 8 were other behavioral health providers or mental health advocates



Question 2: Since November 2021, I have had trouble getting a clozapine prescription filled for myself, a family member, a patient or pharmacy customer, or have observed this with clients I serve, or have heard this from members or families in my organization.

- True: 66.04% (70/106)
- False: 33.96% (36/106)

Question 3: If you answered 'True' to question 2, did this trouble result in access to treatment with clozapine being interrupted or discontinued? Please select the issue that applies to your situation and briefly describe it further.

- Treatment was interrupted but eventually resumed: 36.71% (29/79)
- Treatment was discontinued: 6.33% (5/79)
- Other: 58.23% (46/79)

Out of 79 responses to this question, 66 left comments that overwhelmingly indicated a problem with obtaining or dispensing medication. Comments included:

- *"The treatment was discontinued due to the REMS, the patient decompensated, and has required hospitalization for the past 6 months and has not yet stabilized."*
- *"Pharmacy unable to fill prescription as was every pharmacy in our city. I needed to have prescription moved to large teaching hospital's pharmacy an hour away as they were the only pharmacy my psychiatrist could find capable of filling the prescription."*
- *"Treatment was discontinued and patient has had difficulties since. Has increased polypharmacy to control symptoms."*
- *"Treatment was nearly interrupted; the pharmacist only dispensed when I showed them an FDA article stating that pharmacists would be provided leeway with dispensing, as the REMS program was being rolled out."*

Question 4: If treatment with clozapine was interrupted, discontinued, and/or restarted, were there any mental or physical health complications experienced as a result?

- Yes: 26.42% (28/106)
- No: 41.51% (44/106)
- I don't know: 32.08% (34/106)

57 respondents provided comments (some of which indicated N/A, not relevant, etc.). There were approximately two dozen comments on resulting complications, which ranged from extreme stress to worsening symptoms, decompensation, and difficulty with resuming treatment compliance.

- *"The patient severely decompensated, and has required hospitalization for the past 6 months without any recovery."*
- *"Severely paranoid afraid to go resume clozapine!"*
- *"As it started to look like he might not get his medicine on a timely basis, my son lowered his dosage for a few days and felt a moderate increase in symptoms. He has bipolar and is on a very low dose, 62.5 mg daily. He has done this in past under the previous REMS systems, two new ones since he's been taking it."*
- *"Psychosis returned and it took much longer to convince loved one to try again. Possible permanent damage."*

Question 5: As a prescriber or a pharmacist, I have had difficulty using the new system.

- True: 21.7% (23/106)
- False: 4.72% (5/106)
- N/A, I'm not a prescriber or pharmacist: 73.58%(78/106)

Of 28 prescribers or pharmacists, 23 indicated they experienced difficulties with the new system, and nearly as many offered additional comments. Comments included:

- *"The paperwork burden is redundant and takes an excessive amount of time. Patients are threatened with being cut off from treatment."*
- *"We dispense clozapine to a high volume of patients. These patients are in high turnover facilities that often deal with prescribers unfamiliar with clozapine REMS requirements. This has resulted in extensive training for the medical providers we deal with. Also this has resulted in many treatment delays for patients that are required to be treated through court order."*
- *"Remove REMS now and let doctors do their jobs without government interference."*
- *"Patients were not enrolled under the prescriber for MONTHS and we had no idea. Also there have been problems and glitches that I had to report to the hotline."*
- *"I am also a designee for the REMS for a prescriber. There were multiple issues including patients not being enrolled, even though we thought they were, Athelas devices not communicating with REMS and calls from pharmacies confused on what to do, also long hold times."*

Question 6: As an individual, family member, prescriber, pharmacist, provider, or as a mental health advocate, I have experienced or observed additional unnecessary difficulties as a result of recent changes to REMS (i.e., hospitalization, interaction with the justice system, etc.).

- True: 54.72% (58/106)
- False: 45.28% (48/106)

40+ respondents left comments elaborating on their answer. Comments included:

- *"I have seen numerous hospitalizations due to decompensation following discontinuation of clozapine due to the REMS."*
- *"Well kind of, patient went to the hospital for suicidal ideation and THEY DID NOT GIVE HER CLOZAPINE FOR 5 DAYS upon admission- reasons unclear this happened in March 2022."*
- *"Hospitalization after psychosis returned with missing medication."*
- *"I am part of a community groups on Facebook and have seen fellow members stating issues with delays in receiving Clozapine due to the REMS. It's quite frightening to read about their despair and fear of missing a dose."*
- *"Many had to be hospitalized to get the medication."*
- *"Families were unable to get necessary meds due to pharmacies having challenges recertifying and docs choosing not to use the new system."*

Question 7: I'm willing to investigate this issue locally with my NAMI State and/or Local Affiliate, and/or within my professional network.

- True: 63.21% (67/106)
- False: 36.79% (39/106)

Question 8: Do you have additional comments or concerns regarding the Clozapine REMS Program updates?

- Yes: 54.72% (58/106)
- No: 45.28% (58/106)

Respondents were provided another opportunity to share final comments and concerns. 63 left additional remarks, including:

- *"This seems to have been a solution in search of a problem. Added time consuming effort without clear benefit. I'm concerned it may prove to be a deterrent to providers utilizing a very effective treatment such that the benefits won't outweigh the costs."*
- *"Whose bright idea was it to make things more difficult for our severely mentally ill population?"*
- *"Stop REMS now."*
- *"… It has been the best medication for me and my Schizoaffective / Bipolar type 1 diagnosis. I have been on Clozapine for almost 30 years to the present with very little side effects…"*
- *"… This medication saved my loved one and almost screwed up by this new system. Please stop making it harder for doctors to prescribe this medication. When done right people can have meaningful lives. If everyone had a chance to take this medication there would be a lot less homeless living on the street with severe mental illness and leading meaningful lives."*
- *"Please, stop making it so hard to get a lifesaving medication!!! My daughter has a meaningful recovery because of Clozapine!!!"*
- *"The entire thing is ridiculous. The amount of side effects my daughter went through on other antipsychotics - emotionally, physically far outweighs that of clozaril. The REMS system is dated and the bloodwork should no longer be mandated. It's downright discriminatory to try and keep patients off a less expensive medication!"*
- *"It is unnecessary and burdensome barrier to treatment. It took YEARS to line up Clozapine as an option for my loved one and the weekly blood tests, errors in the system and a lack of providers willing to prescribe it means we can never be sure that she will continue—or will have the medical team in place to do so. The REMS system will no doubt shorten my loved ones' life, because without me to help her navigate The requirements, she will not be able to be compliant. Please remove these unnecessary barriers to the care people deserve."*
- *"Clozapine is an extraordinarily effective treatment for schizophrenia. The REMS program is excessively rigid and inflexible. The result is to create obstacles to access and barriers to treatment for any patient without a dedicated support system. It is also incredibly difficult to find treatment providers because of the restrictive REMS controls. The med should be more readily available to help people who desperately need it."*
- *"REMs is an absurd intrusive harmful practice that has resulted in limiting clozapine use. I agree with mandatory monitoring for 18 weeks but after that the risk of agranulocytosis is extraordinarily remote. Certainly after 1 year when multiple other antipsychotics have as much or more of a risk of agranulocytosis than clozapine mandatory monitoring is irrational and prejudiced against clozapine."*
- *"… While agranulocytosis is obviously very serious, it is also rare, especially after the first few weeks of treatment. The FDA's recent approval of aducanumab for Alzheimer's disease without a REMS illustrates the hypocrisy of how we approach different neuropsychiatric diseases…So: clozapine, which is the most effective pharmacological treatment of schizophrenia and has a risk of severe neutropenia of 0.9%, has a REMS - but aducanumab, which may have no clinical value in the treatment of Alzheimer's disease and has a risk of ARIA of 30%, does not have a REMS."*