Clozapine REMS Program
Pharmacy Professional Society Meeting
August 19, 2021
Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demonstration of REMS Website</td>
<td>3</td>
</tr>
<tr>
<td>How to Certify</td>
<td>5</td>
</tr>
<tr>
<td>How to Obtain an RDA</td>
<td>16</td>
</tr>
<tr>
<td>How to Troubleshoot Common Issues</td>
<td>27</td>
</tr>
<tr>
<td>Closing</td>
<td>29</td>
</tr>
</tbody>
</table>
Demonstration of REMS Website

Until November 15, 2021, continue to use the ClozapineREMS.com website to ensure safe use conditions are met.

1. Pharmacies should certify in the new program as soon as possible and no later than November 15.

2. To certify in the modified program, go to NewClozapineREMS.com, as noted on the Important Program Update on the homepage of ClozapineREMS.com.
To facilitate a smooth transition to the modified Clozapine REMS program on November 15, we encourage pharmacies to certify in the modified program now via:

- The transition website, NewClozapineREMS.com, or
- The transition Contact Center at 1-888-586-0758.

Click Certify Pharmacy on the homepage to start the certification process.
An **inpatient pharmacy** is a pharmacy within a facility dispensing clozapine only to patients receiving inpatient medical care and other related services for surgery, acute medical conditions, or injuries (usually for a short-term illness or condition).

An **outpatient pharmacy** is a pharmacy that dispenses clozapine only to patients treated on an outpatient or chronic basis including, but not limited to, retail drug-stores, ambulatory care pharmacies, and pharmacies dispensing to long-term care, rehabilitation facilities, and prison systems.

- The designated authorized representative for the pharmacy will complete the *Inpatient Pharmacy Enrollment Form* and/or the *Outpatient Pharmacy Enrollment Form*. This form is to certify a single inpatient or a single outpatient pharmacy location.

- The authorized representative for the pharmacy or pharmacies can certify the pharmacy online or by fax.

- Certifying multiple pharmacy locations must be completed online.
How to Certify: Introduction (Continued)

A pharmacy’s certification does not expire. However, if a pharmacy’s Authorized Representative changes, the new Authorized Representative must certify the pharmacy in the REMS Program.

For a pharmacy with a single location, the authorized representative may be a Pharmacy Manager or Staff Pharmacist.

If your pharmacy has more than one pharmacy location and your organization would like to coordinate staff training and implement processes for all the pharmacies in your organization, the Authorized Representative may be a director of pharmacy services or corporate executive overseeing pharmacy services.
How to Certify: Register

Click Register at the top of the home page to create your account.

1. Click Register at the top of the home page to create your account.

2. Type in the Authorized Representative’s username, first and last name, and password, noting that the username must be an email address. Then Click Next.

3. On the account confirmation page, click Login to use your new credentials to continue certification.

4. You will need to verify your account on the next screen by requesting a code via email and clicking Next.

5. On the next screen, enter the code received via email and click Next to proceed with certification.

All users must create new REMS login credentials. Legacy system credentials will not work in the new system.
How to Certify: Knowledge Assessment

1. Click Pharmacy at the top of the home screen to access the certification screen.

2. Following completion of Steps 1 and 2, complete the Knowledge Assessment by clicking Online under Step 3.
The Authorized Representative must successfully complete a 13-question Knowledge Assessment.

Three attempts are allowed. If you exceed this number, then call the Contact Center.

Following successful completion of the Knowledge Assessment, the Authorized Representative can continue the certification process.
How to Certify: Enrollment

After completing Step 4, the Authorized Representative needs to complete enrollment by clicking Online under Step 5.
How to Certify: Enrollment (Continued)

The Authorized Representative completes the Pharmacy Enrollment form online by filling in pharmacy information (e.g., NPI, pharmacy contact information), …

1. The Authorized Representative completes the Pharmacy Enrollment form online by filling in pharmacy information (e.g., NPI, pharmacy contact information), …

2. …information about themselves (e.g., individual contact information and preferences), …
How to Certify: Enrollment (Continued)

...and pharmacy type and understanding of Authorized Representative responsibilities associated with that pharmacy type.

The final step is to sign and submit the form.
How to Certify: Certification Completion

Successful completion of Enrollment and the Knowledge Assessment result in a pharmacy being marked as certified on the Pharmacy dashboard.
How to Certify: Adding Pharmacy Staff

The certified Authorized Representative can then train staff and add them to their pharmacy in the REMS system.

To add staff in your store(s), the Authorized Representative should click the Manage Personnel button under Pharmacy Personnel.
How to Certify: Adding Pharmacy Staff (Continued)

On the next screen, the certified Authorized Representative can add Pharmacy Staff by entering the staff member’s contact information and clicking Send Invite.

This screen can also be used to add a second Authorized Representative (maximum of two).

The REMS system will email the staff member a message that includes a link to establish their own user credentials for login.
How to Obtain an RDA: Introduction

Starting on November 15, 2021, before any pharmacy dispenses clozapine to a patient, you must obtain authorization from the new Clozapine REMS in the form of a REMS Dispense Authorization (RDA).

Until November 15, continue to use the legacy REMS system.
An RDA is an electronic code that indicates the Clozapine REMS has verified that all safe use conditions have been met.

• For the first dispensing, the RDA will verify that:
  - the pharmacy is certified
  - the patient is enrolled
  - the patient’s treatment is not interrupted or discontinued

• For a subsequent dispensing, the RDA will verify that:
  - the pharmacy is certified
  - the patient is enrolled
  - a Patient Status Form has been completed in the last 37 days
    • The prescriber has authorized the continuation of treatment if one or more labs are missing
    • The prescriber has provided a Treatment Rationale if the most current ANC lab value is below the acceptable range
    • The patient’s treatment is not interrupted or discontinued

**Obtain an RDA in one of two ways:**

- By using the Clozapine REMS website at [www.clozapinerems.com](http://www.clozapinerems.com)
- By calling the Clozapine REMS Contact Center at 888-586-0758
How to Obtain an RDA: Pharmacy Dashboard

To obtain an RDA, log into the Clozapine REMS website and click Obtain a Patient’s RDA from your pharmacy dashboard.
The first step in obtaining an RDA is to identify the patient in the REMS system. Enter as much patient information as you have.

After entering available patient identifiers, click Find.
The patient search may return error messages, like those seen below.

If a patient cannot be found or there are too many possible matches, then try entering additional data and searching again.

You can also call the REMS Contact Center for assistance.
How to Obtain an RDA: Find Patient (Continued)

When the REMS system can identify a reasonable number of patient options, you will select the radio button next to the appropriate patient.

Click Continue to move forward in the RDA process.
On the next screen, you can confirm that you have the correct patient and click the Obtain RDA button to request an RDA for that patient.
How to Obtain an RDA: Obtain RDA—Safe Use Conditions Met

On the RDA screen, you should enter the dispensing information.

1. If all REMS elements to assure safe use are met, then the next screen will display an alphanumeric RDA code, which the pharmacy should retain in its records for each fill.

2. You can click Detail to see more information about the conditions satisfied.

3. Upon entry of the dispensing information, click Save.
How to Obtain an RDA: Obtain RDA—Safe Use Conditions **NOT** Met

If all REMS elements to assure safe use are **NOT** met, then the next screen will display a message to not dispense.

You can click Detail to see why the RDA was not issued, such as the examples shown here.
If a prescription is not dispensed to the patient and is returned to stock, the RDA must be reversed. To reverse an RDA, log into your account at [www.clozapinerems.com](http://www.clozapinerems.com) and select the Reverse RDA button.

Find the patient and follow the directions.

You may also reverse an RDA by calling the Clozapine REMS Contact Center at 888-586-0758.
How to Obtain an RDA: Reverse RDA (Continued)

If you need to reverse an RDA, then look up the patient in the REMS. Their latest RDA will be listed on their patient record, and you can click the Reverse button to request a reverse.

The following screen will display a confirmation that the RDA was reversed.
How to Troubleshoot Common Issues: Incomplete Certification

Authorized Representatives must successfully complete the Knowledge Assessment AND enrollment process to be certified; if a user stops in the middle of certification, then one of these elements may be incomplete. In this case, the Pharmacy Dashboard will only show a check mark next to one of the two activities.

**Incomplete Knowledge Assessment with Complete Enrollment**

**Incomplete Enrollment with Complete Knowledge Assessment**
How to Troubleshoot Common Issues: Lost/Forgotten Password

Authorized Representatives are not responsible for staff passwords. Staff members can reset their own password from the Login screen.

The system will ask for the username. If the username is in the system, the system will then ask the user to choose a verification method (e.g., email, text, call). The user can then access password reset via their preferred verification method.
Closing

Pharmacies must certify in the modified program prior to November 15.

- The transition website, NewClozapineREMS.com, or
- The transition Contact Center at 1-888-586-0758.