

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

Clozapine REMS Program Website Screen Captures

September 2015

CLOZAPINE REMS

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1. Static Pages

1.1 Home Page

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What's New »

Username Password Sign in
Forgot Username? Forgot Password? Need an Account?

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Prescriber

All prescribers of clozapine products must certify in the Clozapine REMS Program. Certification requires prescribers to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the Knowledge Assessment

[Start Prescriber Certification](#)

Pharmacy

All pharmacies dispensing clozapine products must certify in the Clozapine REMS Program. Certification requires pharmacies to:

- **Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- **Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- **Assess:** Successfully complete the Knowledge Assessment
- **Implement:** Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

[Start Pharmacy Certification](#)

What is the Clozapine REMS Program?

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.2 Site Guide – Prescriber Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber | Pharmacy | Patient | Designee | Pharmacy Staff

Prescribers will begin the certification process by using the **Learn More** button below, which will navigate the prescriber to the certification landing page or by visiting the **Prescriber** link at the top of the page.

The **Prescriber** page provides specific steps that must be completed to prescribe clozapine. From the **Prescriber** page, prescribers can use the **Begin Now** button to start their certification process.

Once signed into the site and your certification is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as enrolling patients and adding ANC values. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.3 Site Guide – Pharmacy Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber **Pharmacy** Patient Designee Pharmacy Staff

Authorized representatives for a pharmacy will begin the certification process by using the **Learn More** button below, which will navigate the authorized representative to the certification landing page or by visiting the **Pharmacy** link at the top of the page.

The **Pharmacy** page provides specific steps that must be completed to dispense clozapine. From the **Pharmacy** page, authorized representatives can use the **Begin Now** button to start their certification process.

Once signed into the site and your certification is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as adding ANC values and requesting predispense authorizations. The **My Dashboard** page is the main portal for all activities performed on this site.

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1.4 Site Guide – Patient Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber Pharmacy **Patient** Designee Pharmacy Staff

This site is for prescribers and pharmacists with patients on clozapine therapy. Patients must be enrolled in the program by a certified prescriber. If you believe you should be enrolled in the Clozapine REMS Program, please talk to your prescriber.

Additional information is available to patients by using the **Learn More** button below, which will navigate the patient to the patient information page or by visiting the **Patient** link at the top of the page.

[Learn More](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.5 Site Guide – Designee Tab



Site Guide

This website provides users the ability to become certified in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber Pharmacy Patient **Designee** Pharmacy Staff

Prescriber Designees can learn more about the certification process by using the **Learn More** button below, which will navigate the prescriber designee to the certification landing page or by visiting the **Prescriber** link at the top of the page.

The **Prescriber Designee Certification** page provides specific steps that must be completed to manage patients. From the **Prescriber Designee** page, prescriber designees can use the **Begin Now** button to start their certification process.

Once signed into the site and your certification is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as enrolling patients and adding ANC values. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

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1.6 Site Guide – Pharmacy Staff Tab



Site Guide

This website provides users the ability to become enrolled in the Clozapine REMS Program, enroll patients on clozapine, and track patient ANC values.

The links located at the top and bottom of every page offer information for prescribers, pharmacists, and patients. Additional information about the program is also available under **Resources** and through the **FAQs**, **Site Map**, and **Contact Us** links.

Prescriber Pharmacy Patient Designee **Pharmacy Staff**

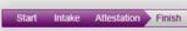
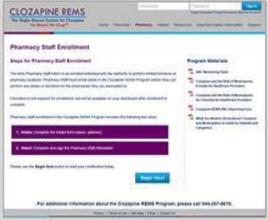
Pharmacy Staff can learn more about the enrollment process by using the **Learn More** button below which will navigate the pharmacy staff to the enrollment landing page or by visiting the **Pharmacy** link at the top of the page.

The **Pharmacy Staff** page provides specific steps that must be completed to dispense clozapine. From the **Pharmacy Staff Enrollment** page, pharmacy staff members can use the **Begin Now** button to start their enrollment process.

Once signed into the site and your enrollment is complete, you can navigate to your **My Dashboard** page to perform various activities that support the Clozapine REMS Program requirements such as adding ANC values and requesting predispense authorizations. The **My Dashboard** page is the main portal for all activities performed on this site.

During specific activities, a *progress bar* will guide you through the required activity from start to finish.

[Learn More](#)



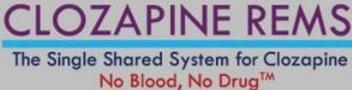
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1.7 Prescriber Certification



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Prescriber Certification

Steps for Prescriber Certification

Prescribers must be certified in the Clozapine REMS Program to prescribe clozapine.

If you choose to allow designees to act on your behalf, each designee must be certified in the Clozapine REMS Program. For more information on the designee certification process, please go to [Prescriber Designee Certification](#).

Certification in the Clozapine REMS Program includes the following three steps:

- 1. Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- 2. Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- 3. Assess:** Successfully complete the Knowledge Assessment

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Prescriber Enrollment Form](#)
-  [What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.8 Prescriber Designee Certification

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Prescriber Designee Certification

Steps for Prescriber Designee Certification

The term designee refers to any person who has been designated or requested to perform some duty or function on behalf of a certified prescriber. Designees must be certified and approved in the Clozapine REMS Program before they can perform any duties or functions for their prescriber.

If you want to associate yourself to a pharmacy and have selected the Prescriber Designee Certification by accident, please go to [Pharmacy Staff Enrollment](#).

Prescriber designee certification in the Clozapine REMS Program includes the following three steps:

1. Enroll: Complete the Enrollment form (name, address)

2. Educate: Review the REMS requirements

3. Confirm: Understanding of the requirements of the REMS

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Prescriber Designee Education Program](#)
-  [Clozapine REMS Prescriber Designee Enrollment Form](#)
-  [What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers](#)

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1.9 Pharmacy Certification

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Pharmacy Certification

Steps for Pharmacy Certification

All inpatient and outpatient pharmacies must be certified in the Clozapine REMS Program in order to purchase and dispense clozapine. Certification requires the identification of an authorized representative for the pharmacy to complete the certification process. The authorized representative must ensure all pharmacists with privileges to dispense understand that clozapine is only available to certified pharmacies through the Clozapine REMS Program.

Pharmacy Staff must enroll in the Clozapine REMS Program to obtain a PDA from the REMS website, to enter ANC, verify the prescriber is certified, or verify the patient is enrolled. If the pharmacy is a non-switch pharmacy, to comply with the REMS the pharmacy staff will either need to obtain a PDA by calling the program or by signing into the website. For more information on the Pharmacy Staff enrollment process, please go to [Pharmacy Staff Enrollment](#).

Certification in the Clozapine REMS Program includes the following three steps:

- 1. Enroll:** Complete the Enrollment form (name, address, NPI, DEA)
- 2. Educate:** Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
- 3. Assess:** Successfully complete the Knowledge Assessment
- 4. Implement:** Implement the necessary staff training and processes to comply with the Clozapine REMS Program requirements

If your browser closes during certification, you can come back to the same point in the process.

Please use the **Begin Now** button to start your certification today.

[Begin Now!](#)

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [Clozapine REMS Chain Pharmacy Enrollment Form](#)
-  [Clozapine REMS Pharmacy Enrollment Form](#)
-  [What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers](#)

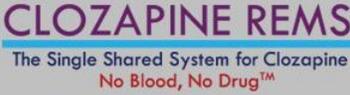
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1.10 Pharmacy Staff Enrollment



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Pharmacy Staff Enrollment

Steps for Pharmacy Staff Enrollment

Pharmacy Staff may include pharmacists or other individuals who assist in dispensing medication in a pharmacy. If your pharmacy is certified to dispense clozapine, Pharmacy Staff can enroll in the Clozapine REMS Program to have access to the Clozapine REMS Program website. Pharmacy Staff can link to multiple REMS certified pharmacy locations.

Pharmacy Staff enroll by creating an online account. Education is not required for enrollment but will be available after your enrollment is complete through your Authorized Representative.

For Outpatient Pharmacies: Pharmacy Staff must enroll in the Clozapine REMS Program to obtain a pre-dispense authorization (PDA) before dispensing each clozapine prescription. Pharmacy Staff who are enrolled can obtain a PDA by calling the Clozapine REMS Contact Center or through electronic claim adjudication if your pharmacy has set up that process. Talk to your authorized representative if you are not sure how your pharmacy must obtain a PDA.

Pharmacy Staff must enroll to obtain a PDA through the Clozapine REMS website.

For Inpatient Pharmacies: Pharmacy Staff must enroll to perform eligibility checks through the Clozapine REMS website or the Clozapine REMS Contact Center.

Pharmacy staff enrollment in the Clozapine REMS Program includes the following two steps.

1. **Enroll:** Complete the enrollment form (name, address)

2. **Attest:** Complete and sign the Pharmacy Staff Attestation

Please use the **Begin Now** button to start your enrollment today.

Begin Now!

Program Materials

-  [ANC Monitoring Table](#)
-  [Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers](#)
-  [Clozapine REMS ANC Lab Reporting Form](#)
-  [What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.11 Patient Information

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Patient Information

Because of the risk of developing severe neutropenia, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for clozapine.

The purpose of the Clozapine REMS Program is to make sure that the benefits of clozapine treatment outweigh the risks.

Prescribers must talk to their patients about the Clozapine REMS Program requirements and the risks of using clozapine. Patients should review the *What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers* program material and talk with their prescriber if they have questions or concerns about using clozapine.

Program Materials



What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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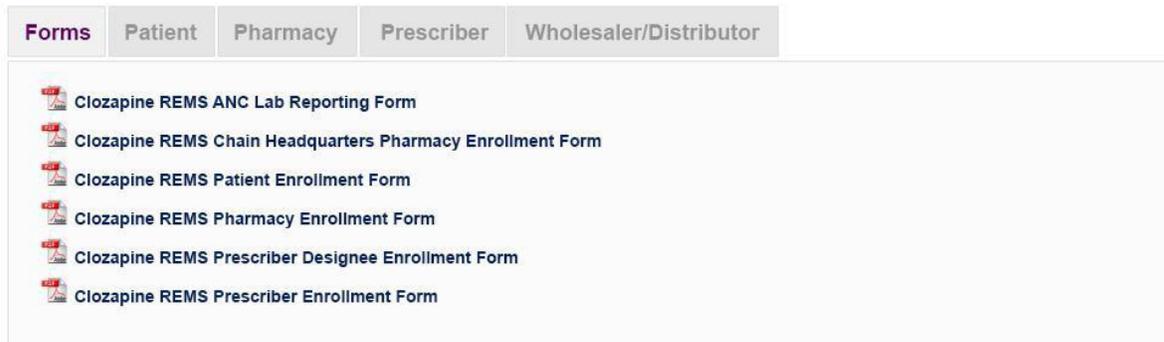
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1.12 Program Materials



Program Materials



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Resources included under the other tabs are listed below:

- Patient
 - What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers
 - Clozapine REMS Patient Enrollment Form
 - Clozapine REMS ANC Lab Reporting Form
- Pharmacy
 - What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers
 - Dear Healthcare Provider Letter
 - Clozapine REMS Pharmacy Enrollment Form
 - Clozapine REMS Chain Headquarters Pharmacy Enrollment Form
 - Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
 - Clozapine REMS Patient Enrollment Form
 - Clozapine REMS ANC Lab Reporting Form
 - Important Safety Information

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- ANC Calculator
 - ANC Monitoring Table
- Prescriber
 - What You Need to Know About Clozapine and Neutropenia: A Guide for Patients and Caregivers
 - Dear Healthcare Provider Letter
 - Clozapine REMS Prescriber Enrollment Form
 - Clozapine REMS Prescriber Designee Enrollment Form
 - Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers
 - Clozapine REMS Patient Enrollment Form
 - Clozapine REMS ANC Lab Reporting Form
 - Important Safety Information
 - ANC Calculator
 - ANC Monitoring Table
- Wholesaler/Distributor
 - Contact the Clozapine REMS Program by sending an email to info@clozapinedistributor.com

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1.13 Prescribing Information

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Prescribing Information

Products covered under the Clozapine REMS Program

Brand Name Products			
Trade Name	Generic Name	Company	Link

Generic Products			
Drug Name	Generic Name	Company	Link

The CPMG attests that the table above will only include products listed in the link titled "List of approved application numbers and sponsors" on the FDA Approved REMS Website.

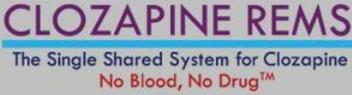
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.14 Certification Lookup



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Certification Lookup

To search for a certified pharmacy, please complete at least one field below and press **Search**. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required):

or or or or

or and

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.15 Certification Lookup Results

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Certification Lookup

To search for a certified pharmacy, please complete at least one field below and press **Search**. Search results include contact information for pharmacies that are certified in the Clozapine REMS Program.

Pharmacy Information (at least one identifier is required):

or or or or

or and

[Search](#)

Pharmacy Name	Certification ID	Pharmacy Address	Pharmacy Phone
Hogan Rx	FAC123456789	1234 W Scottsdale Rd. Scottsdale, AZ 85411	555-555-5555

Showing 1 of 1 entries

1 10

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.16 Site Map

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Site Map

<p>Prescriber</p> <p>Prescriber Certification Prescriber FAQs Prescriber Resources Prescriber Support</p>	<p>Designee</p> <p>Prescriber Designee Certification Prescriber Designee Support</p> <p>Pharmacy Staff</p> <p>Pharmacy Staff Enrollment Pharmacy Staff Support</p> <p>General</p> <p>Contact Us General FAQs Important Safety Information Prescribing Information Privacy Professional Societies Resources Technical Support FAQs Terms of Use Wholesaler/Distributor FAQs Wholesaler/Distributor Resources</p>	<p>Account</p> <p>Forgot Password Forgot Username Need an Account</p>
<p>Pharmacy</p> <p>Pharmacy Certification Pharmacy FAQs Pharmacy Resources Pharmacy Support</p>		
<p>Patient</p> <p>Patient FAQs Patient Information Patient Resources Patient Support</p>		

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.17FAQs

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Frequently Asked Questions (FAQs)

- General**
- Patient
- Pharmacy
- Prescriber
- Technical Support
- Wholesaler/Distributor

- ▶ **What is the Clozapine REMS Program?**
- ▶ **What are the goals of the Clozapine REMS Program?**
- ▶ **What do I do if I am a user of one of the previous individual registries?**
- ▼ **How do I certify in the program?**

Stakeholders can be certified online through the Clozapine REMS Program website or by submitting the appropriate Prescriber, Pharmacy, or Designee Enrollment form via fax to the program contact center at 844-404-8876. To complete certification on the program website, from the Home page you will use the "Get Started" button. You will be taken to the applicable stakeholder certification page, which will explain what is expected and required of you from the Clozapine REMS Program. From that certification page, you can use the "Begin Now" button to start your certification in the program.
- ▶ **Who is a designee?**
- ▶ **How do I enroll my patient?**
- ▶ **What is the National Non-Rechallenge Master File (NNRMF)?**
- ▶ **How do I report patient lab ANC values?**
- ▶ **How do I report an adverse event, product complaint, or need medical information about clozapine?**
- ▶ **How can I find additional forms and program materials?**
- ▶ **How do I view and update my program profile?**
- ▶ **Will the program send me notices if my patient experiences a low ANC count or substantial drop?**
- ▶ **How do I contact the program?**

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1.18 Contact Us

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Contact Us

If you have any questions or require additional information, please contact the Clozapine REMS Program utilizing the information provided below.

Phone Number
844-267-8678

Fax Number
844-404-8876

Mailing Address
Clozapine REMS Program
PO BOX 29058
PHOENIX AZ 85038-9058

Program Manufacturers

Company	Phone Number

The CPMG attests that the table above will only include products listed in the link titled "List of approved application numbers and sponsors" on the FDA Approved REMS Website."

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2. User Identification and Record Search

2.1 User Identification

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User Identification

Please select the option below that **best** describes you and press **Next**.

What type of user are you?

Please choose your program role:

[Next](#)

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Upon starting an enrollment or certification process the users are asked to identify what type of user they are what their role is.

1 - The options for type of user are New User, Previous Registry User, and Phone/Fax User. The tooltip next to the field will include a definition of each for the user, which are also below.

- New User – Users who are new to clozapine and are not part of a previous clozapine registry.
- Previous Registry User – Users who are part of a previous clozapine registry
 - These users will search for their records and start the enrollment or certification process.
- Phone/Fax User – Users who submitted an enrollment form through the contact center via fax and have received an enrollment or certification ID.

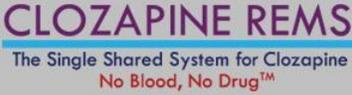
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- When the system locates the user's record and creates a web account, the user's web account and their enrollment or certification record are linked.

2 – The options for role are Prescriber, Authorized Representative for Pharmacy, Prescriber Designee, and Pharmacy Staff

2.2 Previous Registry User Prescriber



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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

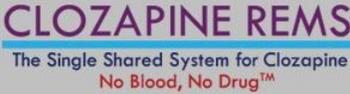
<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	and	<input type="text" value="DEA"/>	or	<input type="text" value="NPI"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>			

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2.3 Previous Registry User Prescriber Search with Results



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Username Password [Sign in](#)
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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

<input type="text" value="Summer"/>	<input type="text" value="Hogan"/>	and	<input type="text" value="AB12345789"/>	or	<input type="text" value="NPI"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>			

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone	DEA	NPI
Summer	Hogan	555-555-5555	AB1234567	

Showing 1 of 1 entries

[New User](#) [Submit](#)

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2.4 Previous Registry User Prescriber Designee Search



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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information

Designee Information

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.5 Previous Registry User Prescriber Designee Search with Results



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Previous Registry User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your registry status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information

Designee Information

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

Showing 1 of 1 entries 1 » 10

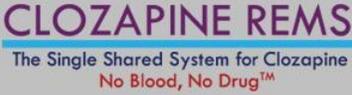
[New User](#) [Submit](#)

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2.6 Previous Registry User Pharmacy Search



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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="Zip Code"/>	and	<input type="text" value="DEA"/>	or	<input type="text" value="NPI"/>	or	<input type="text" value="NCPDP"/>
---------------------------------------	-----	----------------------------------	----	----------------------------------	----	------------------------------------

Authorized Representative Information

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

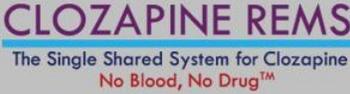
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2.7 Previous Registry User Pharmacy Search with Results



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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

and or or

Authorized Representative Information

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone
Summer	Hogan	Joey's Apothecary	1 Main Street, New York, NY 10001	555-555-5555

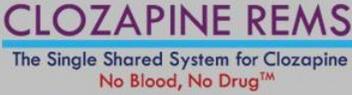
Showing 1 of 1 entries

[New User](#) [Submit](#)

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2.8 Previous Registry User Pharmacy Staff Search



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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="ZIP Code"/>	and	<input type="text" value="DEA"/>	or	<input type="text" value="NCPDP"/>	or	<input type="text" value="NPI"/>
---------------------------------------	-----	----------------------------------	----	------------------------------------	----	----------------------------------

Pharmacy Staff Information

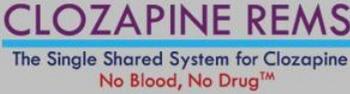
<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

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2.9 Previous Registry User Pharmacy Staff Search with Results



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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Designee Information

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

Showing 1 of 1 entries

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2.10 Previous Registry User Chain Pharmacy Headquarters

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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Authorized Representative Information

[Search](#)

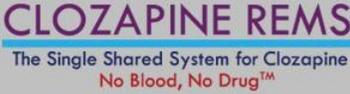
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2.11 Previous Registry User Chain Pharmacy Headquarters with Results



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Previous Registry User

If you are a user of any of the individual clozapine patient registries, your data may already be populated in the new Clozapine REMS Program. Please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Authorized Representative Information

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Phone
Summer	Hogan	Joey's Apothecary	1234 W Nowhere Lane Tempe, AZ 85283	555-555-5555

Showing 1 of 1 entries 1 » 10

[New User](#) [Submit](#)

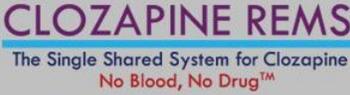
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2.12 Phone/Fax User Prescriber Search



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Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

At least one identifier below is required:

<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	
<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

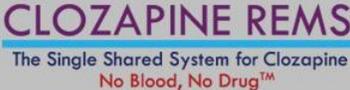
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.13 Phone/Fax User Prescriber Search with Results



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[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

At least one identifier below is required:

<input type="text" value="AB1234567"/>	<input type="text" value="NPI"/>	
<input type="text" value="Summer"/>	<input type="text" value="Hogan"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

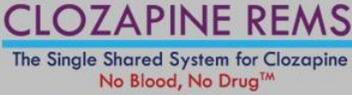
Showing 1 of 1 entries

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.14 Phone/Fax User Prescriber Designee Search



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Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information

Designee Information

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.15 Phone/Fax User Prescriber Designee Search with Results



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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information

Designee Information

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Phone
Summer	Hogan	555-555-5555

Showing 1 of 1 entries

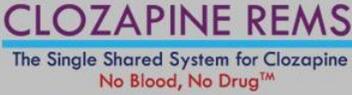
[New User](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.16 Phone/Fax User Pharmacy Search



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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="Zip Code"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="NCPDP"/>
---------------------------------------	-----	----------------------------------	----------------------------------	------------------------------------

Authorized Representative Information

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

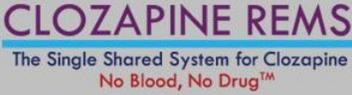
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.17 Phone/Fax User Pharmacy Search with Results



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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="AB1234567890"/>	<input type="text" value="NPI"/>	<input type="text" value="NCPDP"/>
------------------------------------	-----	---	----------------------------------	------------------------------------

Authorized Representative Information

<input type="text" value="First Name"/>	<input type="text" value="Last Name"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, you can either try your search again or press the **New User** button to begin your certification process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Pharmacy Phone
Summer	Hogan	Joey's Apothecary	1 Main Street, New York, NY 10001	555-555-5555

Showing 1 of 1 entries

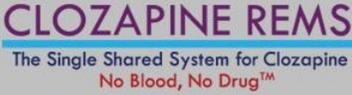
For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.18 Phone/Fax User Chain Pharmacy Headquarters



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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Authorized Representative Information

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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2.19 Phone/Fax User Chain Pharmacy Headquarters with Results



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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

Phone/Fax User

If you began or completed certification through a fax process, you may already be certified in the Clozapine REMS Program. To determine your certification status, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Authorized Representative Information

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or press the **New User** button to begin your enrollment process in the Clozapine REMS Program.

First Name	Last Name	Pharmacy Name	Pharmacy Address	Phone
Summer	Hogan	Joey's Apothecary	1234 W Nowhere Lane Tempe, AZ 85283	555-555-5555

Showing 1 of 1 entries

[New User](#) [Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

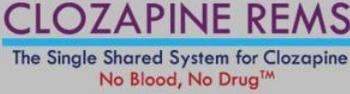
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3. Web Account

3.1 Create an Account



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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Create an Account

Please complete the form below and press **Submit**. The information you provide for your Username must be unique within the Clozapine REMS Program website. Once you have submitted this form you will receive a verification email that includes a link. Please use the link to complete the activation process for your new web account. All fields below are required.

My Information

Sign in

 Use Email Address as Username

 I'm not a robot 
[Privacy](#) - [Terms](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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3.2 Account Verification

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Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Account Verification



A verification email has been sent to remsprogram@gmail.com.
Please use the link within the email to activate your web account for
the Clozapine REMS Program.

Account Summary

Name [Summer Hogan](#)

Email Address remsprogram@gmail.com

Phone Number [480-555-5555](tel:480-555-5555)

Username [summerhogan](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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3.3 Account Confirmation

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Username Password [Sign in](#)

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Account Confirmation



✔ Your web account has been successfully activated. Please sign in to your account using the fields in the upper right corner of this page.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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4. Prescriber Certification

4.1 Prescriber Intake

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Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake **Education** Assessment Review Attestation Finish

Prescriber Intake

To certify as a prescriber in the Clozapine REMS Program, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Prescriber Information

First Name MI (opt)

Last Name

-- Credentials -- ▾

Email Address

Clinic / Practice Name

Address

Address 2 (opt)

City

-- State -- ▾ Zip Code

Phone Ext (opt)

Fax

-- Contact Preference -- ▾

Prescriber Identifiers

DEA

NPI

I do not have a DEA.

Cancel Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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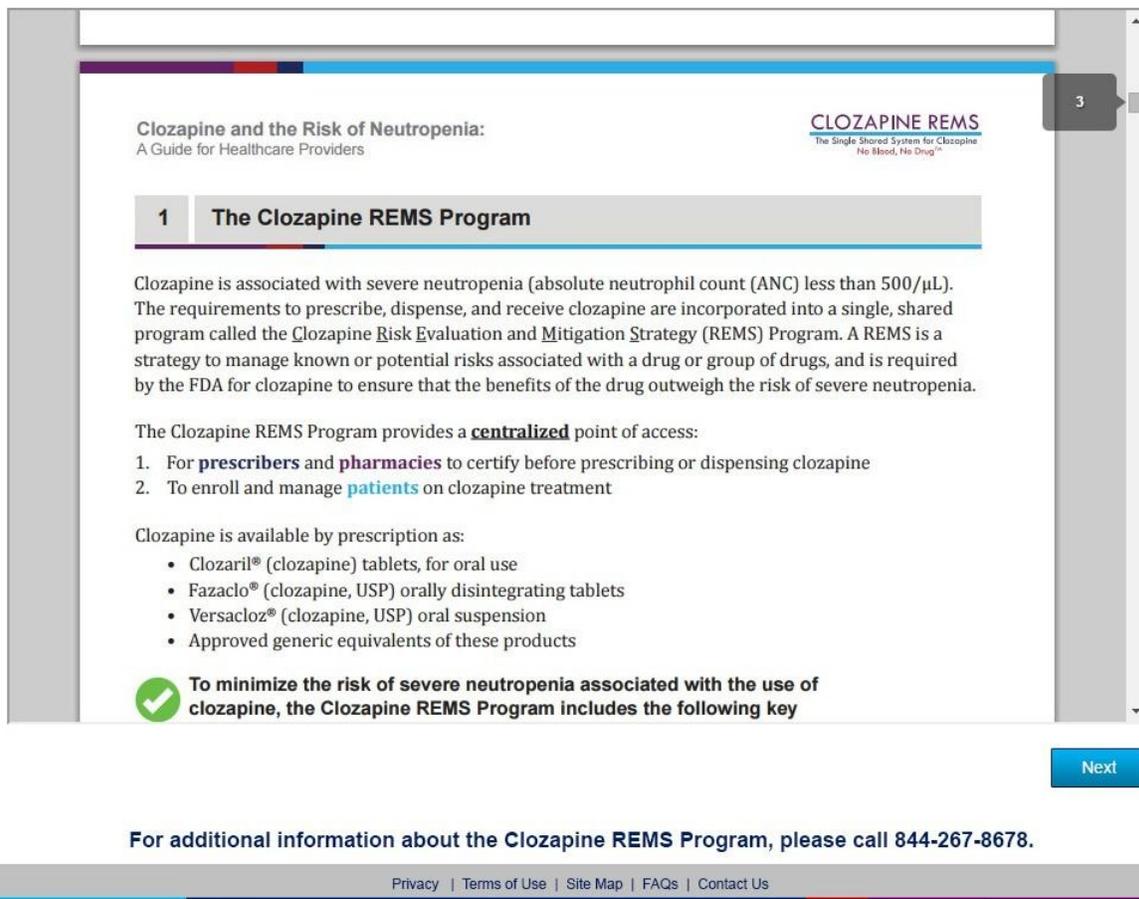
4.2 Prescriber Education Program



Start Intake Education Assessment Review Attestation Finish

Education Program

Below is the education program for clozapine. Please review the program materials and press the **Next** button to continue. It is estimated that it will take 15 – 20 minutes to complete the Education Program and Knowledge Assessment.



Clozapine and the Risk of Neutropenia:
A Guide for Healthcare Providers

1 The Clozapine REMS Program

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

 **To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key**

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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4.3 Prescriber Education Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left is the logo "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". In the top right corner, the user name "Summer Hogan" is shown next to a dropdown arrow, and a "My Dashboard" button is present. A navigation menu below the logo includes links for "Home", "Prescriber" (highlighted), "Pharmacy", "Patient", "Resources", "Important Safety Information", and "Support". A progress bar below the navigation menu shows steps: "Start", "Intake", "Education" (highlighted with a right-pointing arrow), "Assessment", "Review", "Attestation", and "Finish". The main heading is "Education Program Confirmation". Below this, a message states: "You have now completed the Education Program". A paragraph follows: "Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site." A blue "Next" button is centered below the text. At the bottom of the page, a footer contains the text: "For additional information about the Clozapine REMS Program, please call 844-267-8678." and a secondary navigation bar with links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

Note: Upon pressing the Next button on the Education Confirmation page, the user will be navigated through the Knowledge Assessment. KA is shown only once below for all stakeholders except for prescriber designees.

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4.4 Prescriber Intake Review

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[Start](#) [Intake](#) [Education](#) [Assessment](#) **[Review](#)** [Attestation](#) [Finish](#)

Prescriber Intake Review

Please review the information for completeness and accuracy. You may make any changes as necessary. When your review is complete, please use the **Next** button to save your information below and proceed to the final step in your certification process.

Prescriber Information

First Name / MI (opt)

Last Name

Credentials ▾

Email Address

Clinic / Practice Name

Address

Address 2 (opt)

City

State / Zip Code ▾

Phone / Ext (opt)

Fax

Contact Preference ▾

Prescriber Identifiers

DEA

NPI

I do not have a DEA.

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678

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4.5 Prescriber Attestation

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[Home](#) **Prescriber** [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) **Attestation** [Finish](#)

Prescriber Attestation

To complete the prescriber certification for **Summer Hogan** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

As a prescriber, I attest to the following Clozapine REMS Program requirements:

1. I understand that clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements to prescribe clozapine
2. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, reviewed the clozapine Prescribing Information, and successfully completed the *Knowledge Assessment for Healthcare Providers*
3. I understand the risk of severe neutropenia associated with clozapine
4. Prior to initiating treatment, I agree to provide *What You Need To Know About Clozapine: A Guide for Patients and Caregivers* to each patient and/or his/her caregiver. I will review it with him/her to inform them about the risks associated with clozapine, including severe neutropenia and the Clozapine REMS Program requirements – unless I determine that the patient's adherence to the treatment regimen will be negatively impacted by providing *What You Need To Know About Clozapine: A Guide for Patients and Caregivers*
5. I will enroll all patients I treat with a clozapine product in the Clozapine REMS Program
6. I understand the ANC testing and monitoring requirements as described in the clozapine Prescribing Information
7. I understand there is a different ANC monitoring algorithm for patients with Benign Ethnic Neutropenia (BEN)
8. I will order ANC testing for each patient according to the clozapine Prescribing Information
9. I will report the ANC for each patient to the Clozapine REMS Program and I understand the ANC must be provided before clozapine can be dispensed
10. I understand that, as described in *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, I must authorize the continuation of clozapine treatment if the patient has moderate or severe neutropenia before clozapine can be dispensed
11. I agree that personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
12. I understand that clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program
13. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

Signature Date

[Back](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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4.6 Prescriber Confirmation

The screenshot shows the Clozapine REMS website interface. At the top left is the logo and tagline. The top right shows the user name 'Summer Hogan' and a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'. Below this is a progress bar with steps: 'Start', 'Intake', 'Education', 'Assessment', 'Review', 'Attestation', and 'Finish'. The main content area is titled 'Certification Confirmation' and features a green checkmark icon and a message: 'You are now certified in the Clozapine REMS Program.' Below this, it states: 'Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.' The certification ID is 'HCP123456789' with a printer icon. It also provides links for 'Enroll Patient' and 'Manage Your Patients'. At the bottom, there is a call to action: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a footer with links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

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Summer Hogan ▾ My Dashboard

Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake Education Assessment Review Attestation Finish

Certification Confirmation

✓ You are now certified in the Clozapine REMS Program.

Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.

Certification ID: **HCP123456789** 🖨️

If you would like to enroll patients now you can use [Enroll Patient](#). If you need to manage your patients you can use [Manage Your Patients](#).

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5. Prescriber Designee Certification

5.1 Prescriber Designee Intake

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Designee Intake

To certify as a designee in the Clozapine REMS Program, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Designee Information

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.2 Prescriber Designee Education Program Page 1

Summer Hogan ▾ [My Dashboard](#)

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

General Information

Prescribers have the ability to identify and associate designees to their Clozapine REMS Program certification record. This allows prescribers the ability to approve responsible individual(s) to act on behalf of the certified prescriber for patients who are being treated with clozapine. Prescriber designees have the ability to provide ANC, and enroll and manage patients with the following exceptions:

- Designees cannot categorize a patient as diagnosed with BEN
- Designees cannot authorize the continuation of clozapine treatment for patients with moderate (General Population) or severe neutropenia (Patients with BEN)
- Designees cannot categorize a patient as a hospice patient.

[1](#) [2](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.3 Prescriber Designee Education Program Page 2

CLOZAPINE REMS
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[Home](#) **Prescriber** [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Prescriber Designee Responsibilities

To be a designee for a certified prescriber in the Clozapine REMS Program, you must understand that you are acting on behalf of the certified prescriber, that clozapine is available only through the Clozapine REMS Program, and that you understand:

- Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements
- There is a risk of severe neutropenia associated with clozapine
- The ANC testing and monitoring requirements as described in the clozapine Prescribing Information
- **For Outpatients:** An ANC must be reported to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed
- **For Inpatients:** An ANC must be reported to the Clozapine REMS Program for each patient within 7 days from the date of blood draw
- To continue treatment with clozapine, the certified prescriber must provide a valid treatment rationale before clozapine can be dispensed to a patient, if the patient has moderate or severe neutropenia
- Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program
- Personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
- I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

1 | 2

[Back](#)

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CLOZAPINE REMS

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5.4 Prescriber Designee Education Confirmation

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, the user name 'Summer Hogan' is displayed next to a 'My Dashboard' button. Below the logo is a horizontal navigation menu with links for 'Home', 'Prescriber' (highlighted), 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

A horizontal progress bar with seven steps: 'Start', 'Intake', 'Education' (highlighted with a dark background and white arrow), 'Assessment', 'Review', 'Attestation', and 'Finish'.

Education Program Confirmation

You have now completed the Education Program

Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site.

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.5 Prescriber Designee KA

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Education](#) **[Assessment](#)** [Review](#) [Attestation](#) [Finish](#)

Knowledge Assessment

Please select the **best** answer for the question. This question must be answered to proceed with the process to become certified in the program.

I have reviewed the requirements of the Clozapine REMS Program.

A. Yes

B. No

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.6 Prescriber Designee KA Confirmation – Success

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[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Knowledge Assessment Results

✔ You have now completed the assessment.

You answered the question correctly and have passed the assessment. Please press the **Next** button to complete your certification.

Knowledge Assessment Confirmation Code: **1422-FEAF-BE87** 

I have reviewed the requirements of the Clozapine REMS Program.

✔ A. Yes

[Next](#)

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5.7 Prescriber Designee KA Confirmation – Not Successful

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Knowledge Assessment Results

You did not pass the Knowledge Assessment.

Below is your response. Please use the **Retake Assessment** button to begin your assessment again.

I have reviewed the requirements of the Clozapine REMS Program.

✘ B. No

ATTEMPT

1	2	3	4	5	6
---	---	---	---	---	---

[Retake Assessment](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678

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5.8 Prescriber Designee Intake Review

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Education](#) [Assessment](#) [Review](#) [Attestation](#) [Finish](#)

Designee Intake Review

Please review the information below for completeness and accuracy. You may make any changes as necessary. When your review is complete please use the **Next** button to save your information below and proceed to the final step in your certification process.

Designee Information

First Name	<input type="text" value="Joe"/>	
Last Name	<input type="text" value="Smith"/>	
Email Address	<input type="text" value="jsmith@xyz.com"/>	
Phone / Ext (opt)	<input type="text" value="555-555-5555"/>	<input type="text" value="123"/>
Fax (opt)	<input type="text" value="Fax (opt)"/>	
Contact Preference	<input type="text" value="Email"/>	

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678

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5.9 Prescriber Designee Attestation

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake Education Assessment Review **Attestation** Finish

Designee Attestation

To complete the designee certification for **Joe Smith** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to the Clozapine REMS Program at 844-404-8876.

As a designee, I understand:

1. Clozapine is only available through the Clozapine REMS Program and that I must comply with the program requirements
2. There is a risk of severe neutropenia associated with clozapine
3. **For Outpatients:** An ANC must be reported to the Clozapine REMS Program for each patient, and I understand these results must be provided before clozapine can be dispensed
4. **For Inpatients:** An ANC must be reported to the Clozapine REMS Program for each patient within 7 days from the date of the blood draw
5. A certified prescriber must authorize the continuation of clozapine treatment, if the patient has moderate or severe neutropenia before clozapine can be dispensed to a patient
6. Clozapine manufacturers or their agents and contractors may contact me via phone, mail, or email to survey me on the effectiveness of the program requirements for the Clozapine REMS Program
7. Personnel from the Clozapine REMS Program may contact me to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
8. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

By checking this box, I acknowledge that I will act on behalf of a certified prescriber to comply with the Clozapine REMS Program requirements. I hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

Signature Date

Back

Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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5.10 Prescriber Designee Confirmation

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake Education Assessment Review Attestation Finish

Certification Confirmation

✔ You are now certified in the Clozapine REMS Program.

Below is your Clozapine REMS Program Certification ID. Please retain this information for your records.

Certification ID: **HCP123456789** 🖨️

If you are ready to associate yourself as a designee for a prescriber please go to the [Associate to Prescriber](#) page.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

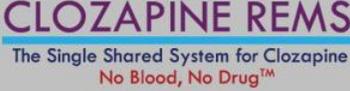
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6. Pharmacy Certification

6.1 Role Selection



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[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Program Role Selection

Please select the option below that **best** describes your role and press **Continue**.

- Authorized Representative of Chain Pharmacy Headquarters** – An authorized representative of a chain pharmacy headquarters is responsible for ensuring certification and training in the Clozapine REMS Program for a corporate pharmacy contracted to participate with a pharmacy network provider. Corporate pharmacies are retail or mail outpatient pharmacy headquarters.
- Authorized Representative of Inpatient Pharmacy** – An authorized representative of an inpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within a pharmacy where the patient's treatment is coordinated at a site of care and pharmacy claims are submitted as a medical benefit.
- Authorized Representative of Outpatient Pharmacy** – An authorized representative of an outpatient pharmacy is responsible for ensuring certification and training of the pharmacy staff within an individual outpatient pharmacy. An authorized representative of an outpatient pharmacy cannot be affiliated with a chain pharmacy that is contracted with a pharmacy network provider.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.2 Role Selection Confirmation – Inpatient Pharmacy

The screenshot displays the Clozapine REMS website interface. At the top, there is a navigation bar with the site logo, a tagline, and a navigation menu. A login section includes fields for Username and Password, and a Sign in button. A confirmation dialog box is centered on the screen, titled "Authorized Representative of Inpatient Pharmacy". The dialog contains text explaining the role and providing instructions on how to proceed. Below the dialog, a "Continue" button is visible. At the bottom of the page, there is a footer with contact information and a list of links.

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Username Password Sign in
Forgot Username? Forgot Password? Need an Account?

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Program Role Selection

Please select the option below that best describes your role:

- Authorized Representative responsible for ensuring a pharmacy network participation
- Authorized Representative certification and training claims are submitted at a site of care
- Authorized Representative certification and training cannot be affiliated with a site of care

Authorized Representative of Inpatient Pharmacy

Based on the response selected, please confirm you are certifying as an Inpatient Pharmacy.

An inpatient pharmacy is where the patient's treatment is coordinated at a site of care where pharmacy claims are submitted as a medical benefit.

If the pharmacy you are certifying does not meet the definition of an inpatient pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

Cancel Confirm

Continue

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.3 Role Selection Confirmation – Outpatient Pharmacy

The screenshot displays the Clozapine REMS website interface. At the top, there is a navigation bar with the site logo, a login section with 'Username' and 'Password' fields, and a 'Sign in' button. Below the navigation bar, there is a main content area with a 'Program Role Selection' section. A modal dialog box is overlaid on the page, titled 'Authorized Representative of Outpatient Pharmacy'. The dialog contains the following text:

Authorized Representative of Outpatient Pharmacy

Based on the response selected, please confirm that you are certifying as an **Outpatient Pharmacy**.

An outpatient pharmacy is a retail or institutional outpatient pharmacy not affiliated with any corporate pharmacy chain. The outpatient pharmacy has an authorized representative that is responsible for ensuring the education and training of pharmacy staff within the individualized location.

If the pharmacy you are certifying does not meet the definition of an outpatient pharmacy, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

At the bottom of the dialog are two buttons: 'Cancel' and 'Confirm'. The background page shows a 'Continue' button and a footer with contact information: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a footer menu with 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

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6.4 Role Selection Confirmation – Chain Pharmacy Headquarters

The screenshot displays the Clozapine REMS website interface. At the top, there is a navigation bar with the site logo, a login section (Username, Password, Sign in), and a menu (Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, Support). The main content area is titled 'Program Role Selection' and contains a confirmation dialog box. The dialog box has a purple border and contains the following text:

Authorized Representative of Chain Pharmacy Headquarters

Based on the response selected, please confirm you are certifying as a Chain Pharmacy Headquarters

A chain pharmacy headquarters is a retail, mail order, or institutional outpatient pharmacy organization where a head office directs, coordinates and oversees a minimum of 10 outpatient pharmacies.

If the pharmacy you are certifying does not meet the definition for a chain pharmacy headquarters, please press **Cancel** to change your response; otherwise, please press **Confirm** to continue with the certification.

At the bottom of the dialog box are two buttons: 'Cancel' and 'Confirm'. The background of the website is dimmed, showing the 'Program Role Selection' form with radio button options and a 'Continue' button.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.5 Authorized Representative Intake

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

Authorized Representative Intake

To begin the process as an authorized representative in the Clozapine REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

Authorized Representative Information

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.6 Authorized Representative Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". The user's name "Summer Hogan" and a "My Dashboard" button are in the top right. A navigation menu includes "Home", "Prescriber", "Pharmacy" (highlighted), "Patient", "Resources", "Important Safety Information", and "Support". Below the menu is a progress bar with four steps: "Intake", "Education", "Assessment", and "Confirmation" (the current step). The main heading is "Confirmation". A green-bordered box contains a checkmark and the text: "You have successfully completed the required authorized representative training." Below this, a paragraph states: "If you are ready to certify your pharmacy now please use [Certify Pharmacy](#). To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session for today, simply close your browser." At the bottom, a footer contains the text: "For additional information about the Clozapine REMS Program, please call 1-844-267-8678." and a link menu: "Privacy | Terms of Use | Site Map | FAQs | Contact Us".

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6.7 Pharmacy Intake

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Intake](#) [Attestation](#) [Confirmation](#)

Pharmacy Intake

To certify your pharmacy, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the contact preference you selected during your authorized representative intake. All fields listed below are required unless otherwise indicated.

Pharmacy Information

Pharmacy Name

Pharmacy Type ?

Address

Address 2 (opt)

City

-- State -- Zip Code

Phone Ext (opt)

Fax

Pharmacy Identifiers

NCPDP

DEA (opt)

NPI

Can your pharmacy management system adjudicate claims online?

-- Please Select -- **1**

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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1 – Adjudicate claims online question – This question will be displayed only if the Pharmacy Type selected on this page is ‘Outpatient Pharmacy’.

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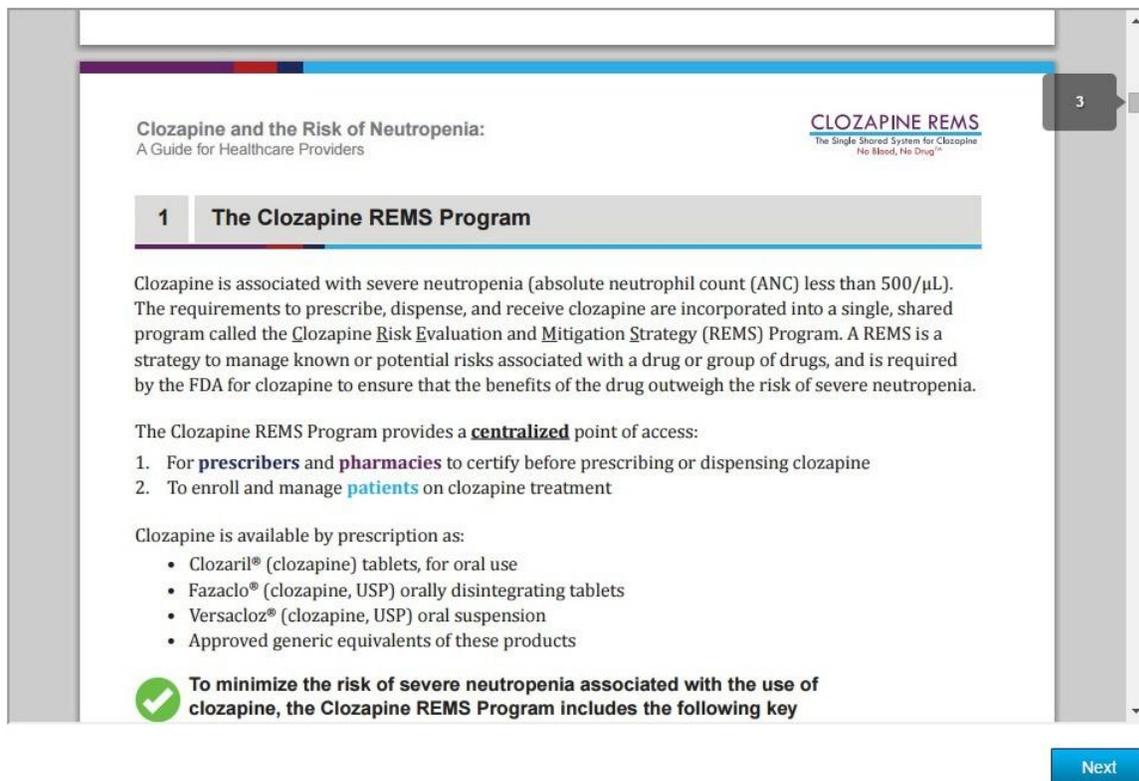
6.8 Pharmacy Education Program



Intake Education Assessment Confirmation

Education Program

Below is the education program for clozapine. Please review the program materials and press the **Next** button to continue. It is estimated that it will take 15 – 20 minutes to complete the Education Program and Knowledge Assessment.



For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.9 Pharmacy Education Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo reads "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". In the top right corner, the user name "Summer Hogan" is shown next to a dropdown arrow, and a "My Dashboard" button is present. A navigation menu below the logo includes links for "Home", "Prescriber", "Pharmacy" (highlighted in purple), "Patient", "Resources", "Important Safety Information", and "Support". A secondary navigation bar below the menu contains buttons for "Intake", "Education" (highlighted in purple), "Assessment", and "Confirmation". The main heading of the page is "Education Program Confirmation". Below this, a message states: "You have now completed the Education Program". A paragraph of text follows: "Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site." A blue "Next" button is positioned below the text. At the bottom of the page, a footer contains the text: "For additional information about the Clozapine REMS Program, please call 844-267-8678." and a secondary navigation bar with links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

Note: Upon pressing the Next button on the Education Confirmation page, the user will be navigated through the Knowledge Assessment. KA is shown only once below for all stakeholders except for prescriber designees.

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6.10 Pharmacy Attestation – Inpatient Pharmacy

This page includes only the attestation text for the Inpatient Pharmacy from the Clozapine REMS Pharmacy Enrollment Form.

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Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Intake Attestation Confirmation

Pharmacy Attestation

To complete the certification for <Pharmacy Name> into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
3. There is a different ANC monitoring algorithm for patients with Benign Ethnic Neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

5. My pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
 - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
 - Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials
12. Inpatient pharmacies are not required to obtain a Predispose Authorization (PDA) prior to dispensing clozapine.

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

- Verify the prescriber is certified in the Clozapine REMS Program
- Verify the patient is enrolled in the Clozapine REMS Program

Before dispensing clozapine to an inpatient for the first time, the inpatient pharmacies must:

1. Sign in into the Clozapine REMS Program website at www.clozapinerems.com, or
2. Call the Clozapine REMS Program contact center at 844-267-8678

Inpatient pharmacies must verify the ANC or prescriber's authorization for a patient to continue clozapine treatment in one of three ways:

1. By signing into the Clozapine REMS Program website at www.clozapinerems.com
2. By calling the Clozapine REMS Program contact center at 844-267-8678
3. By reviewing the patient's medical record in their hospital's medical record system

Prescribers or their designee(s) must submit ANC to the Clozapine REMS Program within 7 days of blood draw.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above) Signature Date

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.11 Pharmacy Attestation – Outpatient Pharmacy

This page includes only the attestation text for the Outpatient Pharmacy from the Clozapine REMS Pharmacy Enrollment Form.

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Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Intake **Attestation** Confirmation

Pharmacy Attestation

To complete the certification for <Pharmacy Name> into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
3. There is a different ANC monitoring algorithm for patients with Benign Ethnic Neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

5. My pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
 - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
 - Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials
12. Outpatient Pharmacies must obtain a Predispose Authorization (PDA) before dispensing clozapine products to a patient to ensure compliance with the required safe use conditions. You are confirming that your pharmacy management system CANNOT support electronic communication with the Clozapine REMS Program and you will access the Clozapine REMS Program website or call the Clozapine REMS Program contact center to confirm safe use conditions (as outlined in attestation #5) before dispensing each clozapine prescription. A complete Predispose Authorization request requires the pharmacist to identify a unique patient, provide dispense information, and provide the prescriber's NPI or DEA.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above) Signature Date

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.12 Pharmacy Attestation – Outpatient Pharmacy with Adjudication

This page includes only the attestation text for the Outpatient Pharmacy from the Clozapine REMS Pharmacy Enrollment Form.

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Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Intake Attestation Confirmation

Pharmacy Attestation

To complete the certification for <Pharmacy Name> into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form using the print icon to the right and fax it to the Clozapine REMS Program at 844-404-8876. 

As an authorized representative responsible for the pharmacy, I, **Summer Hogan**, attest to the following Clozapine REMS Program requirements:

I am the authorized representative designated by my pharmacy to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers* and the Prescribing Information and I understand:

1. Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
2. The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
3. There is a different ANC monitoring algorithm for patients with Benign Ethnic Neutropenia (BEN)
4. Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

5. My pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the requirements of the Clozapine REMS Program, including the following before dispensing clozapine:
 - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - Verify the prescriber is certified and the patient is enrolled in the Clozapine REMS Program
 - Verify the ANC is current and acceptable or verify the prescriber's authorization for continuing clozapine treatment if the ANC is abnormal
 - Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
6. My pharmacy will establish procedures and protocols that are subject to audit, to not sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program
7. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine
8. Pharmacies will make available to the clozapine manufacturers and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
9. Clozapine REMS Program personnel may contact my pharmacists to gather information or resolve discrepancies or to provide other information related to the Clozapine REMS Program
10. Provide dispensing location information to the Clozapine REMS Program
11. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials
12. Outpatient Pharmacies must obtain a Predispose Authorization (PDA) before dispensing clozapine products to a patient to ensure compliance with the required safe use conditions. You are confirming that your pharmacy management system CAN support electronic communication with the Clozapine REMS Program using established telecommunications standards. Clozapine will be dispensed only after obtaining electronic authorization for all clozapine prescriptions, including cash claims, through your pharmacy management system. As part of your certification process, you will receive instructions through the contact preference indicated in the authorized representative information section on how to submit test transactions to the Clozapine REMS Program. This is to ensure that your pharmacy management system has been successfully configured to allow for communication with the Clozapine REMS Program.

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above) Signature Date

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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6.13 Pharmacy Confirmation

This page will be available for:

1. Inpatient Pharmacies
2. Outpatient Pharmacies who cannot adjudicate claims online

The screenshot shows the Clozapine REMS website interface. At the top left is the logo "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". To the right of the logo is the user name "Summer Hogan" and a "My Dashboard" button. Below the logo is a navigation menu with links for "Home", "Prescriber", "Pharmacy", "Patient", "Resources", "Important Safety Information", and "Support". A secondary navigation bar contains three buttons: "Intake", "Attestation", and "Confirmation". The main heading is "Certification Confirmation". Below this is a green-bordered box containing a checkmark icon and the text: "Your pharmacy is now certified in the Clozapine REMS Program." Below the box, it says "Below is your Clozapine REMS Program Certification ID. Please retain this information for your records." The certification ID is displayed as "Certification ID: FAC123456789" with a copy icon. A note follows: "To add additional pharmacies or manage your pharmacies, please use the My Dashboard button at the top of the page." Another note states: "Please download the Education Program, Knowledge Assessment, and Knowledge Assessment Answer Guide from your Profile page. These tools should be used to train all pharmacists and relevant staff involved in dispensing clozapine. A record of the training must be maintained for future review by the Clozapine REMS Program." At the bottom, a call to action reads: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

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6.14 Pharmacy Test Transactions

This page will be available for:

1. Outpatient Pharmacies who can adjudicate claims online
2. Chain Pharmacy Headquarters

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Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Intake Attestation Confirmation

Pharmacy Test Transactions

✓ Thank you! Your enrollment form was successfully submitted.

To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system. This will ensure that your pharmacy management system has been successfully configured to allow communication with the Clozapine REMS Program.

You will soon receive a communication via your contact preference with instructions on how to submit test transactions to the Clozapine REMS Pharmacy Program.

To download the instructions now, please use the **Download Instructions** link below. After successful completion of the test transactions and validation of all required identifiers, you will be notified of your certification in the Clozapine REMS Program through your contact preference.

 [Download Instructions](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7. Chain Pharmacy Certification

7.1 Chain Headquarters Identification

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right are input fields for 'Username' and 'Password', a 'Sign in' button, and links for 'Forgot Username?', 'Forgot Password?', and 'Need an Account?'. Below these is a horizontal navigation menu with links for 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

Chain Headquarters Identification

Please enter the REMS Chain ID assigned to your chain below and press **Search**. If you do not know your REMS Chain ID please contact the Clozapine REMS Program at 844-267-8678.

A simple form with a text input field labeled 'REMS Chain ID' and a blue 'Search' button.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7.2 Chain Headquarters Identification Results

CLOZAPINE REMS
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Username Password [Sign in](#)
[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Chain Headquarters Identification

Please enter the REMS Chain ID assigned to your chain below and press **Search**. If you do not know your REMS Chain ID please contact the Clozapine REMS Program at 844-267-8678.

[Search](#)

The chain headquarters associated with the REMS Chain ID provided is participating in the Clozapine REMS Program. Press **Next** to continue.

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7.3 Chain Authorized Representative Intake

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Intake](#) [Education](#) [Assessment](#) [Confirmation](#)

Authorized Representative Intake

To begin the process as an authorized representative in the Clozapine REMS Program, please complete the form below and press **Next**. All fields listed below are required unless otherwise indicated.

Authorized Representative Information

▾

▾

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7.4 Chain Pharmacy Education Program

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Intake](#) **[Education](#)** [Assessment](#) [Confirmation](#)

Education Program

Below is the education program for clozapine. Please review the program materials and press the **Next** button to continue. It is estimated that it will take 15 – 20 minutes to complete the Education Program and Knowledge Assessment.

Clozapine and the Risk of Neutropenia:
A Guide for Healthcare Providers

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1 The Clozapine REMS Program

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L). The requirements to prescribe, dispense, and receive clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS) Program. A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia.

The Clozapine REMS Program provides a **centralized** point of access:

1. For **prescribers** and **pharmacies** to certify before prescribing or dispensing clozapine
2. To enroll and manage **patients** on clozapine treatment

Clozapine is available by prescription as:

- Clozaril® (clozapine) tablets, for oral use
- Fazaclo® (clozapine, USP) orally disintegrating tablets
- Versacloz® (clozapine, USP) oral suspension
- Approved generic equivalents of these products

 **To minimize the risk of severe neutropenia associated with the use of clozapine, the Clozapine REMS Program includes the following key**

[Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7.5 Chain Pharmacy Education Confirmation

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, the user name 'Summer Hogan' is displayed next to a 'My Dashboard' button. Below the logo, a horizontal menu contains links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

A horizontal progress bar with seven steps: 'Start', 'Intake', 'Education', 'Assessment', 'Review', 'Attestation', and 'Finish'. The 'Education' step is highlighted with a dark purple background and a white arrow pointing to the right, indicating the current step in the process.

Education Program Confirmation

You have now completed the Education Program

Please use the **Next** button below to continue with your certification process. The education program you just completed can always be reviewed again under your user profile in the top right corner of this site.

Next

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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Note: Upon pressing the Next button on the Education Confirmation page, the user will be navigated through the Knowledge Assessment. KA is shown only once below for all stakeholders except for prescriber designees.

Note: Attestation will occur at the pharmacy level during the Certify Headquarters process.

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7.6 Chain Authorized Representative Confirmation

The screenshot shows the top portion of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. On the right, the user name 'Summer Hogan' and a 'My Dashboard' button are visible. Below the logo is a horizontal navigation menu with links for 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

Intake Education Assessment Confirmation

Confirmation



✔ You have successfully completed the required authorized representative training.

If you are ready to enroll your headquarters now please use [Certify Headquarters](#). If you have completed your session for today, simply close your browser.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7.7 Chain Pharmacy Headquarters Intake

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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Intake](#) [Attestation](#) [Confirmation](#)

Chain Pharmacy Headquarters Intake

To certify your headquarters, please complete the form below and press **Next**. Once certified, you will receive a certification confirmation via the contact preference you selected during your authorized representative intake. All fields listed below are required unless otherwise indicated.

Headquarters Information

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7.8 Chain Pharmacy Headquarters Attestation

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[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Intake](#) **[Attestation](#)** [Confirmation](#)

Chain Pharmacy Headquarters Attestation

To complete the certification for **Rite Aid** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to the Clozapine REMS Program at 844-404-8876. 

As the authorized representative responsible for this chain headquarters, I, **Summer Hogan**, attest to the following Clozapine REMS program requirements:

I am the authorized representative designated by this chain headquarters to coordinate the activities of the Clozapine REMS Program. I have reviewed *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*, the Prescribing Information, and I understand:

- Pharmacies must certify in the Clozapine REMS Program to order and dispense clozapine
- The risk of severe neutropenia associated with clozapine and the importance of ANC monitoring
- There is a different ANC monitoring algorithm for patients with Benign Ethnic Neutropenia (BEN)
- Clozapine manufacturers, their agents and contractors may contact me to obtain names of our pharmacists to contact them via phone, mail, or email to survey on the effectiveness of the program requirements for the Clozapine REMS Program

On behalf of the pharmacy, I agree to comply with the following program requirements:

1. My pharmacy will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe use conditions required in the Clozapine REMS Program, including the following, before dispensing clozapine:
 - All pharmacists and relevant staff involved in dispensing clozapine are trained and a record of the training is maintained
 - Through electronic communication with the Clozapine REMS Program using established telecommunications standards, my pharmacy will dispense clozapine to each patient only after obtaining authorization by electronically verifying documentation of the following:
 - Prescriber is certified in the Clozapine REMS Program
 - Pharmacy is certified in the Clozapine REMS Program
 - Patient is enrolled in the Clozapine REMS Program
 - The ANC is current and acceptable or the prescriber has authorized continuing treatment if the ANC is abnormal
 - This information will be verified by processing all clozapine prescriptions, including cash claims, through the pharmacy management system
 - Fill and dispense no more than the amount of clozapine necessary to treat the patient until the next blood draw/ANC or as directed by the prescriber
2. My pharmacy agrees not to sell, loan, or transfer any clozapine inventory to any other pharmacy institution, distributor, or prescriber that is not enrolled in the Clozapine REMS Program, and will establish procedures and protocols to support these requirements that are subject to audit
3. Pharmacies will renew enrollment in the Clozapine REMS Program every two years to maintain certification to order and dispense clozapine.
4. Pharmacies will make documentation available to the clozapine manufacturers and/or a designated third party or the FDA to verify understanding of, and adherence to, the requirements of the Clozapine REMS Program
5. Clozapine REMS Program personnel may contact pharmacists in my pharmacy to gather information, resolve discrepancies, or to provide other information related to the Clozapine REMS Program
6. For each trained dispensing location provide the following information (Pharmacy Name, NCPDP or NPI or DEA, Address, Phone, Fax, Email, Store Number, and Responsible Pharmacist name)
7. I will not share my credentials for the Clozapine REMS Program website or allow others to sign into the website using my credentials

By checking this box, I agree to the responsibilities outlined above and hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

Signature Date

[Back](#)

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

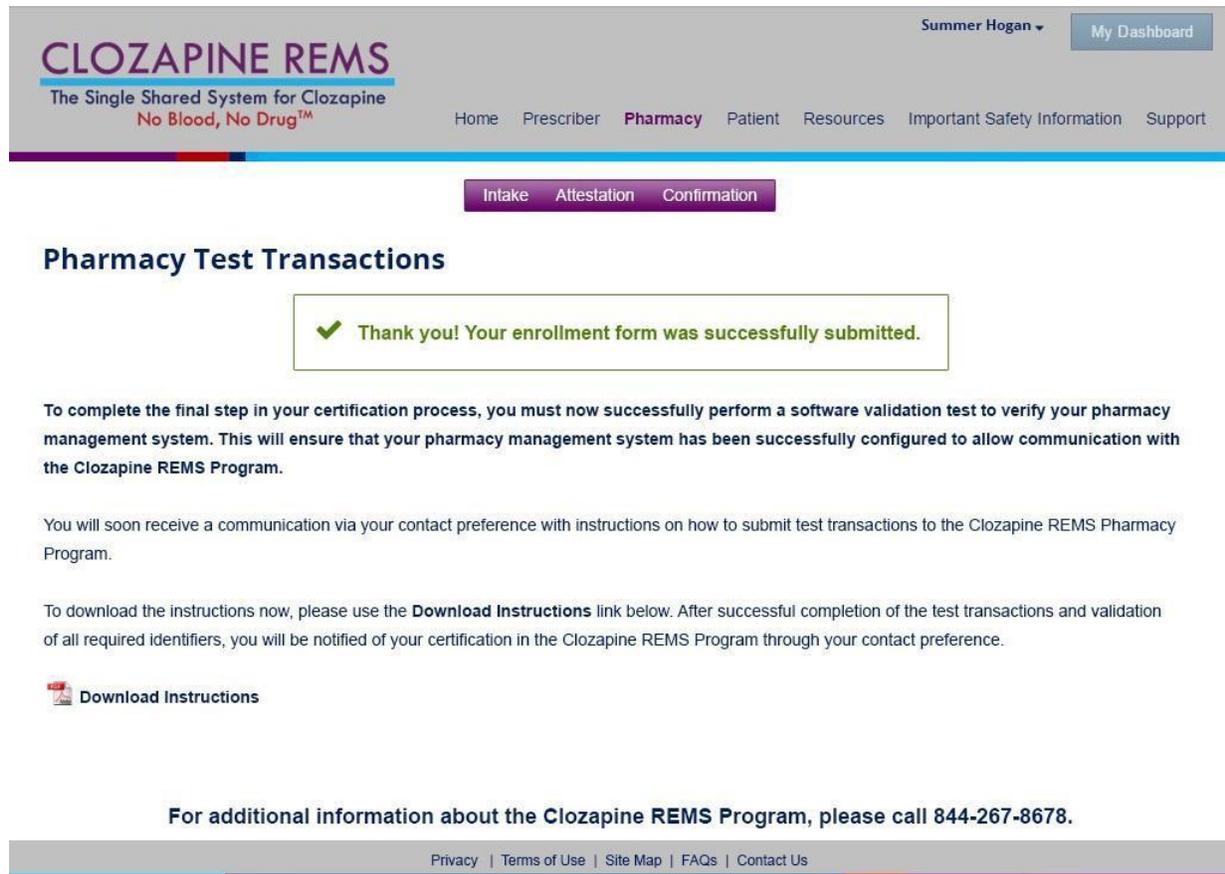
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7.9 Pharmacy Test Transactions

At this point in the chain pharmacy process, the authorized representative must complete test transactions prior to being "Certified" in the program. Once they finish the test transactions they will have the ability to access their My Dashboard page and add a chain store.



The screenshot shows the Clozapine REMS website interface. At the top, the logo "CLOZAPINE REMS" is displayed with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". The user "Summer Hogan" is logged in, and a "My Dashboard" button is visible. The navigation menu includes "Home", "Prescriber", "Pharmacy", "Patient", "Resources", "Important Safety Information", and "Support". Below the navigation, there are three tabs: "Intake", "Attestation", and "Confirmation". The main heading is "Pharmacy Test Transactions". A green checkmark icon is followed by the message: "Thank you! Your enrollment form was successfully submitted." Below this, a paragraph states: "To complete the final step in your certification process, you must now successfully perform a software validation test to verify your pharmacy management system. This will ensure that your pharmacy management system has been successfully configured to allow communication with the Clozapine REMS Program." Another paragraph says: "You will soon receive a communication via your contact preference with instructions on how to submit test transactions to the Clozapine REMS Pharmacy Program." A third paragraph reads: "To download the instructions now, please use the **Download Instructions** link below. After successful completion of the test transactions and validation of all required identifiers, you will be notified of your certification in the Clozapine REMS Program through your contact preference." Below this is a link with a document icon labeled "Download Instructions". At the bottom, a bold text line says: "For additional information about the Clozapine REMS Program, please call 844-267-8678." The footer contains links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

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7.10 Chain Pharmacy Store Intake

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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Chain Pharmacy Store Intake

To certify your chain pharmacy store, please complete the form below and press **Next**. Once the store is certified, you will receive a certification confirmation via the contact preference you selected during your authorized representative intake. All fields below are required unless otherwise indicated.

Pharmacy Information

Pharmacy Identifiers

Please provide at least one:

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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7.11 Chain Pharmacy Store Confirmation

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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Chain Store Confirmation

✓ The chain pharmacy store has been successfully added.

To add another store, please use the **Add Store** button below.

[Add Store](#) [My Dashboard](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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8. Pharmacy Staff Enrollment

8.1 Pharmacy Search

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, the user name 'Summer Hogan' is displayed next to a 'My Dashboard' button. Below the logo, a horizontal menu contains links for 'Home', 'Prescriber', 'Pharmacy' (which is highlighted), 'Patient', 'Resources', 'Important Safety Information', and 'Support'.

Start Intake Attestation Finish

Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

Zip Code	and	DEA	NPI	NCPDP
----------	-----	-----	-----	-------

Search

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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8.2 Pharmacy Search Results

CLOZAPINE REMS
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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) [Intake](#) [Attestation](#) [Finish](#)

Pharmacy Search

To identify the pharmacy you represent, please complete the fields below and press **Search**. Once you are able to access your dashboard, you will be able to associate to additional pharmacies. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

[Search](#)

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

Showing 1 of 1 entries

[Submit](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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8.3 Pharmacy Staff Intake

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Summer Hogan ▾ [My Dashboard](#)

[Home](#) [Prescriber](#) **[Pharmacy](#)** [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

[Start](#) **[Intake](#)** [Attestation](#) [Finish](#)

Pharmacy Staff Intake

To enroll as a pharmacy staff in the Clozapine REMS Program, please complete the form below and press **Next**. Once enrolled, you will receive an enrollment confirmation via your contact preference. All fields listed below are required unless otherwise indicated.

Pharmacy Staff Information

[Cancel](#) [Next](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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8.4 Pharmacy Staff Attestation

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Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Start Intake **Attestation** Finish

Pharmacy Staff Attestation

To complete the pharmacy staff enrollment for **Summer Hogan** into the Clozapine REMS Program online, please review the attestation section below to provide your acknowledgement along with signature and signature date.

As a pharmacy staff, I attest to the following Clozapine REMS Program requirements:

Pharmacy Staff can access the Clozapine REMS Program online to do the following:

- Enter an ANC for a patient
- Verify a prescriber is certified in the Clozapine REMS Program
- Verify a patient is enrolled in the Clozapine REMS Program
- Obtain a Predispose Authorization (PDA) (Inpatient Pharmacies do not have to obtain a PDA)

For online access to perform the above tasks, you must enroll by creating an account.

By enrolling, you agree not to share your credentials for the Clozapine REMS Program website or allow others to sign into the website using your credentials.

As part of your enrollment, you must select the certified pharmacy location(s) where you fill and/or dispense clozapine. It is your responsibility to update this information as necessary.

By checking this box, I hereby state that all of the information I have submitted is truthful and accurate.

Signature: Must match First and Last name (see above)

Signature Date

Back

Submit

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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CLOZAPINE REMS

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8.5 Pharmacy Staff Confirmation

The screenshot displays the Clozapine REMS website interface. At the top left, the logo 'CLOZAPINE REMS' is shown with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The user 'Summer Hogan' is logged in, with a 'My Dashboard' button. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy' (highlighted), 'Patient', 'Resources', 'Important Safety Information', and 'Support'. Below the navigation is a progress bar with buttons for 'Start', 'Intake', 'Attestation', and 'Finish'. The main heading is 'Enrollment Confirmation', followed by a green checkmark and the message: 'You have now enrolled in the Clozapine REMS Program.' Below this, it states: 'Below is your Clozapine REMS Program Enrollment ID. Please retain this information for your records.' The enrollment ID is 'HCP123456789'. A final instruction reads: 'To return to your dashboard for other activities, please use the My Dashboard button at the top of the page. If you have completed your session for today, simply close your browser.' At the bottom, a footer contains the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

CLOZAPINE REMS
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Summer Hogan ▾ My Dashboard

Home Prescriber **Pharmacy** Patient Resources Important Safety Information Support

Start Intake Attestation Finish

Enrollment Confirmation

✓ You have now enrolled in the Clozapine REMS Program.

Below is your Clozapine REMS Program Enrollment ID. Please retain this information for your records.

Enrollment ID: [HCP123456789](#)

To return to your dashboard for other activities, please use the **My Dashboard** button at the top of the page. If you have completed your session for today, simply close your browser.

For additional information about the Clozapine REMS Program, please call 844-267-8678.

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9. Knowledge Assessment

The Knowledge Assessment pages below are for prescribers, prescriber designees, and authorized representatives.

9.1 Knowledge Assessment Landing Page

The screenshot shows the Clozapine REMS website interface. At the top left is the logo "CLOZAPINE REMS" with the tagline "The Single Shared System for Clozapine" and "No Blood, No Drug™". To the right of the logo is the user name "Summer Hogan" and a "My Dashboard" button. Below the logo is a navigation menu with links for "Home", "Prescriber" (which is highlighted), "Pharmacy", "Patient", "Resources", "Important Safety Information", and "Support". A secondary navigation bar contains buttons for "Start", "Intake", "Education", "Assessment" (which is highlighted), "Review", "Attestation", and "Finish". The main heading is "Knowledge Assessment". Below this, there are two paragraphs of text: "You are now going to review questions that will test your knowledge of appropriate use and administration of clozapine. To be a certified prescriber in the Clozapine REMS Program you will need to answer ALL questions correctly. Please select the **best** option for each question." and "You will have a maximum of six attempts to pass the assessment. After three unsuccessful attempts, the education program is required to be reviewed again before retaking the knowledge assessment. After six unsuccessful attempts, your access to retake the knowledge assessment will be suspended and you will need to contact the Clozapine REMS Program to reinstate your ability to complete the knowledge assessment." Below the text is a blue "Start Assessment" button. At the bottom of the page, there is a footer with the text "For additional information about the Clozapine REMS Program, please call 844-267-8678." and a navigation bar with links for "Privacy", "Terms of Use", "Site Map", "FAQs", and "Contact Us".

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Home **Prescriber** Pharmacy Patient Resources Important Safety Information Support

Start Intake Education **Assessment** Review Attestation Finish

Knowledge Assessment

You are now going to review questions that will test your knowledge of appropriate use and administration of clozapine. To be a certified prescriber in the Clozapine REMS Program you will need to answer ALL questions correctly. Please select the **best** option for each question.

You will have a maximum of six attempts to pass the assessment. After three unsuccessful attempts, the education program is required to be reviewed again before retaking the knowledge assessment. After six unsuccessful attempts, your access to retake the knowledge assessment will be suspended and you will need to contact the Clozapine REMS Program to reinstate your ability to complete the knowledge assessment.

[Start Assessment](#)

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9.2 KA Question 1

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Intake Education Assessment **Confirmation**

Knowledge Assessment

QUESTION 1

All clozapine products are only available under the shared Clozapine REMS Program.

- A. True
- B. False

Next

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9.3 KA Question 2

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Knowledge Assessment

QUESTION 2

Clozapine is associated with severe neutropenia.

- A. True
- B. False

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9.4 KA Question 3

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Knowledge Assessment

QUESTION 3

Severe neutropenia is defined as:

- A. A white blood cell count (WBC) less than 2000/ μ L
- B. An absolute neutrophil count (ANC) less than 1000/ μ L
- C. An absolute neutrophil count (ANC) less than 500/ μ L
- D. None of the above

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9.5 KA Question 4

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Knowledge Assessment

QUESTION 4

Before initiating treatment with clozapine:

- A. A baseline absolute neutrophil count (ANC) must be at least 1000/ μ L for a patient with documented Benign Ethnic Neutropenia (BEN)
- B. A baseline absolute neutrophil count (ANC) must be at least 1500/ μ L for a patient who is part of the General Population (i.e., the patient does not have BEN)
- C. A baseline absolute neutrophil count (ANC) is not necessary
- D. Both A and B

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9.6 KA Question 5

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Knowledge Assessment

QUESTION 5

Before clozapine is dispensed to a patient, a prescriber must:

- A. Determine if the patient has Benign Ethnic Neutropenia (BEN)
- B. Enroll the patient in the Clozapine REMS Program
- C. Educate the patient/caregiver about the risk of severe neutropenia
- D. Order blood work to obtain ANC
- E. Review the ANC result and provide it into the Clozapine REMS Program
- F. All of the above

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9.7 KA Question 6

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Intake Education Assessment **Confirmation**

Knowledge Assessment

QUESTION 6

For outpatients, prescribers must report the ANC to the shared Clozapine REMS Program before the patient can be dispensed clozapine.

- A. True
- B. False

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9.8 KA Question 7

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Intake Education Assessment **Confirmation**

Knowledge Assessment

QUESTION 7

Before clozapine can be dispensed, a pharmacist must:

- A. Verify the prescriber is certified in the shared Clozapine REMS Program
- B. Verify the patient is enrolled in the shared Clozapine REMS Program
- C. For outpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by obtaining a pre-dispense authorization from the Clozapine REMS Program
- D. For inpatients - verify the ANC is acceptable or verify the prescriber authorized continuing treatment if the ANC is abnormal by accessing the Clozapine REMS Program or by accessing the ANC through the hospital's medical record system
- E. All of the above

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9.9 KA Question 8

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Knowledge Assessment

QUESTION 8

How much clozapine can be dispensed?

- A. A 30 day supply
- B. A 90 day supply
- C. As much as the patient wants or the insurance will pay for
- D. It depends when the patient's next blood draw is according to the monitoring requirements. Dispense enough medication to treat the patient with clozapine until the next blood draw/ANC or as directed by the prescriber

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9.10KA Question 9

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Intake Education Assessment **Confirmation**

Knowledge Assessment

QUESTION 9

Regarding patients with benign ethnic neutropenia (BEN), which of the following statements are true?

- A. Patients with BEN have a different clozapine treatment algorithm and monitoring requirements
- B. Patients with BEN are healthy and do not suffer from repeated severe infections
- C. Patients with BEN are NOT at increased risk for developing clozapine-induced neutropenia
- D. Before starting clozapine, additional evaluation may be needed to determine if baseline neutropenia is due to BEN. Hematology consultation may be necessary
- E. All of the above statements are true

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9.11KA Question 10

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Knowledge Assessment

QUESTION 10

If a new patient's baseline ANC is within the normal range, how should the ANC monitoring schedule proceed?

- A. Weekly from initiation to discontinuation of therapy
- B. Weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- C. Monthly from initiation to discontinuation of therapy
- D. No additional ANC monitoring is required if the patient's baseline ANC is within the normal range

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9.12KA Question 11

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Knowledge Assessment

QUESTION 11

If a patient's ANC indicates mild neutropenia, which of the following statements is true?

- A. ANC monitoring should be conducted three times weekly until ANC $\geq 1500/\mu\text{L}$ if the patient is part of the General Population (i.e., if the patient does not have Benign Ethnic Neutropenia (BEN))
- B. Mild neutropenia is within the normal range for a patient with BEN
- C. If the patient has BEN, ANC monitoring should be conducted: weekly from initiation to 6 months; every 2 weeks from 6 to 12 months; monthly after 12 months
- D. All of the above

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9.13KA Question 12

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Knowledge Assessment

QUESTION 12

If a patient's ANC indicates moderate neutropenia, which of the following statements is true?

- A. Treatment should be continued regardless of whether the patient is part of the General Population or has Benign Ethnic Neutropenia (BEN)
- B. If the patient is part of the General Population (i.e., if the patient does not have BEN), interrupt therapy and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$; weekly for 4 weeks; then return to the patient's last "Normal Range" ANC monitoring interval
- C. The ANC monitoring schedule is the same regardless of whether the patient is part of the General Population or has BEN
- D. None of the above

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9.14KA Question 13

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Knowledge Assessment

QUESTION 13

If a patient's ANC indicates severe neutropenia, which of the following statements is true?

- A. Treatment should be interrupted regardless of whether the patient is part of the General Population or has Benign Ethnic Neutropenia (BEN) and a hematology consultation should be considered; resume treatment only if the prescriber determines that the benefits of clozapine therapy outweigh the risks
- B. If the patient is part of the General Population (i.e., if the patient does not have BEN), interrupt treatment and conduct ANC monitoring: daily until ANC $\geq 1000/\mu\text{L}$; three times weekly until ANC $\geq 1500/\mu\text{L}$
- C. The patient may still be rechallenged with clozapine at the discretion of the prescriber
- D. All of the above

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9.15KA Confirmation - Success

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Knowledge Assessment Results

✔ You have now completed the assessment.

You answered all the questions correctly and have passed the assessment. Please press the **Next** button to complete your certification.

Knowledge Assessment Code: [1422-FEAF-BE87](#) 🖨️

QUESTION 1

All clozapine products are only available under the shared Clozapine REMS Program.

✔ A. True

QUESTION 2

Clozapine is associated with severe neutropenia.

✔ A. True

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9.16KA Confirmation – Not Successful

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Intake Education Assessment **Confirmation**

Knowledge Assessment Results

You did not pass the Knowledge Assessment.

Below is a summary of your responses. We recommend you review the Education Program again before you attempt to retake the Knowledge Assessment. Once you feel your review is complete, please use the **Retake Assessment** button below to begin your assessment again.

QUESTION 1

All clozapine products are only available under the shared Clozapine REMS Program.

✓ A. True

QUESTION 2

Clozapine is associated with severe neutropenia.

✗ A. False

ATTEMPT
1 2 3 4 5 6

Retake Assessment

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10. Patient Enrollment

10.1 Patient Intake

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[Start](#) [Intake](#) [Lab Info](#) [Finish](#)

Patient Intake

To enroll your patient in the Clozapine REMS Program, please complete the form below and press **Next**. Once the patient enrollment is complete, you will receive an enrollment confirmation via your contact preference. All fields listed below are required.

Patient Information

-- Gender -- ▾

-- Race -- ▾

-- Patient Group -- ▾ ?

Does the patient have Benign Ethnic Neutropenia (BEN)?

-- Please Select -- ▾

[Cancel](#)

[Next](#)

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10.2 Patient Lab Intake

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[Start](#) [Intake](#) [Lab Info](#) [Finish](#)

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

Mike Jones

Lab Entry

ANC value (per μ L)

Blood Draw Date

[Verify Lab](#)

Treatment Status

Pretreatment ▾

Monitoring Frequency

Weekly ▾

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per μ L) ?	None	None	None

[Cancel](#) [Next](#)

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10.3 Patient Lab Intake with Treatment Rationale

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[Start](#) [Intake](#) [Lab Info](#) [Finish](#)

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

Mike Jones

Lab Entry

ANC value (per μL)

Blood Draw Date

[Modify Lab](#)

Treatment Status

Treatment Rationale

Treatment Rationale Duration

Monitoring Frequency

I attest that this patient is terminally ill/in hospice care and monitoring can be reduced per the label.

[Cancel](#) [Next](#)

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per μL)	None	None	None

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10.4 ANC Calculator

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ANC Calculator

WBC count (x10 ⁹ /mm ³)	Segs (%)	Bands (%)	ANC value (per µL)
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

WBC count (x10 ⁹ /mm ³)	Neutrophils (%)	ANC value (per µL)
<input type="text"/>	<input type="text"/>	<input type="text"/>

NOTE:
For WBC count, data should be entered in decimal format (a value of 4,300 should be entered as 4.3).
For Segs, Bands, or Neutrophils, data should be entered without percent sign (20% should be entered as 20).
If the ANC value is populated with a value, the same value is populated in the ANC value field on the form.

Source: Mosby's Diagnostic and Laboratory Test Reference, 8th ed. 2003. White blood cell count and differential, page 942.

Lab Information

The Treatment Status and Monitoring Frequency should be entered in the fields provided below.

Frank Adam

Lab Entry

ANC value (per µL)

Blood Draw Date

Treatment Status

Treatment Rationale

Treatment Rationale Duration

Monitoring Frequency

I attest that this patient is terminally ill/in hospice care and monitoring can be reduced per the label.

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11. Stakeholder Profiles

Stakeholder profiles are accessed via the drop down next to the signed in users name at the top of every page.

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11.1 Prescriber Profile

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My Profile

My Information [Edit](#)

First Name / MI

Last Name

Credentials ▾

Clinic / Practice Name

Address

Address 2

City

State / Zip Code ▾

Phone / Ext

Fax

Contact Preference ▾

DEA

NPI

My Certification

Certification ID: [HCP123456789](#)

Education Program

[Cancel](#) [Save](#)

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11.2 Prescriber Designee Profile

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My Profile

My Information Edit

First Name

Last Name

Phone / Ext

Fax

Contact Preference

My Certification

Certification ID: **HCP123456789**

Education Program

Cancel Save

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11.3 Authorized Representative Profile

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My Profile

My Information [Edit](#)

First Name

Last Name

Credentials

Phone / Ext

Fax

Contact Preference

 **Education Program**

 **Knowledge Assessment**

 **Knowledge Assessment Answer Guide**

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11.4 Chain Authorized Representative Profile

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My Profile

My Information [Edit](#)

First Name

Last Name

Position / Title ▾

Phone / Ext

Fax

Contact Preference ▾

 **Education Program**

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11.5 Chain Headquarters Profile

The chain authorized representative will have two options via the drop down next to the signed in users name at the top of every page; one for My Profile (authorized representative profile above) and Chain Headquarters Profile (below).

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My Profile

My Information Edit

First Name

Last Name

Position/Title

Phone / Ext

Fax

Contact Preference

Chain Name

Address

Address 2

City

State / Zip

Phone / Ext

Fax

Chain ID

My Certification

Certification ID: **FAC258523458**

Education Program

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11.6 Pharmacy Staff Profile

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My Profile

My Information Edit

First Name

Last Name

Phone / Ext

Fax ▾

Contact Preference

My Enrollment

Enrollment ID: **HCP123456789**

[Cancel](#) [Save](#)

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12. My Account

My Account pages are accessed via the drop down next to the signed in users name at the top of every page.

12.1 Change Username



Change Username

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program website.

Use Email Address as Username [Suggest Username](#)
[Change Password](#)
[Change Email Address](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.2 Change Username Confirmation

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Change Username

✔ Your username has been successfully saved.

To change your username, please provide your new username below. The information you provide for your username must be unique within the Clozapine REMS Program website.

Use Email Address as Username [Suggest Username](#)
[Change Password](#)
[Change Email Address](#)

[Cancel](#) [Save](#)

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12.3 Change Password

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Change Password

To change your password, please complete the fields below.

[Change Username](#)
[Change Email Address](#)

[Cancel](#) [Save](#)

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12.4 Change Password Confirmation

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Change Password

✔ Your password has been successfully saved.

To change your password, please complete the fields below.

[Change Username](#)
[Change Email Address](#)

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12.5 Change Email Address

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Change Email Address

To change your email address, please complete the fields below.

[Change Username](#)
[Change Password](#)

[Cancel](#) [Save](#)

For additional information about the Clozapine REMS Program, please call 844-267-8678.

12.6 Change Email Address Confirmation

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Change Email Address

✔ Your email address has been successfully updated. A verification email has been sent to <email address>. Please use the link within the email to confirm this change.

To change your email address, please complete the fields below.

[Change Username](#)
[Change Password](#)

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13. Patient Groups

13.1 Manage Groups

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Manage Groups

The table below contains all of your patient groups. If you need to add a new patient group, please use the **Add Group** button.

[Add Group](#)

Group Name	Actions
Group A	-- Please Select -- <input type="button" value="Go"/>
Group B	-- Please Select -- <input type="button" value="Go"/>

[My Dashboard](#)

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The manage groups page will include a list of all groups the prescriber or designee has created for themselves. The actions the prescriber and designee can take are:

- 1 – Add Group – will take the user to the Add Group page
- 2 – Change Group Name – will take the user to the Edit Group page
- 2 – Remove Group – will take the user to the Remove Group page

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13.2 Add Group

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Add Group

To add a new group, please specify the group name below and press **Submit**. You can add a patient to the group by accessing the patients profile.

[Cancel](#) [Submit](#)

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13.3 Change Group Name

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Change Group Name

To change the group, simply edit the group name in the field below and press **Submit**.

Group Name

[Cancel](#) [Submit](#)

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13.4 Remove Group

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Remove Group

To remove the group below simply press **Remove**; otherwise, press **Cancel** to return to Manage Groups.

Group Name: **Group A**

[Cancel](#) [Remove](#)

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13.5 Remove Group Warning

The screenshot shows the Clozapine REMS website interface. At the top, the logo 'CLOZAPINE REMS' is displayed with the tagline 'The Single Shared System for Clozapine' and 'No Blood, No Drug™'. The user 'Summer Hogan' is logged in, and a 'My Dashboard' button is visible. A navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'. The main content area is titled 'Remove Group' and shows a form with 'Group Name: Group A'. A white warning dialog box is centered on the screen, containing a red warning icon and the text: 'Warning', 'Patients are currently assigned to the group you are removing.', and 'Would you like to reassign all the patients to a new group?'. Below the text are two buttons: a red 'No' button and a green 'Yes' button. In the background, a 'Cancel' button and a green 'Remove' button are visible. At the bottom of the page, there is a footer with the text 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with links for 'Privacy', 'Terms of Use', 'Site Map', 'FAQs', and 'Contact Us'.

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13.6 Reassign Patients

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Reassign Patients

Please select the new group below and press **Submit**.

Group Name:

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14. Dashboard

14.1 Dashboard Alerts and Notifications

14.1.1 Dashboard Alerts

Alerts will be displayed for all stakeholders. The Alerts and Notifications tabs are common across all stakeholders.

The screenshot shows the 'Alerts' tab selected in the dashboard. The header includes the Clozapine REMS logo and navigation links. Below the tabs, a message states: 'All program alerts are listed below. Please use the link within an alert to take the necessary action to satisfy the alert.' A search bar is present. A table displays one alert entry with columns for Alert Date, Alert Category, Alert Reference Name, and Alert Subject. The entry shows an alert on 03/02/2015 for 'Certification' for 'Hogan, Summer' with a 'Begin Certification' link. A pagination bar at the bottom indicates 'Showing 1 of 1 entries'.

Alert Date	Alert Category	Alert Reference Name	Alert Subject
03/02/2015	Certification	Hogan, Summer	Begin Certification

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14.1.2 Dashboard Notifications

Notifications will be displayed for all stakeholders. The Alerts and Notifications tabs are common across all stakeholders.

The screenshot shows the Clozapine REMS dashboard interface. At the top, the user is identified as Summer Hogan, with a 'My Dashboard' button. The main navigation bar includes links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. Below this, there are tabs for Alerts (1), Notifications (1), Patients, and Designees. The Notifications tab is active, displaying a message: 'All program notifications are listed below. Please select a notification and use the Acknowledge button to clear the notification.' A search bar is present. A table lists one notification:

<input type="checkbox"/>	Notification Date	Notification Category	Notification Reference Name	Notification Subject
<input type="checkbox"/>	01/15/2015	General	Hogan, Summer	Certification Confirmation

Below the table, it says 'Showing 1 of 1 entries' and includes pagination controls for 1 to 10 entries. An 'Acknowledge' button is located at the bottom right of the notification area.

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14.2 Prescriber Dashboard

14.2.1 Prescriber Dashboard Patient Tab Collapsed

Summer Hogan ▾ My Dashboard

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts ¹ Notifications ¹ Patients Designees Manage Groups

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

[Enroll Patient](#) [Eligibility Check](#)

First Name	Last Name	DOB	Treatment Status	Enrollment Status	Group	Relationship	Actions
 Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- <input type="button" value="Go"/>
 Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- <input type="button" value="Go"/>
 Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- <input type="button" value="Go"/>
 Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- <input type="button" value="Go"/>
 Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- <input type="button" value="Go"/>

Showing 10 of 10 entries 1 » 10 ▾

 = NNRMF (National Non-Rechallenge Master File) Patients

For definitions of terms used on this page, click [here](#).

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14.2.2 Prescriber Dashboard Patient Tab Expanded

Summer Hogan ▾ My Dashboard

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Alerts ¹ Notifications ¹ Patients Designees Manage Groups

1 2

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

Enroll Patient Eligibility Check Search

First Name	Last Name	DOB	Treatment Status	Enrollment Status	Group	Relationship	Actions
Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- Go
Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- Go
Enrollment ID: PAT123456		View ANC Monitoring table		Current	Highest	Lowest	Add Lab Change Treatment Status Change Treatment Rationale View Patient History View Patient Profile
Gender: Male	Blood Draw Date		N/A	N/A	N/A		
NNRMF: No	ANC value (per µL)		N/A	N/A	N/A		
BEN: No							
Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- Go
Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- Go
Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- Go

Showing 10 of 10 entries 1 10 ▾

= NNRMF (National Non-Rechallenge Master File) Patients

For definitions of terms used on this page, click [here](#).

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The dashboard for the prescriber will include a list of all patients the prescriber is managing. The actions the prescriber can take are:

For patients with an enrollment status of "Incomplete" the prescriber can "Resume Patient Enrollment"

1 – Enroll Patient – will take the users to the Patient Intake page and through the patient enrollment process

2 – Eligibility Check – will take the users to the Eligibility Check page. *This page will not be available until the 12/14 launch.*

For patients with an enrollment status of "Enrolled" the prescriber can take the following actions:

3 – Add Lab – will take the user to the Lab Information page

3 – Change Treatment Status – will take the user to the Lab Information page

3 – Change Treatment Rationale – will take the user to the Lab Information page

3 – View Patient History – will take the user to the Patient History page

3 – View Patient Profile – will take the user to the Patient Profile page

4 – For definitions of terms used on this page – will pop-up the definitions on the page (see next mockup)

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14.2.3 Definitions of Terms Pop-up

Definition of Terms

Treatment Status

Pretreatment - Patient has been enrolled in the Clozapine REMS Program, prior to beginning therapy on clozapine

Active - Patient is actively taking clozapine

Interrupted - Patient is temporarily removed from clozapine therapy

Discontinued - Patient is removed from clozapine therapy (includes permanent discontinuation due to severe neutropenia or other reasons, patient death, etc...)

Enrollment Status

Enrolled (for patients and pharmacy staff) - All enrollment requirements have been met

Certified (for all other stakeholders) - All certification requirements have been met

Incomplete - Requirements for enrollment or certification have not been met and must be continued

BEN Patient - Benign Ethic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients who have been diagnosed with BEN have a separate ANC monitoring algorithm when treated with clozapine

NNRMF - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ μ L or an ANC less than 1000/ μ L. All patients who were listed in the NNRMF, and all their lab data were transferred into the Clozapine REMS Program

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14.2.4 Add Lab, Change Treatment Status, Change Monitoring Frequency, and Change Treatment Rationale for Prescribers

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Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below. Additionally, if you have lab information you may enter it now; otherwise, please press **Next** to continue.

Mike Jones

Lab Entry

ANC value (per μ L)

Blood Draw Date

[Modify Lab](#)

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per μ L)	None	None	None

Treatment Status

Treatment Rationale

Treatment Rationale Duration

Monitoring Frequency

I attest that this patient is terminally ill/in hospice care and monitoring can be reduced per the label.

[Cancel](#) [Next](#)

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14.2.5 View Patient History Lab History Tab

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Patient History

Lab History Treatment Status History Monitoring Frequency History

Name **Chester Smith**
DOB **03/5/1983**
Gender **Male**

Entry Date	Blood Draw Date	ANC
01/27/2015	01/26/2015	1570
02/27/2015	02/26/2015	900
03/27/2015	03/26/2015	1650



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14.2.6 View Patient History Treatment Status Tab

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Patient History

[Lab History](#) **[Treatment Status History](#)** [Monitoring Frequency History](#)

Name Chester Smith	Entry Date	Treatment Status	Rationale	Duration
DOB 03/5/1983	01/27/2015	Active		
Gender Male	02/27/2015	Interrupted		
	02/27/2015	Active	Benefit Outweighs Risk	07/27/2015

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14.2.7 View Patient History Monitoring Frequency Tab

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Patient History

Lab History Treatment Status History **Monitoring Frequency History**

Name Chester Smith	Entry Date ▾	Monitoring Frequency ▾
DOB 03/5/1983	01/27/2015	Monthly
Gender Male		

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14.2.8 View Patient Profile

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Patient Profile

Patient Information [Edit](#)

First Name

Last Name

DOB

Zip Code

Gender

Race

Group

BEN Patient No

NNRMF Patient No

Patient Enrollment Information

Enrollment ID: [PAT132456789](#)

[Cancel](#) [Save](#)

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14.2.9 Eligibility Check

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Eligibility Check

This Eligibility Check is only intended for **inpatient pharmacy** use to determine if the safe use conditions have been met for your inpatient to receive clozapine. Please complete the Eligibility Check information below and **Submit**. If you have lab updated information you wish to also submit for your inpatient, you may enter it here. The results of the Eligibility Check will be displayed after the information is submitted. All fields below are required unless otherwise indicated.

Patient Information

?

▾

▾

At least **one** identifier is required

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Prescriber Eligibility Check Screen (1.2.9) and Prescriber Designee Eligibility Check Screen (1.3.7):

- The eligibility check will be the only option for selection from web dashboards for prescribers, prescriber designees, pharmacy auth reps, and pharmacy staff (for both inpatient and outpatient pharmacies) for Phase 2 (Oct 12th through Dec 14th) to allow any stakeholder to check eligibility before PDA functionality is available
- The eligibility check fields have been updated to not require manufacturer and NDC knowing these may not be fields that prescribers or their designees may have or know
- At PDA launch (Dec 14th), prescribers, prescriber designees, authorized representatives and pharmacy staff for **inpatient** pharmacies will only have the option to access patient eligibility check from their dashboard (not PDA)
 - Additional Point: For consistency, functionality has been provided to both Prescribers and Prescriber Designees.
- At PDA launch (Dec 14th), authorized representatives and pharmacy staff for **outpatient** pharmacies will only have the option to access patient PDA request from their dashboard (not eligibility)
- Instructions on the Prescriber and Prescriber Designee Eligibility Check Screens have been updated to clearly explain the purpose of the eligibility check.

14.2.10 Prescriber Dashboard Designees Tab

The table below contains all the designees that are currently assigned or requesting approval from you. If you need to add a new designee to your list, please use the **Add Designee** button.

First Name	Last Name	Certification ID	Approval Status	Actions
Anantharaman	Manickavasagam	HCP123456	Approved	-- Please Select -- Remove Designee
Chester	Smith	HCP123456	Approved	-- Please Select --
Jane	Brown	HCP055254	Pending	-- Please Select -- Approve Designee
Mike	Jones	HCP173277	Approved	-- Please Select --
Terry	White	HCP173285	Approved	-- Please Select --

Showing 10 of 10 entries

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The dashboard for the prescriber will include a list of all designees the prescriber is associated to. The actions the prescriber can take are:

- 1 – Add Designee – will take the user to the Add Designee page
- 2 – Remove Designee – will take the user to the Remove Designee page
- 3 – Approve Designee – will take the user to the Approve Designee page

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14.2.11 Add Designee with Results

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Add Designee

To add a designee, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Designee Information

<input type="text" value="Terry"/>	<input type="text" value="White"/>	<input type="text" value="Certification ID (opt)"/>
<input type="text" value="Phone (opt)"/>	<input type="text" value="Fax (opt)"/>	<input type="text" value="Email (opt)"/>

[Search](#)

If the search results have returned the designee you want to associate to, please select the row and press **Submit**. If you do not see the designee you are looking for, please try your search again or contact the designee to ensure they are certified in the program.

First Name	Last Name	Phone
Terry	White	555-555-5555

Showing 1 of 1 entries

[Cancel](#) [Submit](#)

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14.2.12 Remove Designee

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Remove Designee

Removing this designee will revoke their ability to perform actions on your behalf. To continue, please check the box below and press **Submit**.

Designee Name: [Anantharaman Manickavasagam](#)

Certification ID: [HCP123456](#)

I hereby remove this designee's ability to perform actions on my behalf in the Clozapine REMS Program.

Cancel

Submit

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14.2.13 Approve Designee

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Designee Determination

This designee will act on my behalf in fulfilling the requirements for the Clozapine REMS Program.

Designee Name: **Jane Brown**

Certification ID: **HCP055254**

Decline

Approve

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14.3 Prescriber Designee Dashboard

14.3.1 Prescriber Designee Dashboard Patient Tab Collapsed

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts ¹ Notifications ¹ Patients Prescribers Manage Groups

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

[Enroll Patient](#) [Eligibility Check](#)

First Name ▲	Last Name ◆	DOB ◆	Treatment Status ◆	Enrollment Status ◆	Group ◆	Relationship ◆	Actions
 Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- <input type="button" value="Go"/>
 Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- <input type="button" value="Go"/>
 Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- <input type="button" value="Go"/>
 Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- <input type="button" value="Go"/>
 Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- <input type="button" value="Go"/>

Showing 10 of 10 entries 1 » 10 ▾

 = NNRMF (National Non-Rechallenge Master File) Patients

For definitions of terms used on this page, click [here](#).

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14.3.2 Prescriber Designee Dashboard Patient Tab Expanded

Summer Hogan ▾ My Dashboard

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts 1 Notifications 1 Patients Prescribers Manage Groups

1 2

The table below contains the patients you have treated with clozapine. If you do not find a patient, please use the Enroll Patient button to add the patient. A flagged row indicates an NNRMF patient.

Enroll Patient Eligibility Check Search

First Name	Last Name	DOB	Treatment Status	Enrollment Status	Group	Relationship	Actions
Anantharaman	Manickavasagam	11/15/1980	Interrupted	Enrolled	Group A	Active	-- Please Select -- Go
Chester	Smith	03/05/1983	Active	Enrolled	Group B	Active	-- Please Select -- Go
Enrollment ID: PAT123456		View ANC Monitoring table		Current	Highest	Lowest	Add Lab Change Treatment Status View Patient History View Patient Profile
Gender: Male	Blood Draw Date		N/A	N/A	N/A		
NNRMF: No	ANC value (per µL)		N/A	N/A	N/A		
BEN: No							
Jane	Brown	07/13/1975	Pretreatment	Incomplete	Group C	Transferred	-- Please Select -- Go
Mike	Jones	11/07/1977	Active	Incomplete	Group D	Active	-- Please Select -- Go
Terry	White	01/15/1988	Active	Enrolled	Group E	Active	-- Please Select -- Go

Showing 10 of 10 entries 1 10 ▾

▣ = NNRMF (National Non-Rechallenge Master File) Patients

For definitions of terms used on this page, click [here](#).

4

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The dashboard for the prescriber designee will include a list of all patients the designee's prescribers are managing. The actions the prescriber designee can take are:

For patients with an enrollment status of "Incomplete" the prescriber designee can "Resume Patient Enrollment"

1 – Enroll Patient – will take the users to the Patient Intake page and through the patient enrollment process

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2 – Eligibility Check – will take the users to the Eligibility Check page. *This page will not be available until the 12/14 launch.*

For patients with an enrollment status of “Enrolled” the prescriber can take the following actions:

3 – Add Lab – will take the user to the Lab Information page

3 – Change Treatment Status – will take the user to the Lab Information page

3 – View Patient History – will take the user to the Patient History page

3 – View Patient Profile – will take the user to the Patient Profile page

4 – For definitions of terms used on this page – will pop-up the definitions on the page (see next mockup)

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14.3.1 Definitions of Terms Pop-up

Definition of Terms

Treatment Status

Pretreatment - Patient has been enrolled in the Clozapine REMS Program, prior to beginning therapy on clozapine

Active - Patient is actively taking clozapine

Interrupted - Patient is temporarily removed from clozapine therapy

Discontinued - Patient is removed from clozapine therapy (includes permanent discontinuation due to severe neutropenia or other reasons, patient death, etc...)

Enrollment Status

Enrolled (for patients and pharmacy staff) - All enrollment requirements have been met

Certified (for all other stakeholders) - All certification requirements have been met

Incomplete - Requirements for enrollment or certification have not been met and must be continued

BEN Patient - Benign Ethic Neutropenia (BEN) is a condition observed in certain ethnic groups whose average ANC's are lower than "standard" laboratory ranges for neutrophils. Because of this condition, patients who have been diagnosed with BEN have a separate ANC monitoring algorithm when treated with clozapine

NNRMF - Patients were listed in the National Non-Rechallenge Master File (NNRMF) if a patient had a WBC less than 2,000/ μ L or an ANC less than 1000/ μ L. All patients who were listed in the NNRMF, and all their lab data were transferred into the Clozapine REMS Program

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14.3.2 Add Lab and Change Treatment Status for Prescriber Designees

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Lab Information

The Treatment Status and Monitoring Frequency for the patient have been defaulted based on program rules. If you need to change the values you may do so in the fields provided below.

Mike Jones

Lab Entry

ANC value (per μL)

Blood Draw Date

Treatment Status

Active ▾

Treatment Rationale

-- Please Select -- ▾

Monitoring Frequency

-- Please Select -- ▾

Alert this prescriber that this patient should be under hospice care.

Lab	Current	Highest	Lowest
Blood Draw Date	None	None	None
ANC value (per μL) <input data-bbox="1003 884 1024 911" type="button" value="?"/>	None	None	None

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14.3.3 View Patient History Lab History Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Patient History

Lab History Treatment Status History Monitoring Frequency History

Name Chester Smith	Entry Date	Blood Draw Date	ANC
DOB 03/5/1983	01/27/2015	01/26/2015	1570
Gender Male	02/27/2015	02/26/2015	900
	03/27/2015	03/26/2015	1650



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14.3.4 View Patient History Treatment Status Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Patient History

	Lab History	Treatment Status History	Monitoring Frequency History	
Name Chester Smith				
DOB 03/5/1983				
Gender Male				
	Entry Date	Treatment Status	Rationale	Duration
	01/27/2015	Active		
	02/27/2015	Interrupted		
	02/27/2015	Active	Benefit Outweighs Risk	07/27/2015

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14.3.5 View Patient History Monitoring Frequency Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Patient History

Lab History Treatment Status History **Monitoring Frequency History**

Name Chester Smith	Entry Date ▾	Monitoring Frequency ▾
DOB 03/5/1983	01/27/2015	Monthly
Gender Male		

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14.3.6 View Patient Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Patient Profile

Patient Information [Edit](#)

First Name

Last Name

DOB

Zip Code

Gender ▾

Race ▾

Group ▾

BEN Patient No

NNRMF Patient No

Patient Enrollment Information

Enrollment ID: [PAT132456789](#) 🖨

[Cancel](#) [Save](#)

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14.3.7 Eligibility Check

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Eligibility Check

This Eligibility Check is only intended for **inpatient pharmacy** use to determine if the safe use conditions have been met for your inpatient to receive clozapine. Please complete the Eligibility Check information below and **Submit**. If you have lab updated information you wish to also submit for your inpatient, you may enter it here. The results of the Eligibility Check will be displayed after the information is submitted. All fields below are required unless otherwise indicated.

Patient Information

?

▾

▾

At least **one** identifier is required

[Cancel](#) [Submit](#)

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14.3.8 Prescriber Designee Dashboard Prescribers Tab

The table below contains all the prescribers you are currently a designee for. If you need to be a designee for a prescriber not in your list, please use the **Associate to Prescriber** button.

Last Name	First Name	Certification ID	Approval Status	Actions
Anantharaman	Manickavasagam	HCP123456	Approved	-- Please Select --
Chester	Smith	HCP223245	Approval Pending	Remove Designee Relationship -- Please Select --
Jane	Brown	HCP173277	Approved	Cancel Designee Request -- Please Select --
Mike	Jones	HCP373240	Approved	-- Please Select -- Go
Terry	White	HCP173285	Approved	-- Please Select -- Go

Showing 10 of 10 entries

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The dashboard for the prescriber designee will include a list of all prescribers the designee is acting on behalf of. The actions the prescriber designee can take are:

- 1 – Associate to Prescriber – will take the user to the Associate to Prescriber page
- 2 – Remove Designee Relationship – will take the user to the Remove Designee Relationship page
- 3 – Cancel Designee Request – will take the user to the Cancel Designee Request page

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14.3.9 Associate to Prescriber

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Username Password [Sign in](#)
Forgot Username? Forgot Password? Need an Account?

[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Associate to Prescriber

To associate to a prescriber, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Prescriber Information (at least one identifier is required):

and or

[Search](#)

If the search results have returned the prescriber you want to associate to, please select the row and press **Submit**. If you do not see the prescriber you are looking for, please try your search again or contact the prescriber to ensure they are certified in the program.

First Name	Last Name	Phone	DEA	NPI
Terry	White	555-555-5555	TW1234567	

Showing 1 of 1 entries

[Cancel](#) [Submit](#)

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14.3.10 Remove Designee Relationship

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Remove Designee Relationship

To remove your relationship with this prescriber, please check the box below and press **Submit**.

Prescriber Name: **Summer Hogan**

Relationship Status: **Approved**

I hereby remove my relationship with this prescriber and understand that I will no longer have the ability to perform actions on their behalf in the Clozapine REMS Program.

Cancel

Submit

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14.3.11 Cancel Designee Request

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Cancel Designee Request

To cancel the approval request to act on behalf of this prescriber, please check the box below and press **Submit**.

Prescriber Name: **Summer Hogan**

Relationship Status: **Pending**

I hereby cancel my request to act on behalf of this prescriber in the Clozapine REMS Program.

Cancel

Submit

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14.4 Pharmacy Dashboard

14.4.1 Pharmacy Dashboard Pharmacies Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts ³ Notifications ¹ Pharmacies Pharmacy Staff

Please search for your pharmacy in the table below and take the appropriate action. If you need to add a new pharmacy to your list, please use the Add Pharmacy button. For patient actions, use the Actions list below.

Add Pharmacy Search

Pharmacy Name	Address	Pharmacy Type	Certification ID	Certification Status	Actions
Joey's Apothecary	1 East Main Street, New York NY 10001	Inpatient	FAC1002345831	Certified	-- Please Select -- Go
Hogan RX	2 Park Avenue, New York NY 10201	Independent Outpatient	FAC2234583304	Certified	Add Lab and Eligibility Check View Pharmacy Profile Remove Pharmacy Go
Walgreens	311 Bell Road, Anaheim CA 92805	Inpatient	FAC0057124807	Incomplete	-- Please Select -- Go
CVS	423 Main Street, Tampa FL 33614	Inpatient	FAC0057124807	Incomplete	-- Please Select -- Go
Rite Aid	52 Milky Way Dr, Anchorage, AK 99508	Inpatient	FAC2585234583	Certified	Resume Pharmacy Certification -- Please Select -- Go

Showing 10 of 10 entries

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The dashboard for the authorized representative of inpatient and outpatient pharmacy types will include a list of all pharmacies the authorized representative is managing. The actions the authorized representative can take are:

1 – Add Pharmacy – will take the users to the Pharmacy Intake page and through the pharmacy certification process

For pharmacies with an enrollment status of “Certified” the authorized representative can take the following actions:

2 – Add Lab and Eligibility Check – will take the user to the Add Lab and Eligibility Check page. *This page will only be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

2 – Add Lab and Predisense Authorization – will take the user to the Add Lab and Predisense Authorization page. *This page will not be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

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- 2 – View Pharmacy Profile – will take the user to the Pharmacy Profile page
- 2 – Remove Pharmacy – will take the user to the Remove Pharmacy page
- 3 – For pharmacies with an enrollment status of “Incomplete” the authorized representative can “Resume Pharmacy Certification”

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14.4.2 Add Lab and Eligibility Check

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Eligibility Check

To determine if the safe use conditions have been met for your patient to receive clozapine, please complete the Eligibility Check information below and **Submit**. If you have lab information for your patient you may enter it here. The results of the Eligibility Check will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

Add Patient Lab (optional)

Eligibility Check Request (optional)

[?](#)

▾

▾

At least one identifier is required

[Cancel](#) [Submit](#)

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14.4.3 Eligibility Check Result – Unsuccessful

This result is displayed for both the Predispose Authorization and the Eligibility Check when the result is unsuccessful.

The screenshot displays the Clozapine REMS website interface. At the top, the logo and tagline 'The Single Shared System for Clozapine No Blood, No Drug™' are visible. A navigation menu includes links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. A user profile for 'Summer Hogan' and a 'My Dashboard' button are in the top right. The main heading is 'Eligibility Check Result'. A prominent red warning box states: 'Do not dispense clozapine to this patient.' Below this, a patient summary shows the name 'Chester Smith' and 'DOB'. To the right, a list of reasons for the failed check is provided: 'The patient is not enrolled in the REMS program', 'The prescriber is not certified in the REMS program', 'Acceptable patient lab is not on file', and 'Lab Status Lab was not saved'. A note at the bottom of this list suggests contacting the prescriber for further assistance. A footer contains the contact number '844-267-8678' and a navigation bar with links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

Do not dispense clozapine to this patient.

Name **Chester Smith**
DOB

- ✘ The patient is not enrolled in the REMS program
- ✘ The prescriber is not certified in the REMS program
- ✘ Acceptable patient lab is not on file
- ✘ **Lab Status Lab was not saved**

For further assistance with this patient's eligibility, please contact the patient's prescriber.

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14.4.4 Add Lab and Predispose Authorization

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Predispose Authorization

To determine if the safe use conditions have been met for your patient to receive clozapine, please complete the Predispose Authorization information below and **Submit**. If you have lab information for your patient you may enter it here. The results of the Predispose Authorization will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

Add Patient Lab (optional)

Predispose Authorization Request

?

▾

▾

At least one identifier is required

[Cancel](#) [Submit](#)

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14.4.5 Predispense Authorization Result – Successful

This result is displayed for both the Predispense Authorization and the Eligibility Check when the result is successful.

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the text 'CLOZAPINE REMS' and 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, there is a user profile 'Summer Hogan' with a dropdown arrow and a 'My Dashboard' button. Below the logo, a horizontal navigation menu contains the following links: Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support.

Predispense Authorization

✓ You are now authorized to dispense clozapine to the below patient.

Name Chester Smith	Lab Status Lab was saved
DOB 03/05/1983	
Predispense Authorization Code XXXXXXX	

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14.4.6 View Pharmacy Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Pharmacy Profile

Pharmacy Information Edit

Pharmacy Name

Pharmacy Type

Address

Address 2

City

State / Zip Code

Phone / Ext

Fax

NCPDP

DEA

NPI

Pharmacy Certification Information

Certification ID: **HCP123456789**

[Cancel](#) [Save](#)

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14.4.7 Remove Pharmacy

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: [Joey's Apothecary](#)

Certification ID: [PRS123456789](#)

I hereby remove this pharmacy from the Clozapine REMS Program.

Cancel

Submit

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14.4.8 Pharmacy Dashboard Pharmacy Staff Tab

The screenshot shows the 'Pharmacy Staff' tab selected in a dashboard. The dashboard header includes the user's name 'Summer Hogan' and a 'My Dashboard' button. The main navigation menu includes 'Home', 'Prescriber', 'Pharmacy', 'Patient', 'Resources', 'Important Safety Information', and 'Support'. Below the navigation, there are tabs for 'Alerts', 'Notifications', 'Pharmacies', and 'Pharmacy Staff'. A search bar is located above the table. The table contains one entry for Sally Smith at Joey's Apothecary. The 'Actions' column for this entry has a dropdown menu with the option 'Remove Pharmacy Staff' highlighted. A callout box with the number '1' points to this option. The text above the table states: 'The table below contains all the pharmacy staff that are currently assigned to you.'

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	-- Please Select -- Remove Pharmacy Staff

Showing 1 of 1 entries

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The dashboard for the authorized representative of inpatient and outpatient pharmacy types will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:

- 1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

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14.4.9 Remove Pharmacy Staff

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Summer Hogan ▾ My Dashboard

Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

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14.5 Chain Pharmacy Dashboard

14.5.1 Chain Pharmacy Dashboard Pharmacies Tab

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Home Prescriber Pharmacy Patient Resources Important Safety Information Support

Alerts ³ Notifications ¹ Pharmacies Pharmacy Staff

To certify a store that has been trained on all program requirements, select the store(s) and use the **Certify Store** button.
To add a store not in your list, use the **Add Chain Store** button. For all other activities, use the Actions list for the store.

1 Add Chain Store Search

<input type="checkbox"/>	Store Name	Address	Certification ID	Certification Status	Actions
<input type="checkbox"/>	Joey's Apothecary	1 East Main Street, New York NY 10001	FAC1002345831	Certified	-- Please Select -- Go
<input type="checkbox"/>	Hogan RX	2 Park Avenue, New York NY 10201	FAC2234583304	Certified	View Pharmacy Profile Remove Pharmacy
<input type="checkbox"/>	Apollo Pharmacy	311 Bell Road, Anaheim CA 92805	FAC0057124807	Incomplete	-- Please Select -- Go
<input type="checkbox"/>	Life Pharmacy	423 Main Street, Tampa FL 33614	FAC0057124807	Certified	-- Please Select -- Go
<input type="checkbox"/>	Mercury Drug	52 Milky Way Dr, Anchorage, AK 99508	FAC2585234583	Certified	-- Please Select -- Go

Showing 10 of 10 entries

3 Certify Store **3**

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The dashboard for the authorized representative of chain pharmacy headquarters will include a list of all chain store pharmacies the authorized representative is managing. The actions the authorized representative can take are:

1 – Add Chain Store – will take the users to the Chain Pharmacy Store Intake page and through the chain store certification process

For pharmacies with an enrollment status of "Certified" the authorized representative can take the following actions:

2 – View Pharmacy Profile – will take the user to the Pharmacy Profile page

2 – Remove Pharmacy – will take the user to the Remove Pharmacy page

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3 – For pharmacies with a certification status of “Incomplete” the authorized representative can check one, numerous, or all checkboxes (located on the left side of the data grid) and press the Certify Store button to certify the store once the staff is trained.

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14.5.2 View Pharmacy Profile

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[Home](#) [Prescriber](#) [Pharmacy](#) [Patient](#) [Resources](#) [Important Safety Information](#) [Support](#)

Pharmacy Profile

Pharmacy Information Edit

Pharmacy Name

Pharmacy Type

Address

Address 2

City

State / Zip Code

Phone / Ext

Fax

NCPDP

DEA

NPI

Pharmacy Certification Information

Certification ID: [HCP123456789](#) 🖨️

[Cancel](#) [Save](#)

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14.5.3 Remove Pharmacy

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Remove Pharmacy

Removing this pharmacy will deactivate it from the Clozapine REMS Program. The pharmacy will no longer be authorized to dispense clozapine. To continue, please check the box below and press **Submit**.

Pharmacy Name: [Joey's Apothecary](#)

Certification ID: [PRS123456789](#)

I hereby remove this pharmacy from the Clozapine REMS Program.

[Cancel](#)

[Submit](#)

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14.5.4 Chain Pharmacy Dashboard Pharmacy Staff Tab

The screenshot shows the 'Pharmacy Staff' tab selected in a dashboard. At the top, the user is identified as 'Summer Hogan' with a 'My Dashboard' button. The main header includes the 'CLOZAPINE REMS' logo and navigation links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. Below the header, there are tabs for Alerts (3), Notifications (1), Pharmacies, and Pharmacy Staff. A search bar is located above a table. The table contains one entry for Sally Smith at Joey's Apothecary. The 'Actions' column for this entry has a dropdown menu open, showing 'Remove Pharmacy Staff' as the selected option. A callout box with the number '1' points to this menu item. The table footer indicates 'Showing 10 of 10 entries'.

First Name	Last Name	Pharmacy Name	Address	Enrollment ID	Enrollment Status	Actions
Sally	Smith	Joey's Apothecary	1 East Main Street, New York NY 10001	HCP123456789	Enrolled	-- Please Select -- Remove Pharmacy Staff

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The dashboard for the authorized representative of chain pharmacy headquarters will include a list of all pharmacy staff that is representing the authorized representative. The actions the authorized representative can take are:

- 1 – Remove Pharmacy Staff – will take the user to the Remove Pharmacy Staff page

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14.5.5 Remove Pharmacy Staff

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Remove Pharmacy Staff

Removing this pharmacy staff member will revoke their ability to perform actions on behalf of this pharmacy. To continue, please check the box below and press **Submit**.

Staff Member: [Sally Smith](#)

Pharmacy Name: [Joey's Apothecary](#)

Enrollment ID: [HCP123456789](#)

I hereby remove this pharmacy staff member's ability to perform actions on behalf of this pharmacy in the Clozapine REMS Program.

[Cancel](#) [Submit](#)

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14.6 Pharmacy Staff Dashboard

14.6.1 Pharmacy Staff Dashboard Pharmacies Tab

The screenshot displays the 'Pharmacies' tab in the Clozapine REMS Pharmacy Staff Dashboard. At the top, there is a navigation bar with the logo and the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. Below the navigation bar, there are tabs for 'Alerts', 'Notifications', and 'Pharmacies'. The 'Pharmacies' tab is active, and a callout box labeled '1' points to the 'Associate to Pharmacy' button. Below the tabs, there is a text box stating: 'The table below contains all the pharmacies that you are currently associated to. If you need to associate yourself to a new pharmacy, please use the Associate to Pharmacy button.' To the right of this text is a search bar and a 'Go' button. Below the text is a table with the following data:

Pharmacy Name	Address	Certification Status	Actions
Berry Store	Address One, TAMPA, Florida 33004	Certified	-- Please Select -- Go
Cherry Store	Address Two, ORLANDO, Florida 32807	Certified	Add Lab and Eligibility Check Go
Complete Pharmacy Name	Address, WEST MONROE, Louisiana 71291	Certified	-- Please Select -- Go
Complete Training STORE	Address, MIAMI, Florida 33135	Certified	-- Please Select -- Go
New Apple Store	Address, MALIBU, California 90265	Certified	-- Please Select -- Go
Pharmacy One	Address, SHREVEPORT, Louisiana 71109	Certified	-- Please Select -- Go
Test Pharmacy	1234123434, MONROE, Louisiana 71201	Certified	-- Please Select -- Go

Below the table, there is a pagination control showing 'Showing 1 to 7 of 7 entries' and a 'Go' button. At the bottom of the page, there is a footer with the text: 'For additional information about the Clozapine REMS Program, please call 844-267-8678.' and a navigation bar with links for 'Privacy | Terms of Use | Site Map | FAQs | Contact Us'.

The dashboard for the pharmacy staff will include a list of all pharmacies the pharmacy staff is representing. The actions the pharmacy staff member can take are:

1 – Associate to Pharmacy – will take the user to the Associate to Pharmacy page

2 – Add Lab and Eligibility Check – will take the user to the Add Lab and Eligibility Check page. *This page will only be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

2 – Add Lab and Predispose Authorization – will take the user to the Add Lab and Predispose Authorization page. *This page will not be available between 10/12 and 12/14. On 12/14, PDA will take over and Eligibility Check will be removed.*

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14.6.2 Associate to Pharmacy

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Associate to Pharmacy

To identify the pharmacy you represent, please complete the fields below and press **Search**. All fields listed below are required unless otherwise indicated.

Pharmacy Information (at least one identifier is required):

<input type="text" value="10001"/>	and	<input type="text" value="DEA"/>	<input type="text" value="NPI"/>	<input type="text" value="3456789"/>
------------------------------------	-----	----------------------------------	----------------------------------	--------------------------------------

If the search results have returned your record, please highlight the row and press **Submit**. If you do not see your record, please try your search again or contact the Clozapine REMS Program for assistance.

Pharmacy Name	Pharmacy Address	Pharmacy Phone
CVS	423 Main Street, Tampa FL 33614	555-555-5555

Showing 1 of 1 entries

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14.6.3 Add Lab and Eligibility Check

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Eligibility Check

To determine if the safe use conditions have been met for your patient to receive clozapine, please complete the Eligibility Check information below and **Submit**. If you have lab information for your patient you may enter it here. The results of the Eligibility Check will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

Add Patient Lab (optional)

Eligibility Check Request (optional)

[?](#)

▾

▾

At least one identifier is required

[Cancel](#) [Submit](#)

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14.6.4 Eligibility Check Result – Unsuccessful

This result is displayed for both the Predispose Authorization and the Eligibility Check when the result is unsuccessful.

The screenshot shows the Clozapine REMS website interface. At the top, the logo and tagline are present. A navigation menu includes links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support. A user profile for Summer Hogan and a My Dashboard button are visible in the top right. The main heading is "Eligibility Check Result". A prominent red warning box states: "Do not dispense clozapine to this patient." Below this, a patient summary card for Chester Smith is shown, listing fields for Name and DOB. To the right of the patient information, a list of reasons for the failed eligibility check is provided, each marked with a red 'X':

- ✘ The patient is not enrolled in the REMS program
- ✘ The prescriber is not certified in the REMS program
- ✘ Acceptable patient lab is not on file
- ✘ **Lab Status Lab was not saved**

Below the list, a note reads: "For further assistance with this patient's eligibility, please contact the patient's prescriber." A printer icon is located in the bottom right corner of the patient summary card. At the bottom of the page, a footer contains the text: "For additional information about the Clozapine REMS Program, please call 844-267-8678." and a navigation bar with links for Privacy, Terms of Use, Site Map, FAQs, and Contact Us.

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14.6.5 Add Lab and Predispose Authorization

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Predispose Authorization

To determine if the safe use conditions have been met for your patient to receive clozapine, please complete the Predispose Authorization information below and **Submit**. If you have lab information for your patient you may enter it here. The results of the Predispose Authorization will be displayed after the information is submitted. All fields listed below are required unless otherwise indicated.

Patient Information

Add Patient Lab (optional)

Predispose Authorization Request

?

▾

▾

At least one identifier is required

[Cancel](#) [Submit](#)

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14.6.6 Predispense Authorization Result – Successful

This result is displayed for both the Predispense Authorization and the Eligibility Check when the result is successful.

The screenshot shows the top navigation bar of the Clozapine REMS website. On the left is the logo with the tagline 'The Single Shared System for Clozapine No Blood, No Drug™'. On the right, there is a user profile for 'Summer Hogan' with a 'My Dashboard' button. A horizontal navigation menu includes links for Home, Prescriber, Pharmacy, Patient, Resources, Important Safety Information, and Support.

Predispense Authorization

✓ You are now authorized to dispense clozapine to the below patient.

Name Chester Smith	Lab Status Lab was saved
DOB 03/05/1983	
Predispense Authorization Code XXXXXXX	

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