CLOZAPINE REMS

Clozapine REMS Program

Pharmacy Professional Society Meeting

August 19, 2021

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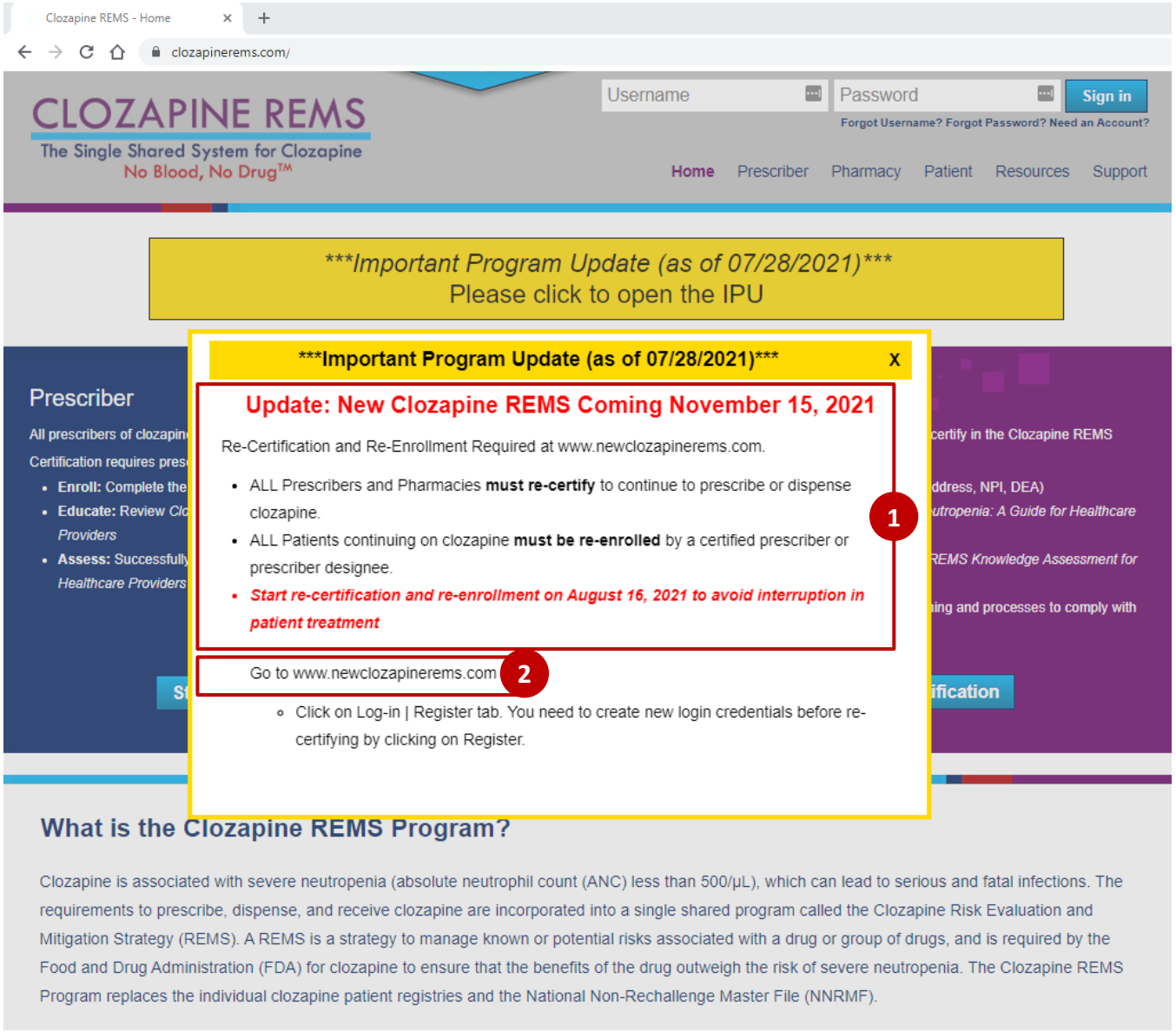
CLOZAPINE REMS

Demonstration of REMS Website



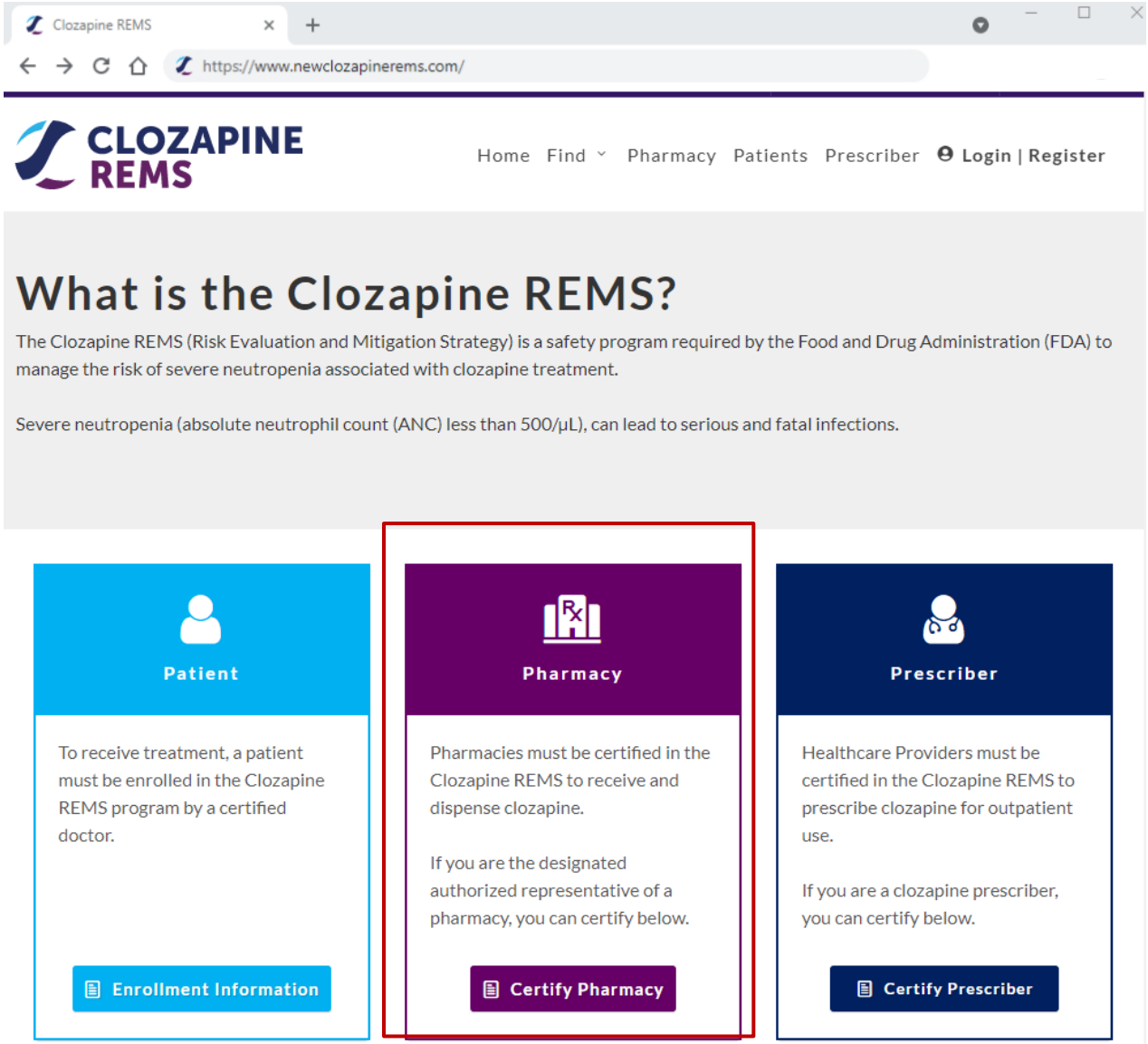
Until November 15, 2021, continue to use the ClozapineREMS.com website to ensure safe use conditions are met.

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

2 ***To certify in the modified program, go to NewClozapineREMS.com, as noted on the Important Program Update on the homepage of ClozapineREMS.com.***

CLOZAPINE REMS

Demonstration of REMS Website (Continued)



To facilitate a smooth transition to the modified Clozapine REMS program on November 15, we encourage pharmacies to certify in the modified program now via

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

Click Certify Pharmacy on the homepage to start the certification process.

How to Certify: Introduction

All inpatient and outpatient pharmacies must certify in the Clozapine REMS to purchase and dispense clozapine. The requirements for outpatient pharmacies are different from the requirements for inpatient pharmacies.

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

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

- The designated authorized representative for the pharmacy will complete the *Inpatient Pharmacy Enrollment Form* and/or the *Outpatient Pharmacy Enrollment Form*. This form is to certify a single inpatient or a single outpatient pharmacy location.
- The authorized representative for the pharmacy or pharmacies can certify the pharmacy online or by fax.
- Certifying multiple pharmacy locations must be completed online.

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How to Certify: Introduction (Continued)

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

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

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

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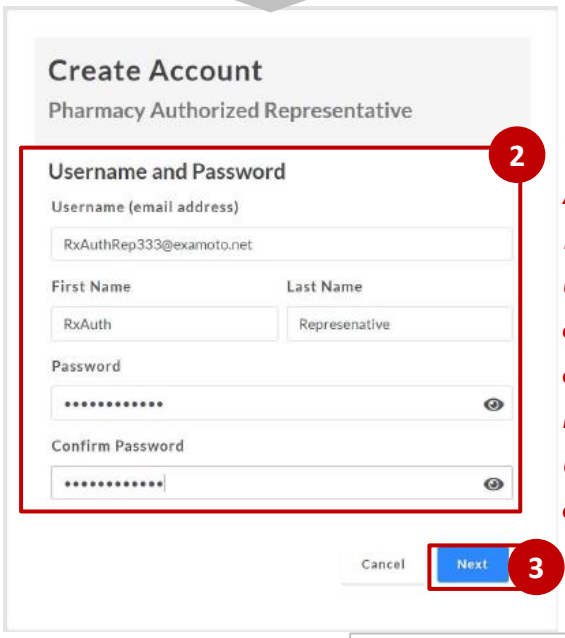
CLOZAPINE REMS

How to Certify: Register

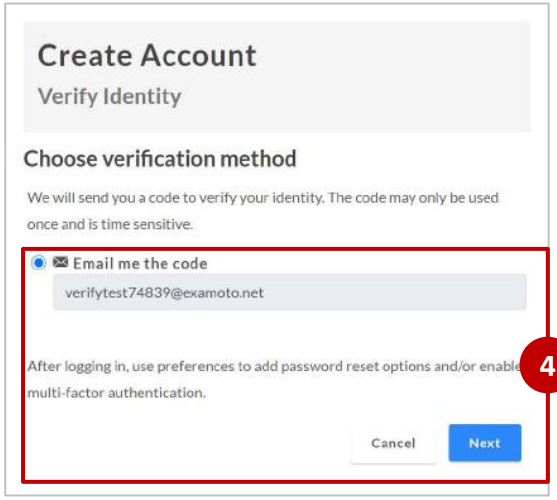
All users must create new REMS login credentials. Legacy system credentials will not work in the new system.

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

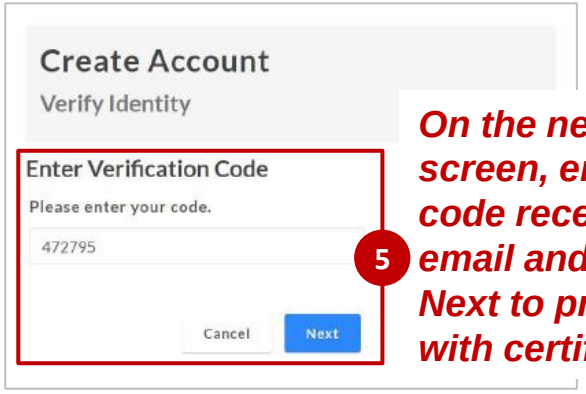


Type in the Authorized Representative's username, first and last name, and password, noting that the username must be an email address.

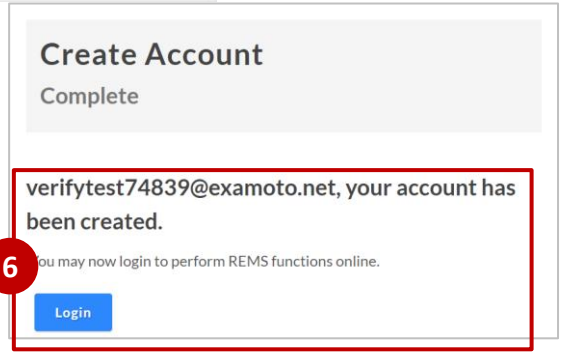
Then Click Next.



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

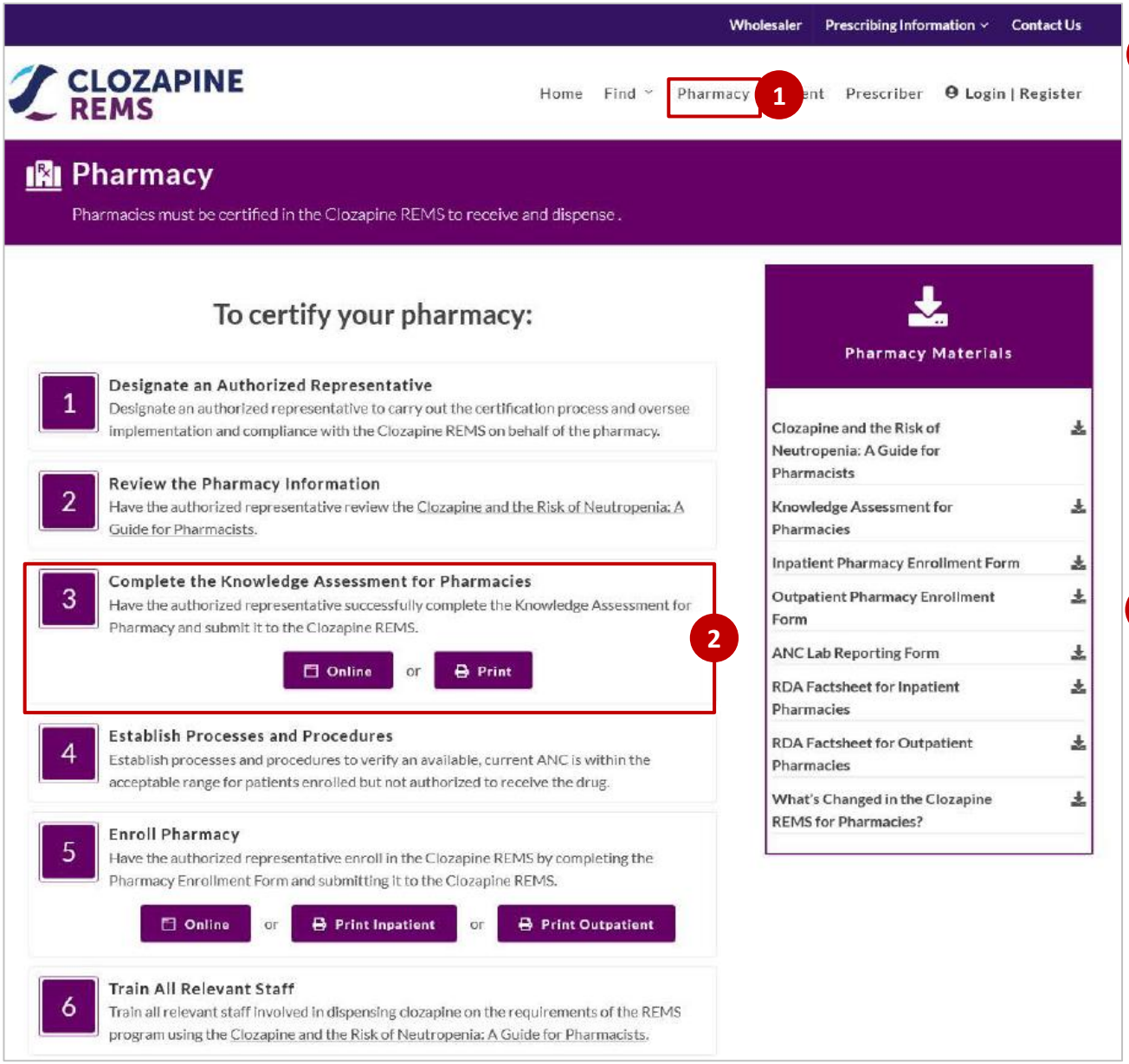


On the next screen, enter the code received via email and click Next to proceed with certification.



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

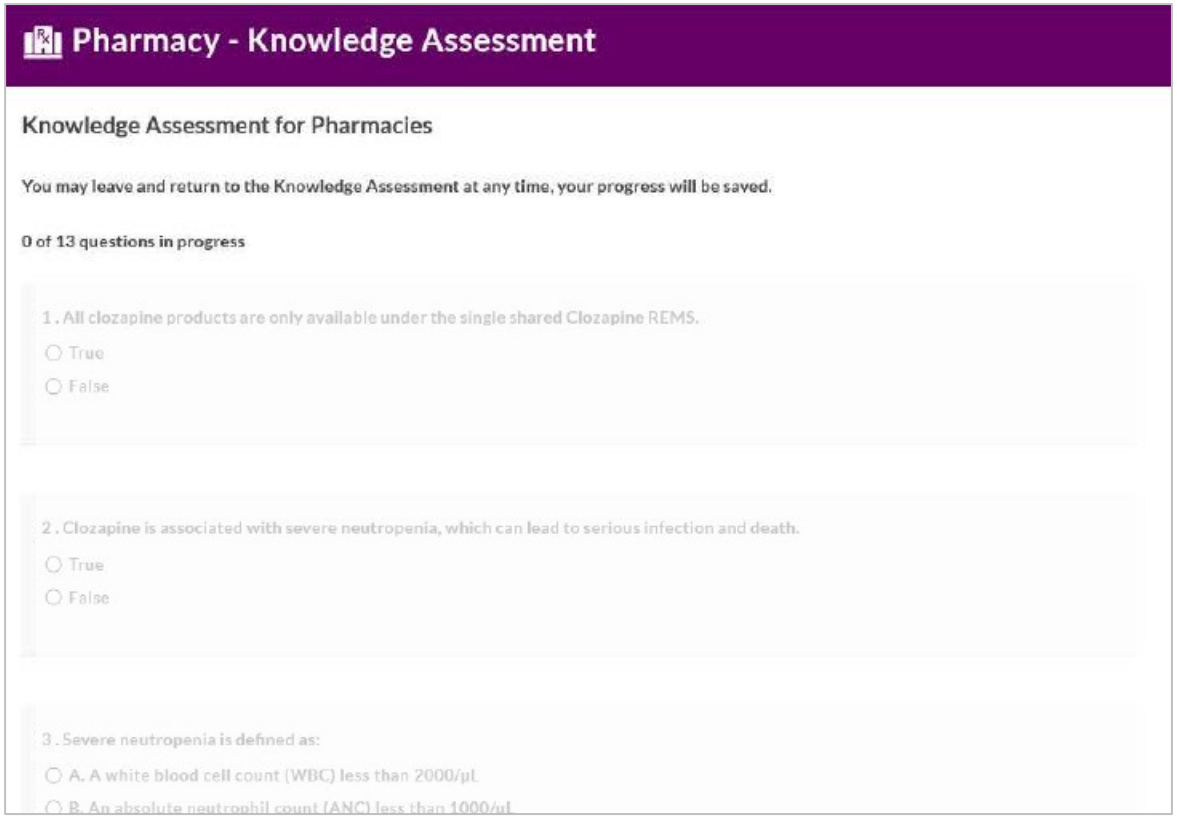
How to Certify: Knowledge Assessment



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

2 ***Following completion of Steps 1 and 2, complete the Knowledge Assessment by clicking Online under Step 3.***

How to Certify: Knowledge Assessment (Continued)



The Authorized Representative must successfully complete a 13-question Knowledge Assessment.

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

Following successful completion of the Knowledge Assessment, the Authorized Representative can continue the certification process.

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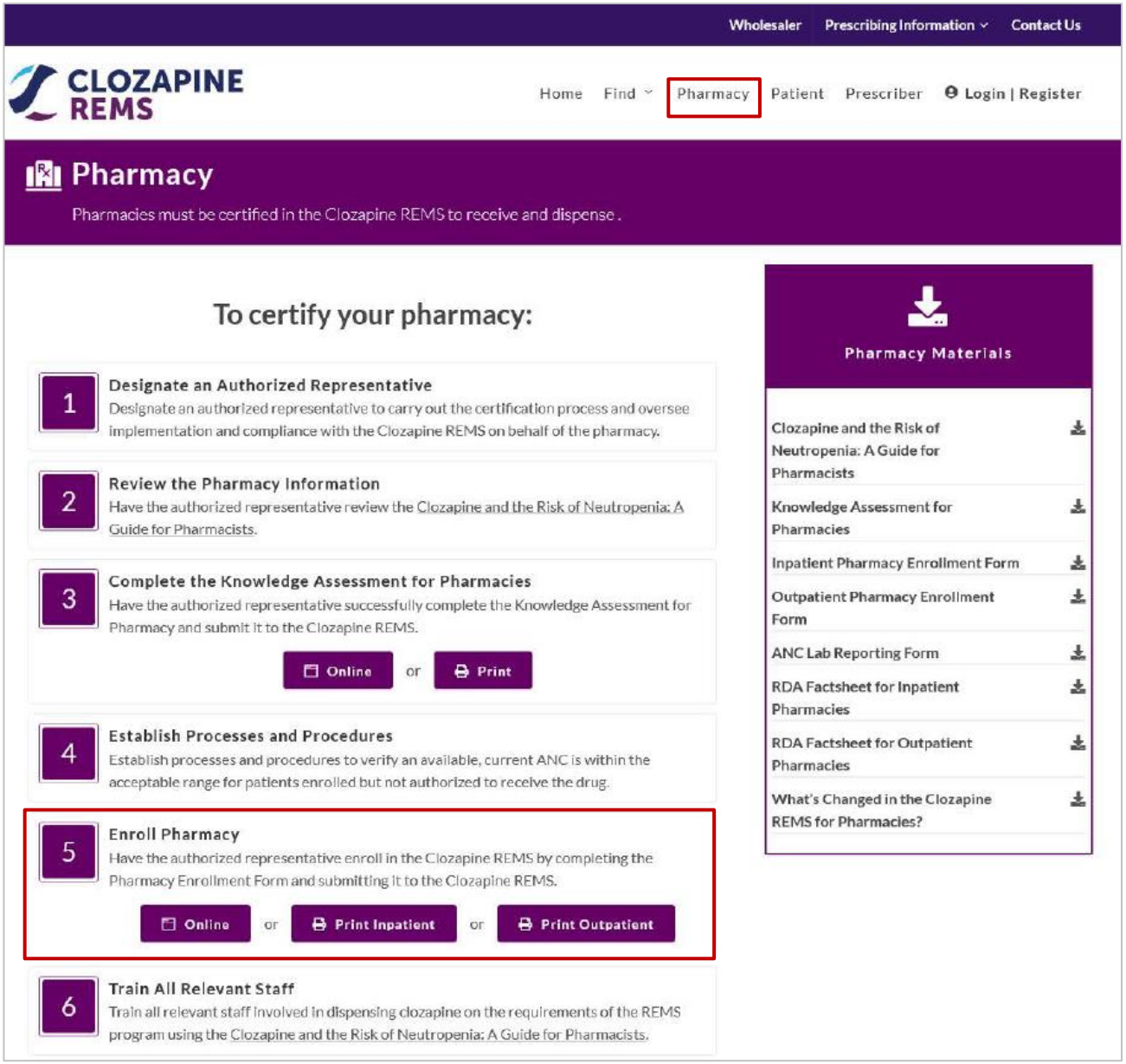
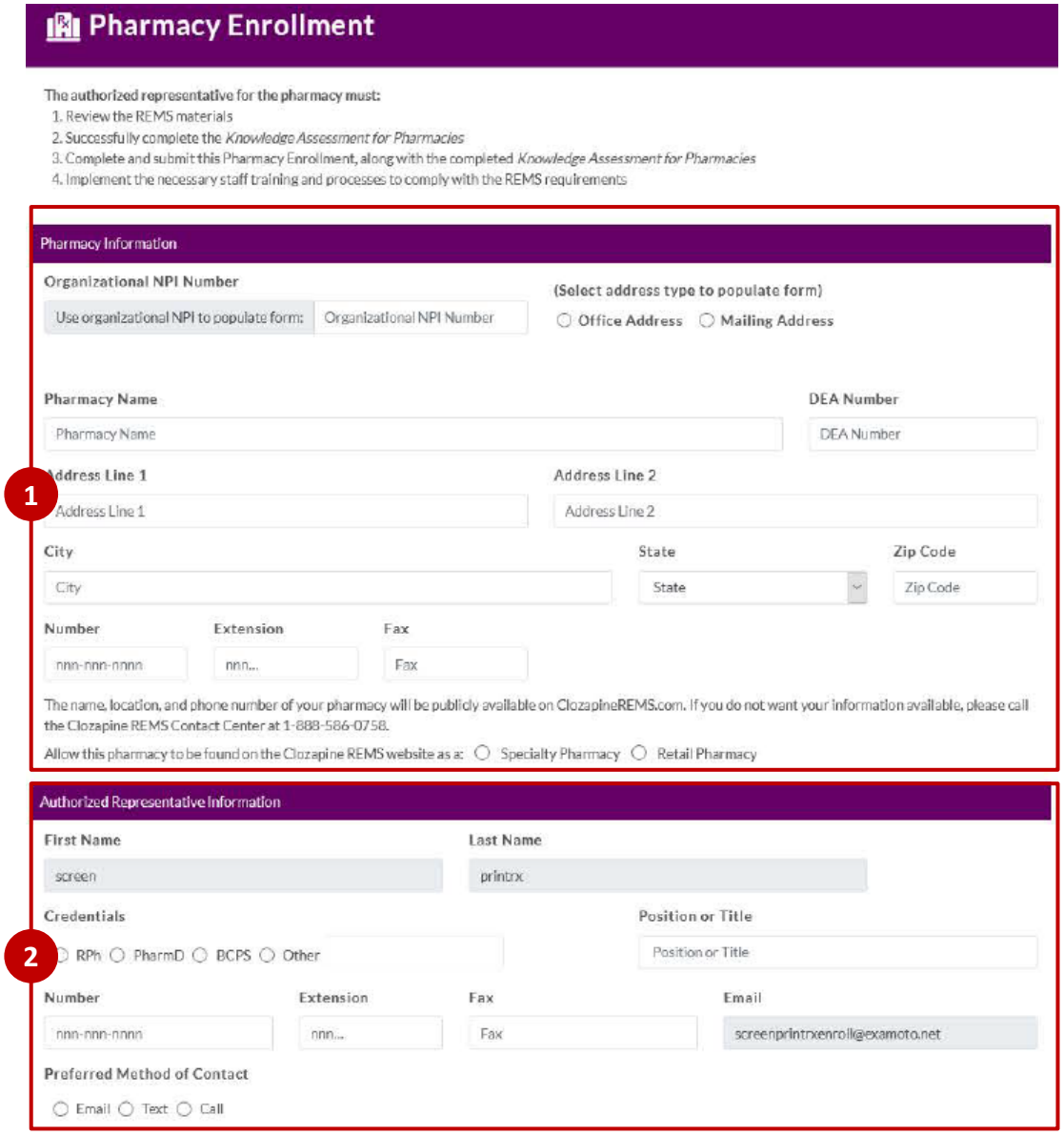
How to Certify: Enrollment



After completing Step 4, the Authorized Representative needs to complete enrollment by clicking Online under Step 5.

How to Certify: Enrollment (Continued)



Pharmacy Enrollment

The authorized representative for the pharmacy must:
1. Review the REMS materials
2. Successfully complete the *Knowledge Assessment for Pharmacies*
3. Complete and submit this Pharmacy Enrollment, along with the completed *Knowledge Assessment for Pharmacies*
4. Implement the necessary staff training and processes to comply with the REMS requirements

Pharmacy Information

Organizational NPI Number
Use organizational NPI to populate form: Organizational NPI Number

(Select address type to populate form)
Office Address Mailing Address

Pharmacy Name
Pharmacy Name

DEA Number
DEA Number

1

Address Line 1
Address Line 1

Address Line 2
Address Line 2

City
City

State
State

Zip Code
Zip Code

Number
nnn-nnn-nnnn

Extension
nnn...

Fax
Fax

The name, location, and phone number of your pharmacy will be publicly available on ClozapineREMS.com. If you do not want your information available, please call the Clozapine REMS Contact Center at 1-888-586-0758.

Allow this pharmacy to be found on the Clozapine REMS website as a: Specialty Pharmacy Retail Pharmacy

Authorized Representative Information

First Name
screen

Last Name
printrx

Credentials

2

RPh PharmD BCPS Other

Position or Title
Position or Title

Number
nnn-nnn-nnnn

Extension
nnn...

Fax
Fax

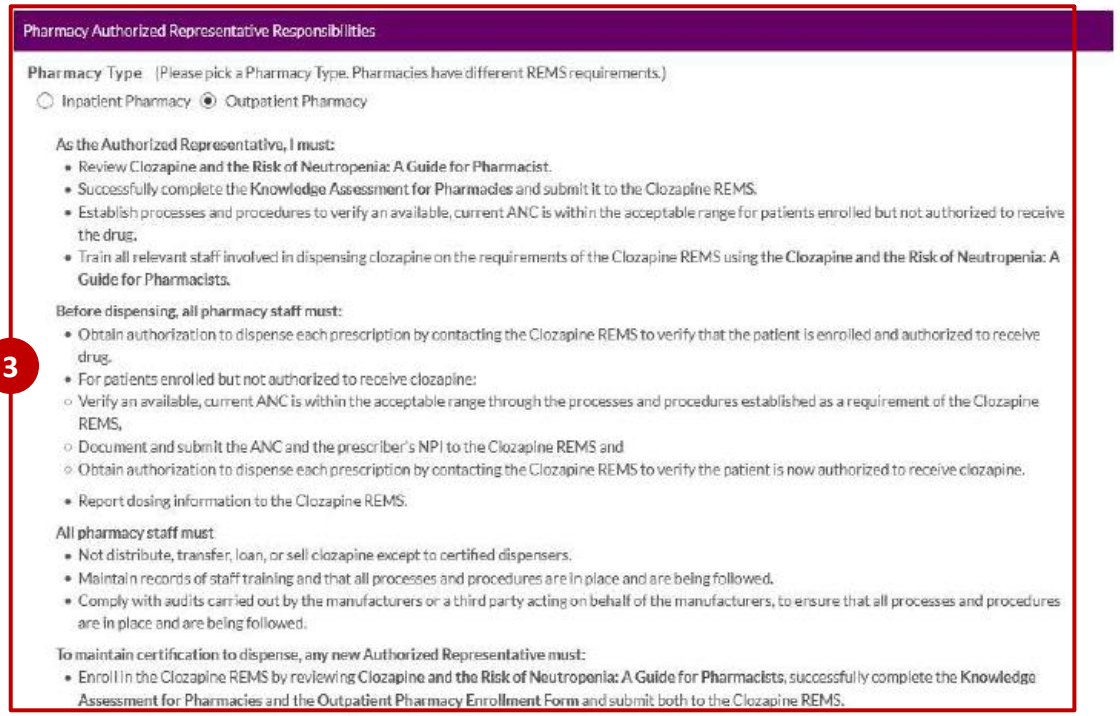
Email
screenprintrxenroll@examoto.net

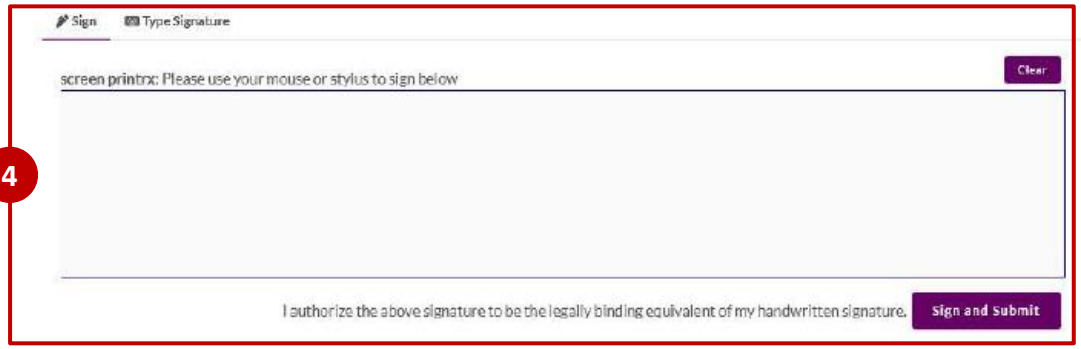
Preferred Method of Contact
Email Text Call

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

…information about themselves (e.g., individual contact information and preferences),…

How to Certify: Enrollment (Continued)





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

The final step is to sign and submit the form.

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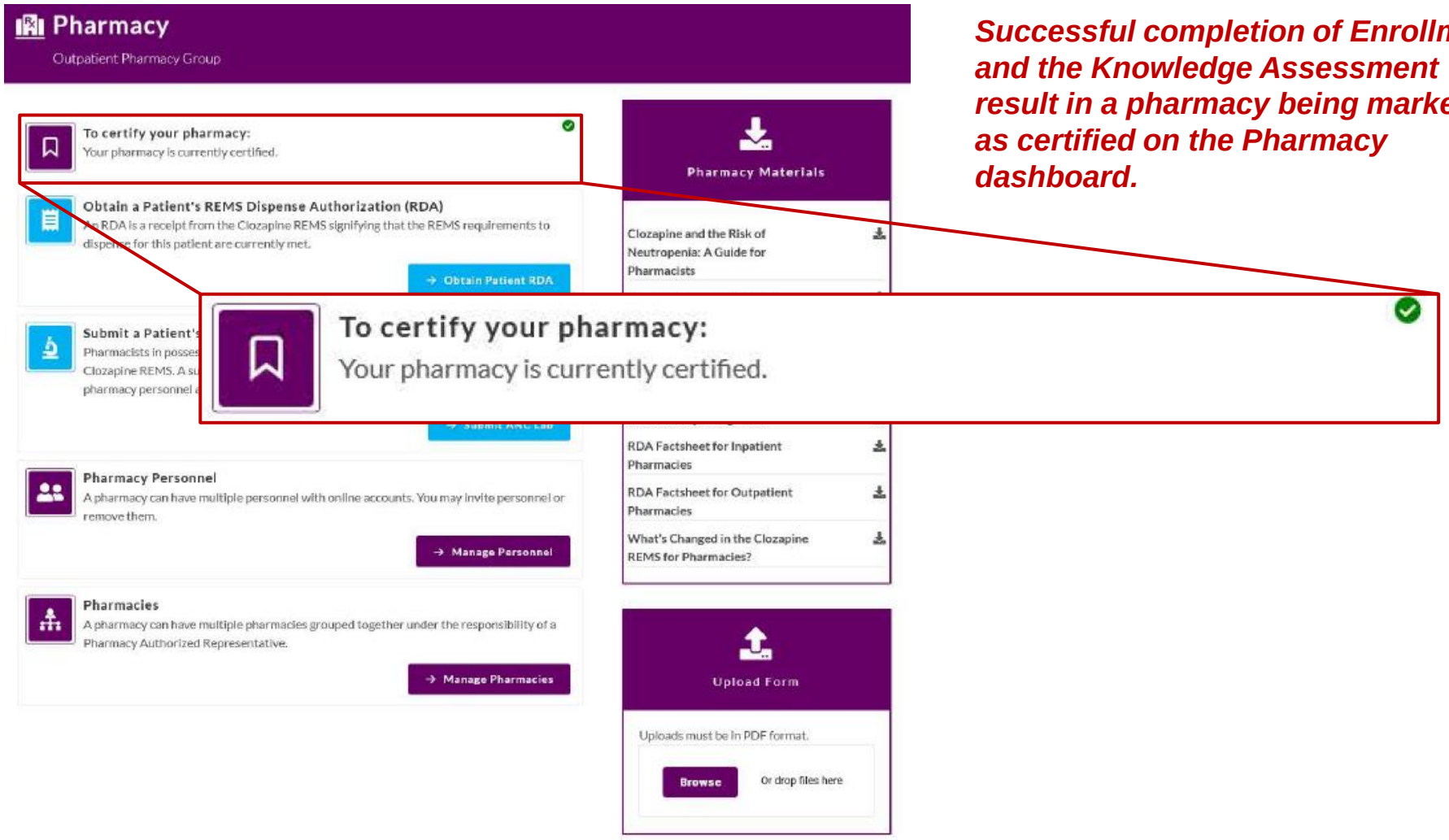
How to Certify: Certification Completion



Successful completion of Enrollment and the Knowledge Assessment result in a pharmacy being marked as certified on the Pharmacy dashboard.

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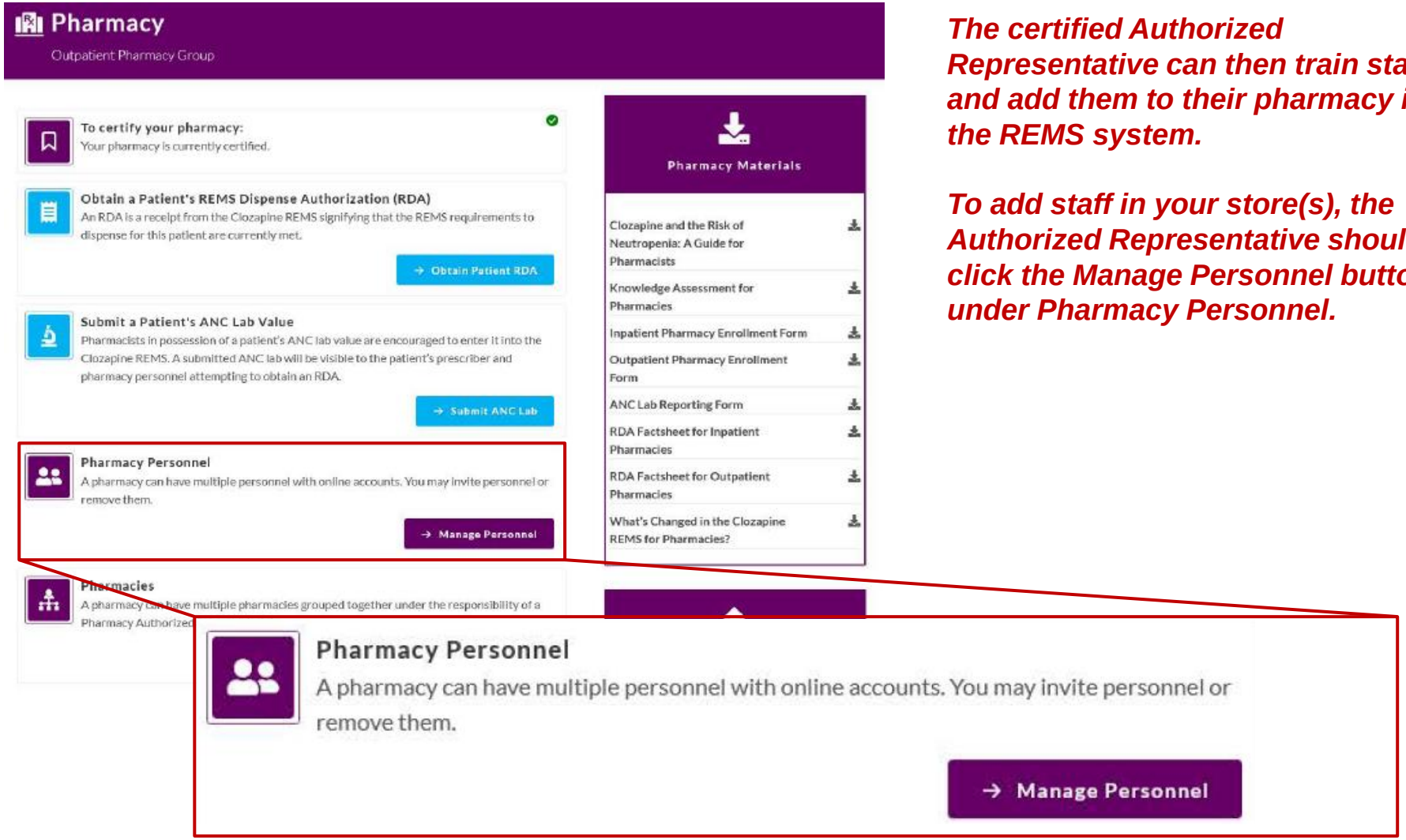
How to Certify: Adding Pharmacy Staff



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

To add staff in your store(s), the Authorized Representative should click the Manage Personnel button under Pharmacy Personnel.

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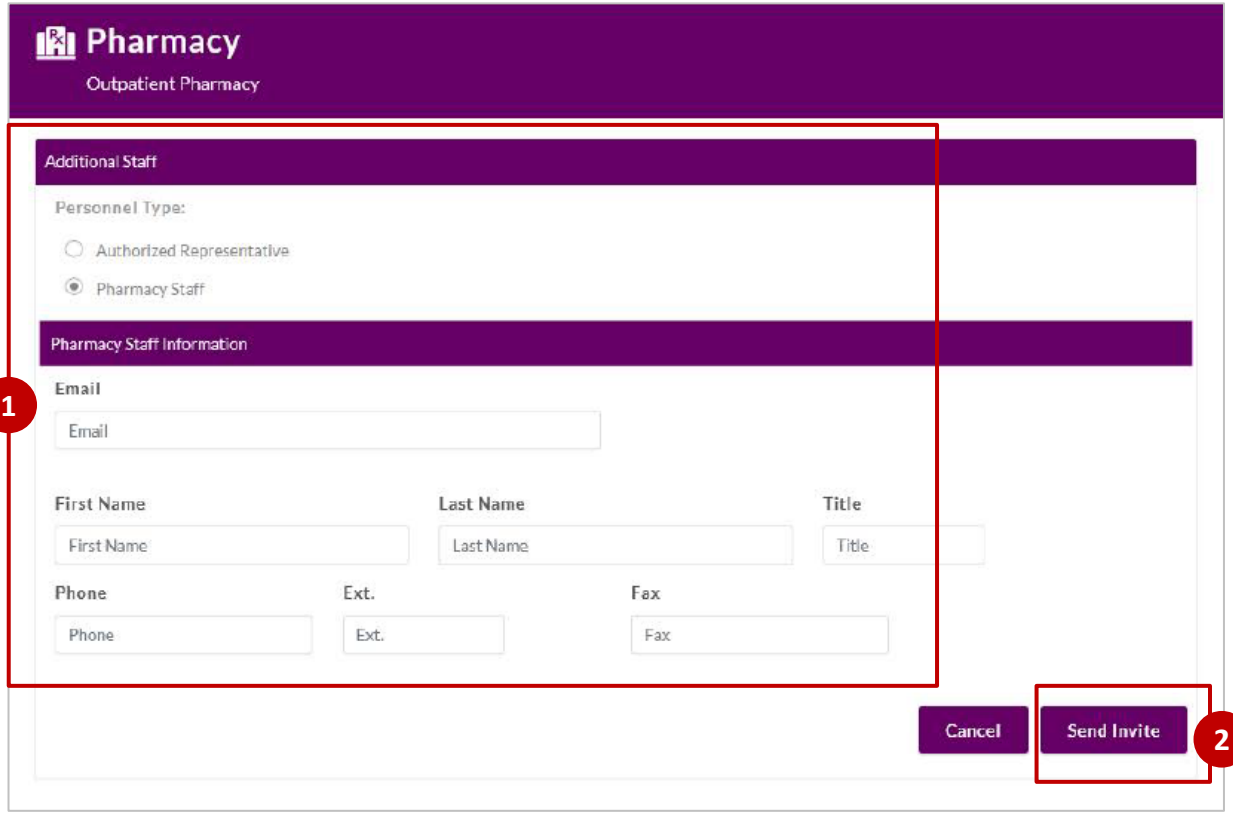
How to Certify: Adding Pharmacy Staff (Continued)



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

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

2 ***The REMS system will email the staff member a message that includes a link to establish their own user credentials for login.***

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CLOZAPINE REMS

How to Obtain an RDA: Introduction

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

Until November 15, continue to use the legacy REMS system.

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CLOZAPINE REMS

How to Obtain an RDA: Introduction (Continued)

An RDA is an electronic code that indicates the Clozapine REMS has verified that all safe use conditions have been met.

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

Obtain an RDA in one of two ways:

By using the Clozapine REMS website at www.clozapinerems.com

By calling the Clozapine REMS Contact Center at 888-586-0758

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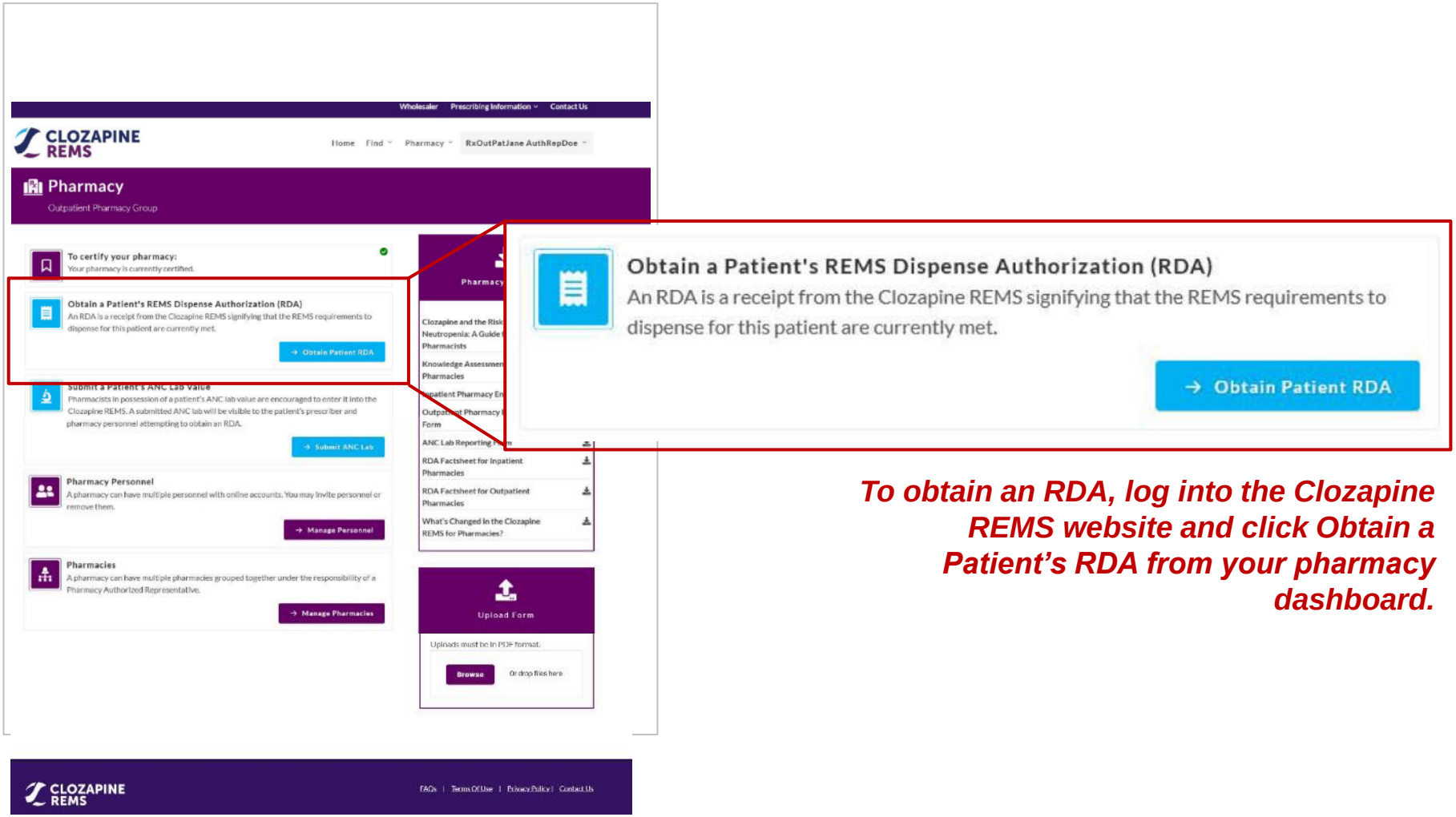
CLOZAPINE REMS

How to Obtain an RDA: Pharmacy Dashboard



To obtain an RDA, log into the Clozapine REMS website and click Obtain a Patient's RDA from your pharmacy dashboard.

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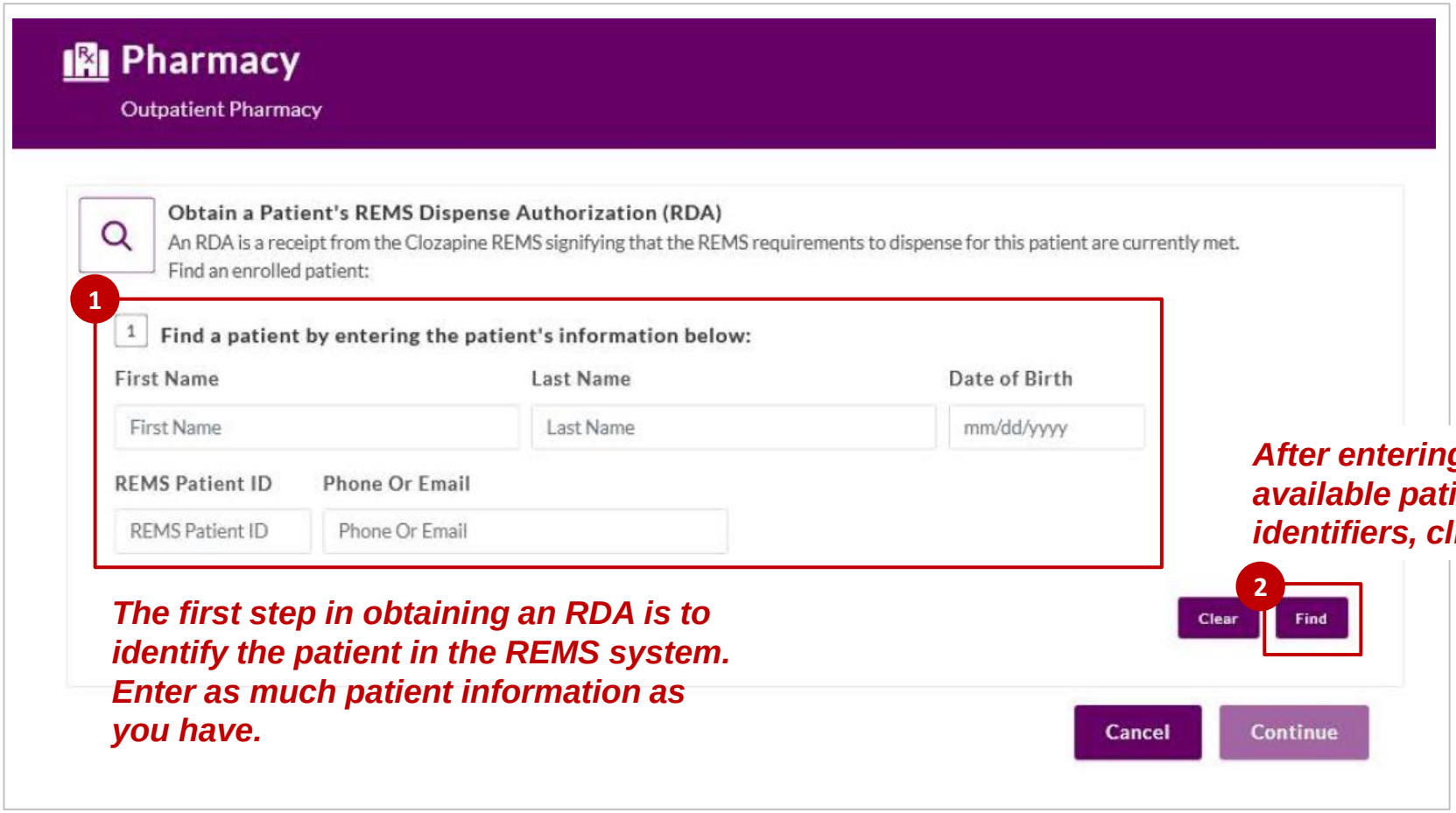
How to Obtain an RDA: Find Patient



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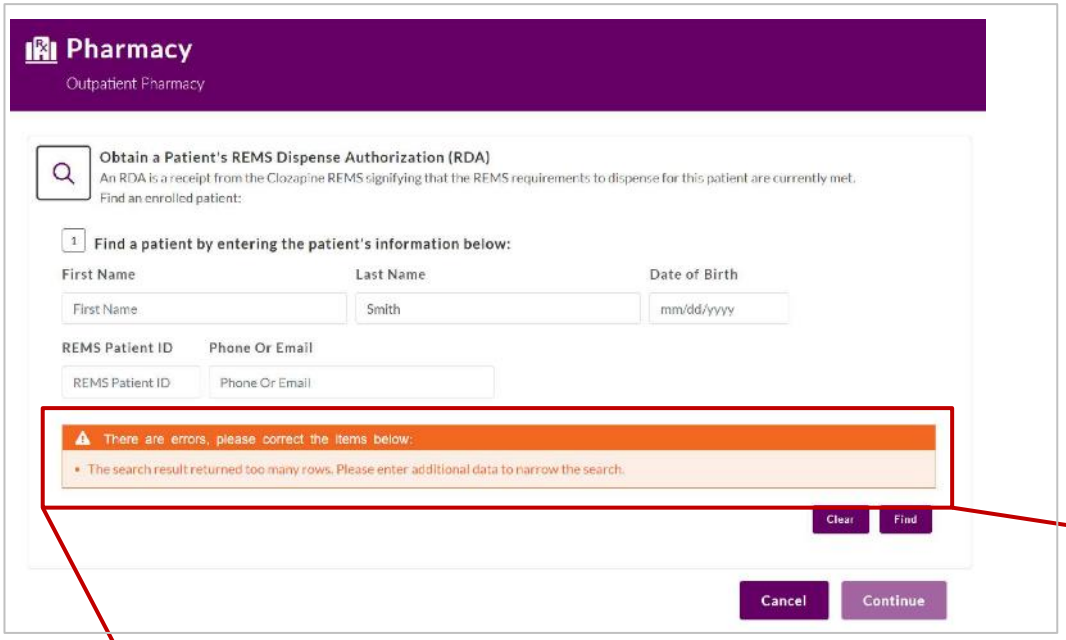
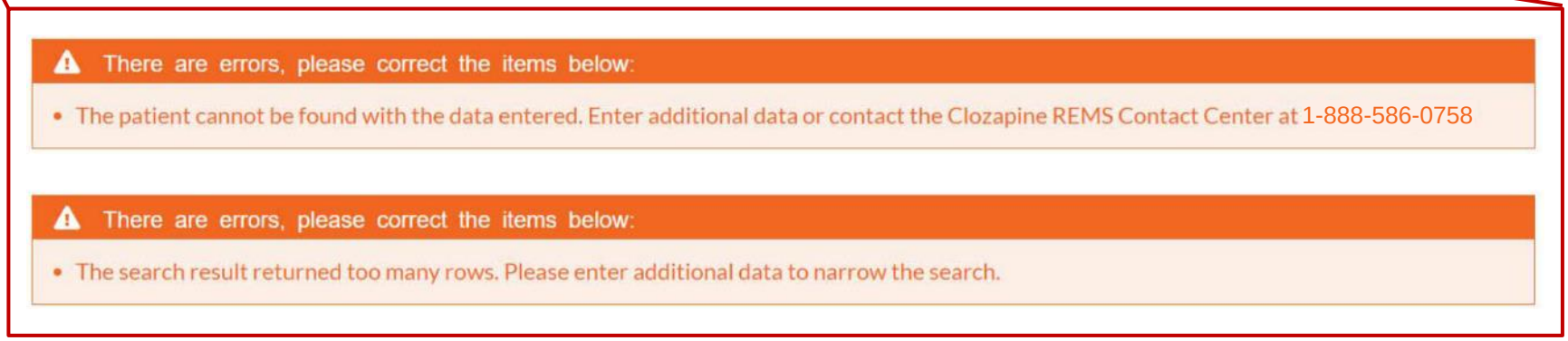
How to Obtain an RDA: Find Patient (Continued)



The patient search may return error messages, like those seen below.

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

You can also call the REMS Contact Center for assistance.



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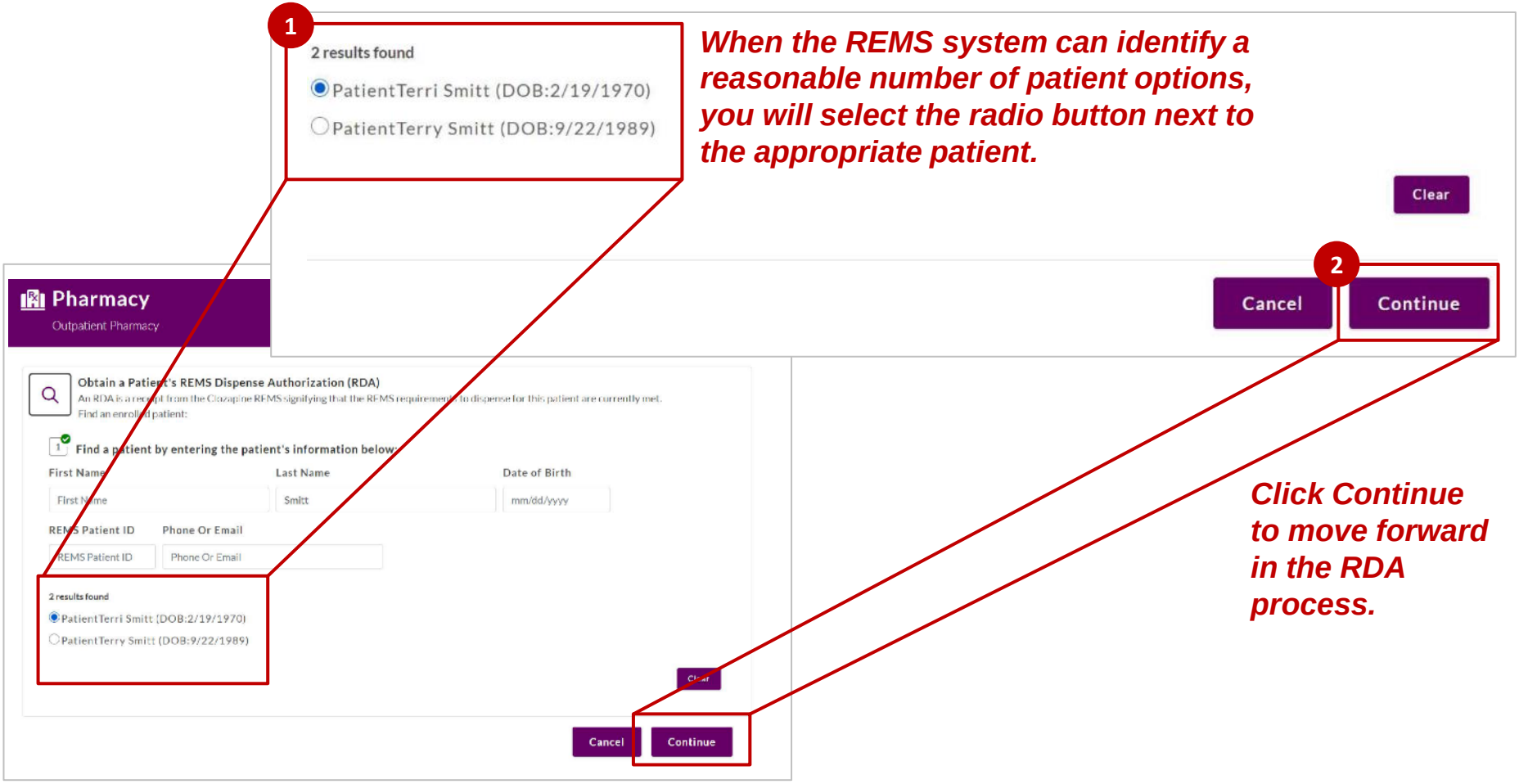
CLOZAPINE REMS

How to Obtain an RDA: Find Patient (Continued)



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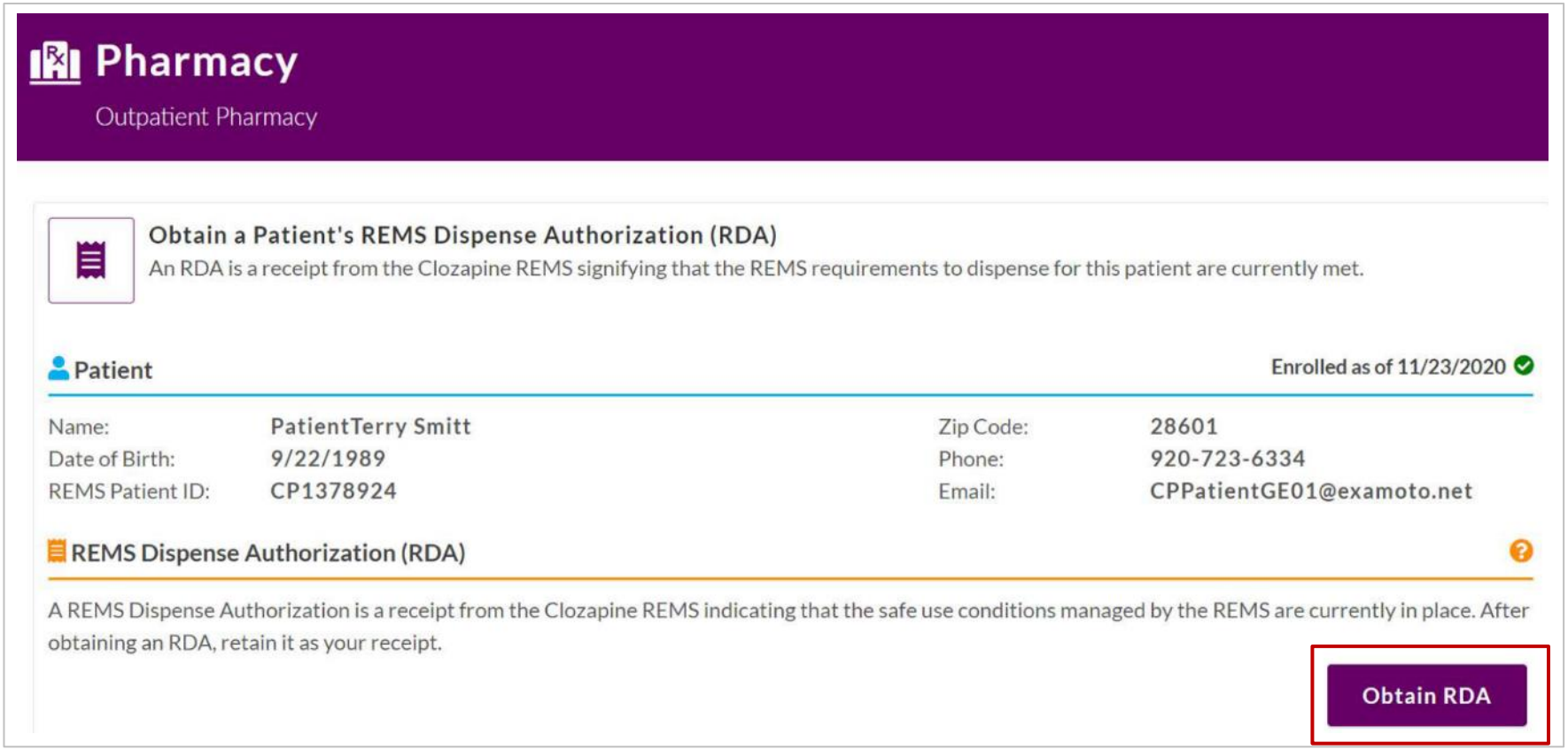
How to Obtain an RDA: Obtain RDA



On the next screen, you can confirm that you have the correct patient and click the Obtain RDA button to request an RDA for that patient.

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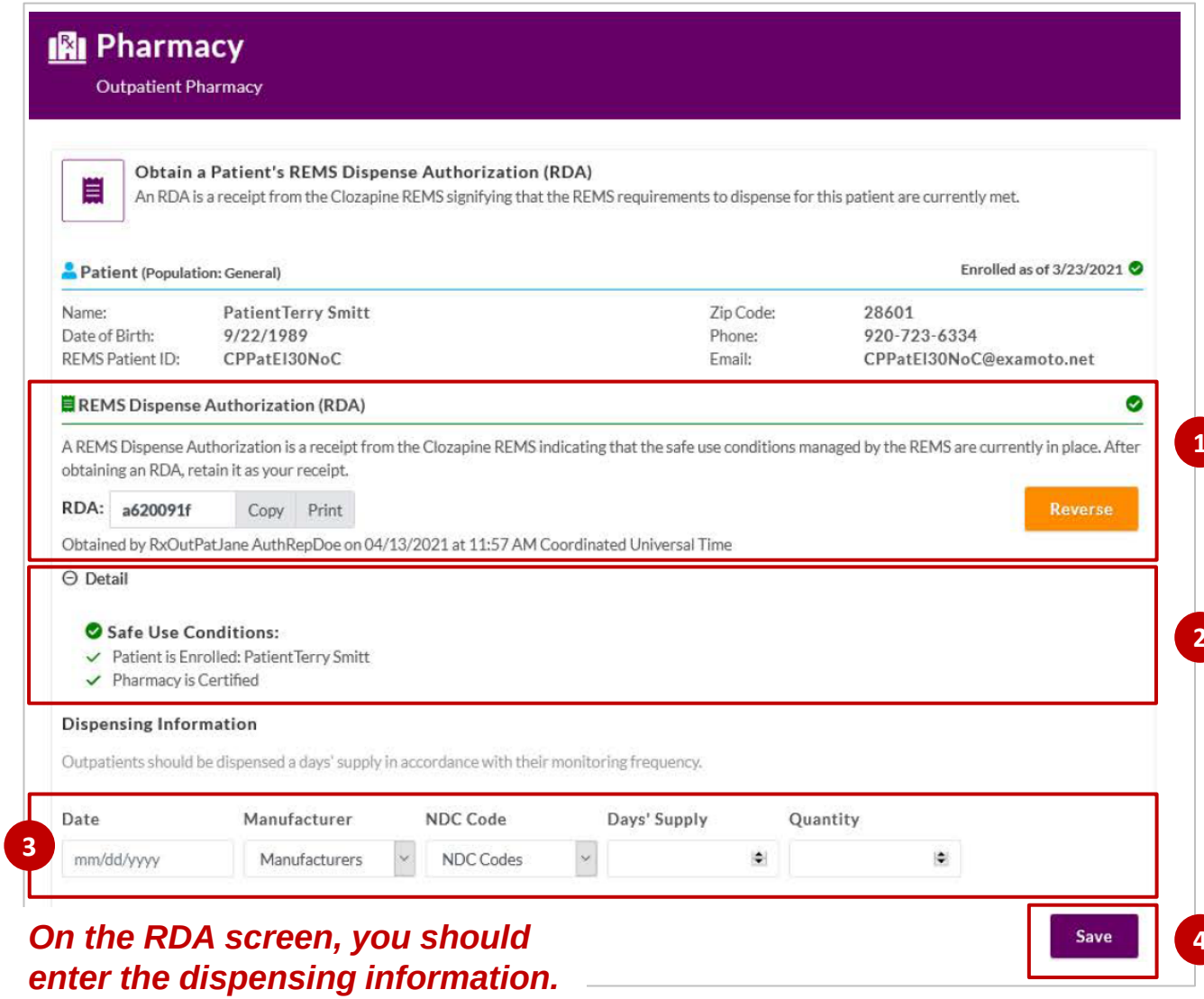
CLOZAPINE REMS

How to Obtain an RDA: Obtain RDA—Safe Use Conditions Met



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

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

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

4 *Upon entry of the dispensing information, click Save.*

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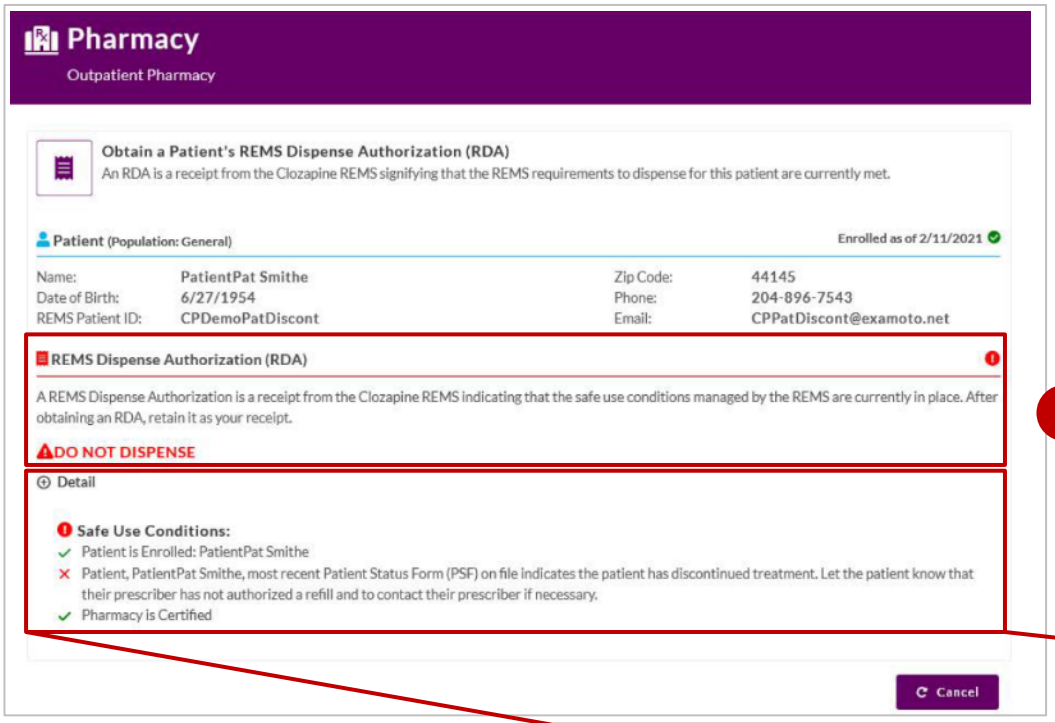
CLOZAPINE REMS

How to Obtain an RDA: Obtain RDA—Safe Use Conditions NOT Met



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

You can click Detail to see why the RDA was not issued, such as the examples shown here.

2

Safe Use Conditions:
- Patient is Enrolled: PatientAli Smithson
- Patient, PatientAli Smithson, most recent Patient Status Form (PSF) on file indicates the patient has interrupted treatment. Let the patient know that their prescriber has not authorized a refill and to contact their prescriber if necessary.
- Pharmacy is Certified

Safe Use Conditions:
- Patient is Enrolled: PatientHospPat Smith
- General population Patient, PatientHospPat Smith, has a Dispense Rationale with an ANC greater than 999 per µl.
- Pharmacy is Certified
- Patient, PatientHospPat Smith, has a reached the Dispense Rationale limit. Please contact the patient's prescriber, the prescriber is required to submit a Patient Status Form (PSF) for this patient to receive drug.
- Prescriber is Certified: PRJane PRDoe

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How to Obtain an RDA: Reverse RDA

If a prescription is not dispensed to the patient and is returned to stock, the RDA must be reversed. To reverse an RDA, log into your account at www.clozapinerems.com and select the Reverse RDA button.

Find the patient and follow the directions.

You may also reverse an RDA by calling the Clozapine REMS Contact Center at 888-586-0758.

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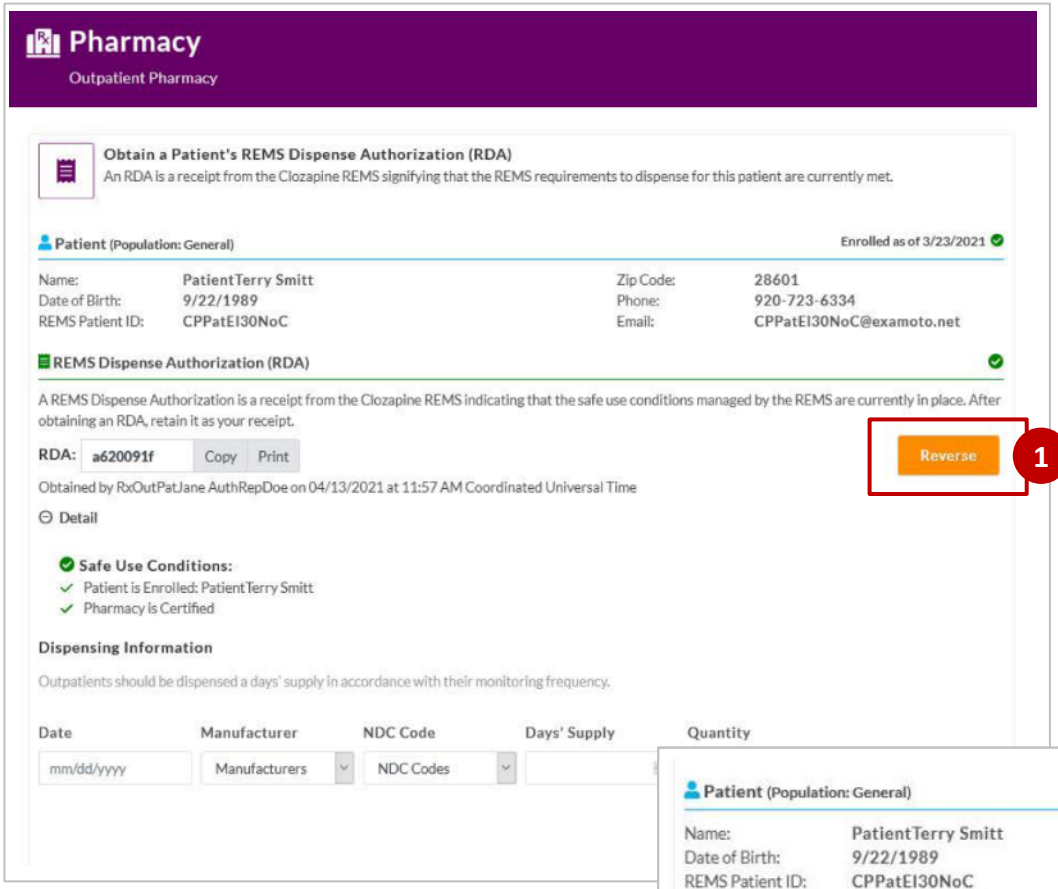
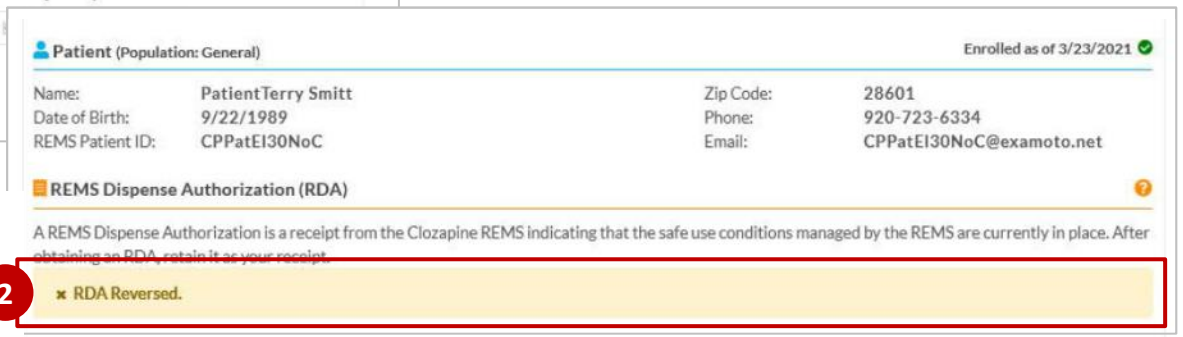
CLOZAPINE REMS

How to Obtain an RDA: Reverse RDA (Continued)



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

The following screen will display a confirmation that the RDA was reversed.



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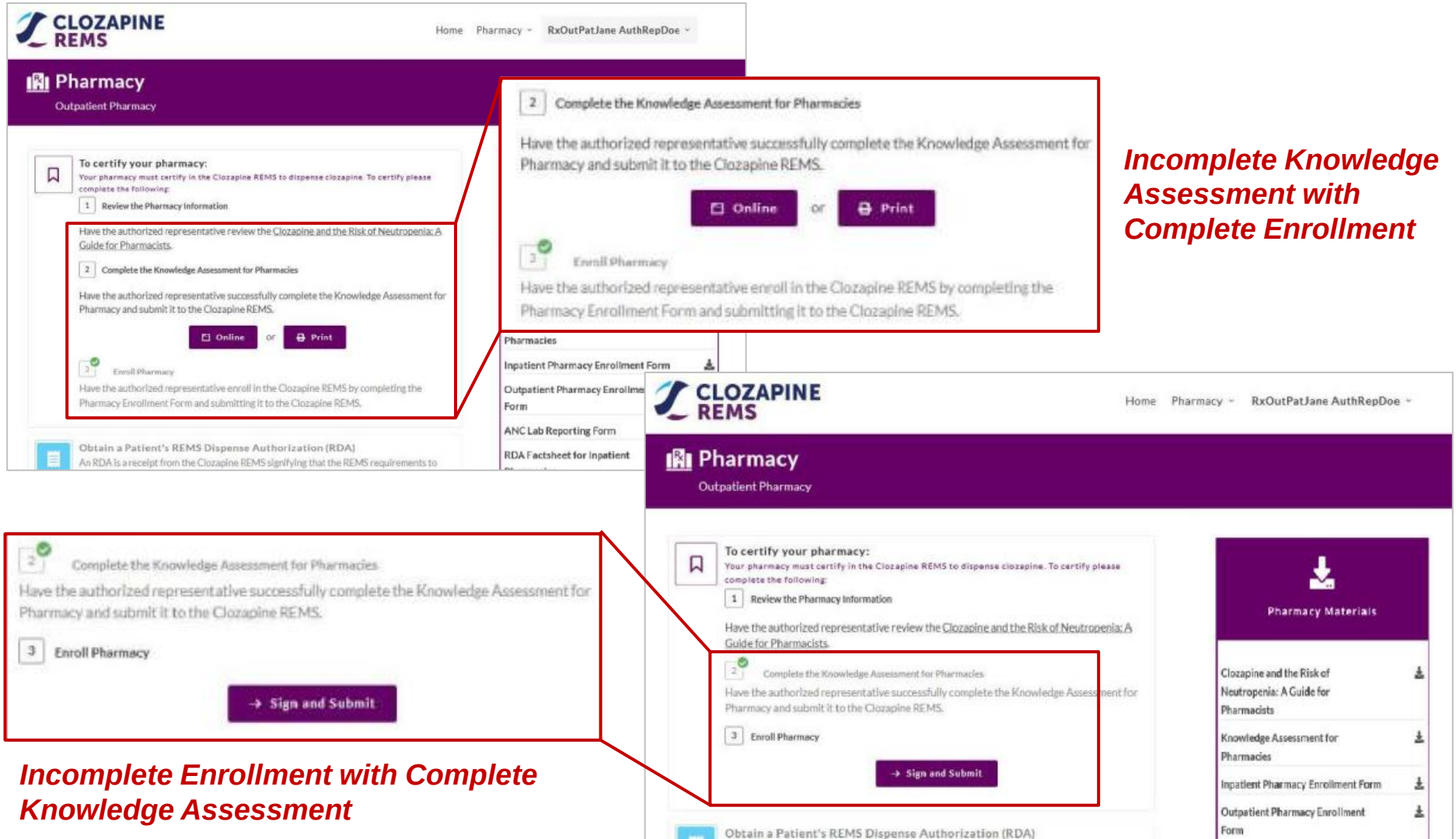
CLOZAPINE REMS

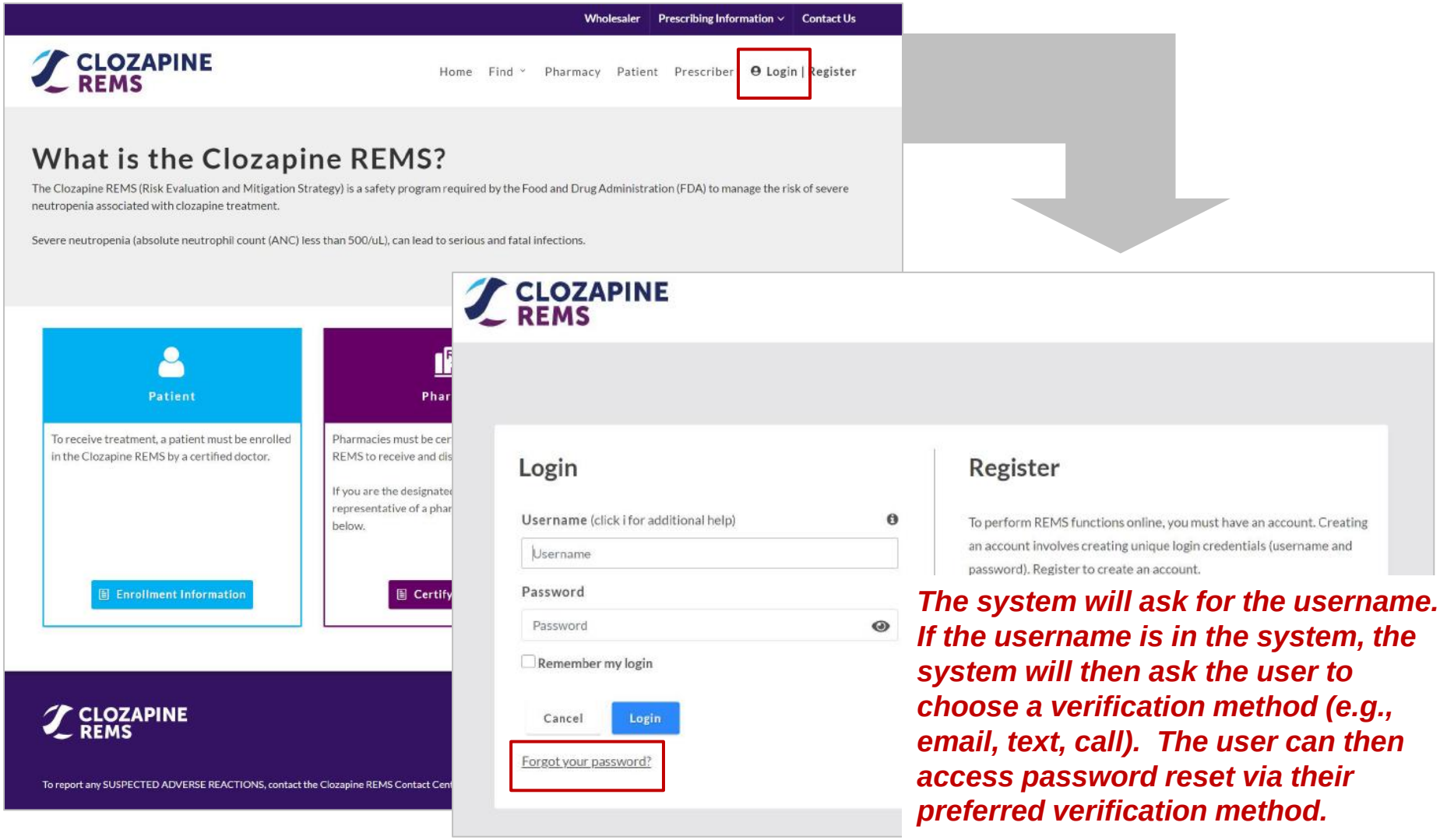
How to Troubleshoot Common Issues: Incomplete Certification

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



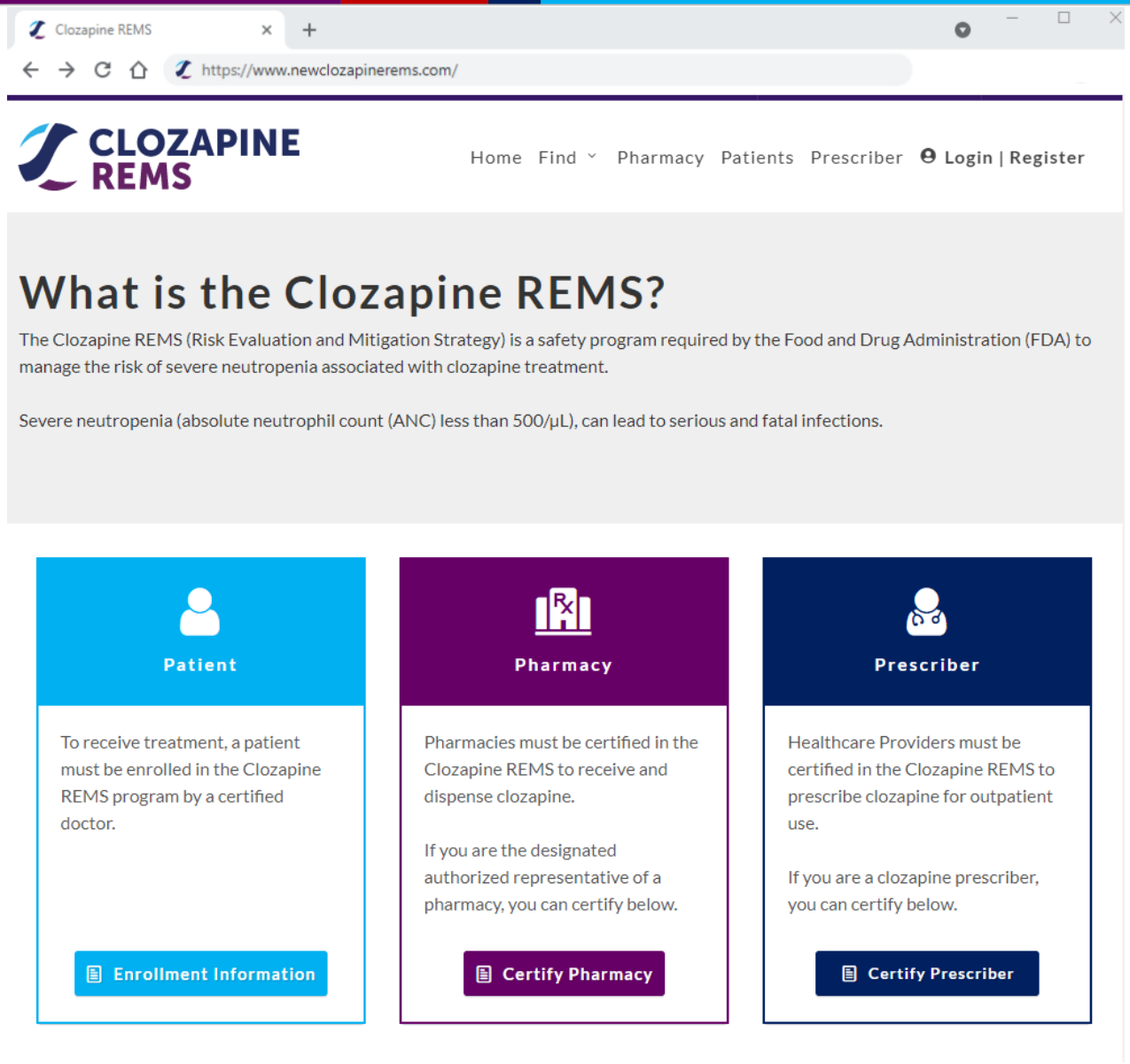
How to Troubleshoot Common Issues: Lost/Forgotten Password

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



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

Closing



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

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