CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219083Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document
MYQORZO™ (aficamten) REMS

I. Administrative Information

Risk: heart failure due to systolic dysfunction
Application Number: NDA 219083
Application Holder: Cytokinetics, Inc.
Initial REMS Approval: 12/2025

II. REMS Goal

The goal of the MYQORZO REMS is to mitigate the risk of heart failure due to systolic dysfunction.

Objective 1: Healthcare providers monitor left ventricular ejection fraction (LVEF) by echocardiogram during treatment according to the frequency described in the Prescribing Information to detect heart failure due to systolic dysfunction.

III. REMS Requirements

Cytokinetics, Inc. must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe MYQORZO must:	
To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the REMS Overview and Education Program for Healthcare Providers and Pharmacies. 3. Successfully complete the Healthcare Provider Knowledge Assessment and submit it to the REMS. 4. Enroll by completing and submitting the Healthcare Provider Enrollment Form to the REMS.
Before treatment initiation (first dose)	5. Counsel the patient on the risk of heart failure due to systolic dysfunction using the Patient Guide. Provide a copy of the material to the patient. 6. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit confirmation of review of the patient's echocardiogram results and authorization for treatment to the REMS using the Patient Enrollment Form. 7. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS.

During treatment, between 2 to 8 weeks after treatment initiation and each dose adjustment, then every 3 or 6 months thereafter (depending on echocardiogram results)	8. Counsel the patient on the risk of heart failure due to systolic dysfunction using the Patient Guide. 9. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. 10. Document and submit confirmation of review of the patient's echocardiogram results and authorization for treatment to the REMS using the Patient Monitoring Form.
At all times	11. Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc.
2. Patients who are prescribed MYQORZO must:	
Before treatment initiation (first dose)	1. Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction (where the heart cannot pump with enough force) using the Patient Guide. 2. Get an echocardiogram to check their heart. 3. Enroll in the REMS by completing the Patient Enrollment Form with the healthcare provider. Enrollment information will be provided to the REMS.
During treatment, between 2 to 8 weeks after treatment initiation and each dose adjustment, then every 3 or 6 months thereafter (depending on echocardiogram results)	4. Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction (where the heart cannot pump with enough force) using the Patient Guide. 5. Get an echocardiogram to check their heart.
At all times	6. Inform the healthcare provider or seek other medical attention if there are new or worsening symptoms of heart failure.
3. Pharmacies that dispense MYQORZO must:	
To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the Authorized Representative review the Prescribing Information, REMS Overview, and Education Program for Healthcare Providers and Pharmacies. 3. Have the Authorized Representative enroll by completing and submitting the Pharmacy Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing MYQORZO using the REMS Overview and Education Program for Healthcare Providers and Pharmacies.
Before dispensing	5. Obtain authorization to dispense each prescription from the MYQORZO REMS to verify that the healthcare provider is certified, the patient is enrolled, the healthcare provider

	has authorized the patient to receive MYQORZO, and the requested dose is an allowable dose. 6. For patients initiating treatment, undergoing a dose adjustment, or re-initiating dose titration: Dispense no more than a 30 days' supply. 7. For patients on a maintenance dose: Dispense no more than a 90 days' supply.
At all times	8. Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc. 9. Not distribute, transfer, loan, or sell MYQORZO, except to a certified pharmacy. 10. Maintain records of dispensing information and provide such data during audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc. 11. Maintain records of completion of the REMS training by relevant staff. 12. Maintain records that all processes and procedures are in place and are being followed. 13. Comply with audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc. to ensure that all processes and procedures are in place and are being followed.
To maintain certification to dispense	14. Any new Authorized Representative must enroll by completing and submitting the Pharmacy Enrollment Form to the REMS.
4. Wholesalers-distributors that distribute MYQORZO must:	
To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies. 2. Train all relevant staff involved in distributing MYQORZO on the REMS requirements.
At all times	3. Distribute only to certified pharmacies. 4. Maintain records of drug distribution for all MYQORZO shipments. 5. Maintain records that all processes and procedures are in place and are being followed. 6. Comply with audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc. to ensure that all processes and procedures are in place and are being followed.

Cytokinetics, Inc. must provide training to healthcare providers who prescribe MYQORZO.
The training includes the following educational materials: REMS Overview, Education Program for Healthcare Providers and Pharmacies, and Healthcare Provider Knowledge Assessment. The training must be available online and by hard copy via fax and mail.

Cytokinetics, Inc. must provide training to pharmacies that dispense MYQORZO.
The training includes the following educational materials: REMS Overview and Education Program for Healthcare Providers and Pharmacies. The training must be available online and by hard copy via fax and mail.

To support REMS operations, Cytokinetics, Inc. must:

1. Authorize dispensing for each patient based on verifying the healthcare provider is certified, the pharmacy is certified, and the patient is enrolled and authorized to receive MYQORZO on the following schedule:
    - Treatment Initiation
        i. If the Patient Enrollment Form is not completed, the patient is not authorized to receive drug until the completed form is received.
        ii. The initial dispense authorization is valid for 3 months from the date the completed Patient Enrollment Form is received.
        iii. Additional dispenses at the starting dose are authorized within the first 60 days, up to a total of a 60 days' supply.
    - Dose Titration / Dose Adjustments
        i. After treatment initiation or a dose adjustment, the Patient Monitoring Form indicating the patient is authorized to continue receiving MYQORZO must be received within 60 days.
        ii. If a valid Patient Monitoring Form is not received, the patient is not authorized to receive the drug until the completed Patient Monitoring Form is received.
    - Maintenance Dose
        i. The Patient Monitoring Form indicating the patient is authorized to continue MYQORZO must be received every 6 months (for LVEF ≥55%) or every 3 months (for LVEF <55% and ≥50%) from the most recent Patient Monitoring Form.
        ii. If a valid Patient Monitoring Form is not received, the patient is not authorized to receive the drug until the completed Patient Monitoring Form is received.

2. Establish and maintain a REMS website, www.MYQORZOREMS.com. The REMS website must include the capability to complete healthcare provider and pharmacy certification online; the capability to enroll and manage patients online, including completion of the Patient Monitoring Form; the capability to review patient enrollment and authorization status and healthcare provider certification status, as well as obtain authorization to dispense; and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS website. The REMS website must not link back to the promotional product website(s).

3. Make the REMS website fully operational and all REMS materials available through www.MYQORZOREMS.com and the MYQORZO REMS Call Center at the time that MYQORZO first becomes commercially available.

4. Establish and maintain a REMS Call Center for REMS participants at 1-844-285-7367.

5. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the MYQORZO REMS.

6. Ensure healthcare providers and pharmacies are able to complete the certification process online and by fax.

7. Ensure healthcare providers are able to complete the Patient Enrollment Form online and by fax.

8. Ensure healthcare providers are able to complete the Patient Monitoring Form online and by fax.

9. Ensure pharmacies are able to obtain authorization to dispense online and by phone.

10. Provide the REMS Overview, Education Program for Healthcare Providers and Pharmacies, Healthcare Provider Enrollment Form or Pharmacy Enrollment Form, and Prescribing Information to REMS participants who (1) attempt to prescribe or dispense MYQORZO and are not yet certified or (2) inquire about how to become certified.

11. Notify healthcare providers and pharmacies within two (2) business days when they become certified in the REMS.

12. Notify healthcare providers within two (2) business days when patient enrollment is complete.

13. Provide certified healthcare providers access to the database of enrolled patients and certified pharmacies.

14. Provide certified pharmacies access to the database of certified healthcare providers and enrolled patients.

15. Provide authorized wholesalers-distributors access to the database of certified pharmacies.

To ensure REMS participants' compliance with the REMS, Cytokinetics, Inc. must:

16. Verify annually that each Authorized Representative's name and contact information corresponds to those of a current designated Authorized Representative for the certified pharmacy. If different and there is no other certified Authorized Representative, the pharmacy must be required to certify a new Authorized Representative.

17. Maintain adequate records to demonstrate that the REMS requirements have been met, including but not limited to records of the following: MYQORZO distribution and dispensing, certification of healthcare providers and pharmacies, enrollment of patients, completed Patient Monitoring Forms, and audits of certified pharmacies and wholesalers-distributors. These records must be readily available for FDA inspections.

18. Establish and maintain a plan for addressing noncompliance with the REMS requirements.

19. Monitor healthcare providers, pharmacies, and wholesalers-distributors on an ongoing basis to ensure the REMS requirements are being met. Take corrective action if noncompliance is identified, including de-certification.

20. Audit all pharmacies no later than 180 calendar days after they become certified, and annually thereafter, to ensure all REMS processes and procedures are in place, functioning, and support the REMS requirements.

21. Audit all wholesalers-distributors no later than 180 calendar days after they place their first order of MYQORZO, and annually thereafter, to ensure all REMS processes and procedures are in place, functioning, and support the REMS requirements.

22. Take reasonable steps to improve operations of and compliance with the requirements in the MYQORZO REMS based on monitoring and evaluation of the MYQORZO REMS.

IV. REMS Assessment Timetable

Cytokinetics, Inc. must submit REMS assessments at 12 months and annually thereafter from the date of the initial approval of the REMS (12/19/2025). To facilitate the inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Cytokinetics, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the MYQORZO REMS:

Enrollment Forms:

Healthcare Providers:

1. Healthcare Provider Enrollment Form

Patient:

2. Patient Enrollment Form

Pharmacy:

3. Pharmacy Enrollment Form

Training and Educational Materials:

Healthcare Providers:

4. Education Program for Healthcare Providers and Pharmacies
5. REMS Overview
6. Healthcare Provider Knowledge Assessment

Patient:

7. Patient Guide

Pharmacy:

8. Education Program for Healthcare Providers and Pharmacies
9. REMS Overview

Patient Care Form:

10. Patient Monitoring Form

Other Material:

11. REMS Website

VI. Statutory Elements

This REMS is approved under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Elements to Assure Safe Use (ETASU):
    - Healthcare providers who prescribe MYQORZO are specially certified under 505-1(f)(3)(A)
    - Pharmacies that dispense MYQORZO are specially certified under 505-1(f)(3)(B)
    - MYQORZO is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
    - Each patient using MYQORZO is subject to certain monitoring under 505-1(f)(3)(E)
2. Implementation System
3. Timetable for Submission of Assessments

MYQORZO™ REMS

Healthcare Provider Enrollment Form

MYQORZO™ (aficamten) 5·10·15·20 mg tablets

Instructions:

1. Review the Prescribing Information, **REMS Overview**, and the **Education Program for Healthcare Providers and Pharmacies**.
2. Successfully complete the **Healthcare Provider Knowledge Assessment** by receiving a passing score of 100% and submit to the REMS.
3. Enroll by completing and submitting the **Healthcare Provider Enrollment Form** to the REMS:
   - Online at **www.MYQORZOREMS.com**, or
   - By fax to 1-844-285-7399

Complete all required fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you of your successful certification within 2 business days.

Healthcare Provider Information (Fields marked * are REQUIRED)

*First Name:	Middle Initial:	*Last Name:

*Credentials: ☐ MD ☐ DO ☐ PA ☐ NP ☐ Other (please specify):

*Specialty: ☐ Cardiology ☐ Internal/General Medicine ☐ Other (please specify):

*Healthcare Provider NPI #:

*Practice/Facility Name:

*Address:

*City:	*State:	*ZIP Code:

*Phone Number: Area Code/Telephone Number	*Fax Number: Area Code/Fax Number

*Email:

*Preferred Method of Contact (please specify): ☐ Email ☐ Phone ☐ Fax	Preferred Time of Contact: ☐ AM ☐ PM

REMS Support Staff Information (Optional): Healthcare providers may grant administrative rights to up to four REMS support staff per affiliated healthcare setting. REMS support staff may fill out **Patient Enrollment Forms** and/or **Patient Monitoring Forms** on behalf of the certified healthcare provider online or by hard copy. The certified healthcare provider of record is responsible for reviewing, signing, and submitting these forms to the REMS.

I, the healthcare provider, grant administrative rights to the REMS support staff listed below, affiliated with the healthcare setting named above, and understand that I must review all paperwork prior to submitting to the REMS.

First Name:	Last Name:
Phone Number:	Email:
First Name:	Last Name:
Phone Number:	Email:
First Name:	Last Name:
Phone Number:	Email:
First Name:	Last Name:
Phone Number:	Email:

MYQORZO™ REMS

Healthcare Provider Enrollment Form

MYQORZO™ (aficamten) 5·10·15·20 mg tablets

Healthcare Provider Agreement

By completing, signing, and submitting this form, I agree and acknowledge that:

To become certified, I must:

- Review the drug's Prescribing Information, **REMS Overview**, and the **Education Program for Healthcare Providers and Pharmacies**.
- Successfully complete the **Healthcare Provider Knowledge Assessment** and submit it to the REMS.
- Enroll by completing and submitting the **Healthcare Provider Enrollment Form** to the REMS.

Before treatment initiation (first dose), I must:

- Counsel the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide**. Provide a copy of the material to the patient.
- Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit confirmation of an echocardiogram and authorization for treatment to the REMS using the **Patient Enrollment Form**.
- Enroll the patient by completing and submitting the **Patient Enrollment Form** to the REMS.

During treatment: 2 to 8 weeks after treatment initiation and each dose change, then every 3 or 6 months thereafter (depending on echocardiogram results), I must:

- Counsel the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide**.
- Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram.
- Document and submit confirmation of review of the patient's echocardiogram results and authorization for treatment to the REMS using the **Patient Monitoring Form**.

At all times, I must:

- Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc.

Provide Signature Below

By signing below, I acknowledge the above agreements and my obligations as a MYQORZO healthcare provider to comply with MYQORZO REMS requirements, and I understand my personally identifiable information provided above will be shared with Cytokinetics, Inc., its agents, contractors, and affiliates and entered into a healthcare provider database for the MYQORZO REMS. I agree that I may be contacted in the future by mail, email, fax, and/or phone concerning MYQORZO, the MYQORZO REMS, and other MYQORZO programs and services.

*Healthcare Provider Signature:	*Date (MM/DD/YYYY):

Note: MYQORZO REMS certified healthcare providers may add additional practices/facilities and or REMS support staff either through the MYQORZO REMS Website or by contacting the MYQORZO REMS Call Center.

If you have any questions about the MYQORZO REMS, please call the MYQORZO REMS Call Center at 1-844-285-7367. For MYQORZO REMS Call Center hours, visit www.MYQORZOREMS.com.

PHONE: 1-844-285-7367 FAX: 1-844-285-7399 www.MYQORZOREMS.com

Cytokinetics®

Reference ID: 5715575

MYQORZO™ REMS

Patient Enrollment Form

MYQORZO™ (aficamten) 5·10·15·20 mg tablets

Instructions:

Enroll in the REMS by completing the **Patient Enrollment Form** with your healthcare provider.

- Complete this form online at **www.MYQORZOREMS.com**, or
- Print and complete this form and submit by fax to 1-844-285-7399

Patient Information (Fields marked * are REQUIRED)

*First Name:	Middle Initial:	*Last Name:
*Date of Birth: Month/Day/Year		
*Address:		
*City:	*State:	*ZIP Code:
*Phone: Area Code/Telephone Number	Alternate Phone: Area Code/Telephone Number	
*Email:		
Preferred Method of Contact (please select one): ☐ Phone ☐ Email		
Person to Contact if Patient Is Not Available/ Secondary Contact:	Phone Number for Secondary Contact:	

Patient Agreement

Before treatment initiation (first dose), I must:

- Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction (where the heart cannot pump with enough force) using the **Patient Guide**.
- Get an echocardiogram to check my heart.
- Enroll in the REMS by completing the **Patient Enrollment Form** with my healthcare provider. Enrollment information will be provided to the REMS.

During treatment: 2 to 8 weeks after treatment initiation and each dose change, then every 3 or 6 months thereafter (depending on echocardiogram results), I must:

- Receive counseling from my healthcare provider on the risk of heart failure due to systolic dysfunction (where the heart cannot pump with enough force), using the **Patient Guide**.
- Get an echocardiogram to check my heart.

At all times, I will:

- Inform my healthcare provider or seek other medical attention if there are new or worsening symptoms of heart failure.

Provide Signature Below

By signing below, I acknowledge the above agreements and my obligations as a MYQORZO patient to comply with REMS requirements, and I understand that my protected health information will be stored in a secure and confidential database of all patients who receive MYQORZO in the United States. Cytokinetics, Inc. and its agents will use and share my protected health information for the MYQORZO REMS program and for FDA reporting. I agree that Cytokinetics, Inc. and its agents may contact me by phone, mail, or email to manage the MYQORZO REMS.

***Patient/Legal Guardian Signature:**	***Date (MM/DD/YYYY):**
Printed Legal Guardian Name (REQUIRED if not signed by the patient):	

Reference ID: 5715575

MYQORZO™ REMS

Patient Enrollment Form

MYQORZO™ (aficamten) 5·10·15·20 mg tablets

Certified Healthcare Provider Information

*First Name:	*Last Name:
*Healthcare Provider NPI #:	*Phone Number: Area Code/Telephone Number

Certified Healthcare Provider Acknowledgment

- I have counseled the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide**. A copy of the **Patient Guide** has been provided to the patient.
- I have assessed the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram.
- I understand that treatment must be initiated within three months of submitting this form. If treatment is not initiated within this timeframe, a new **Patient Enrollment Form** must be submitted.

Treatment Authorization (select one):*

☐ I authorize this patient to initiate or continue treatment with MYQORZO at **5 mg**, or

☐ I authorize this patient to continue treatment with MYQORZO at a different dose.

If authorizing a different dose, answer the following:

Authorized dose: ☐ 10 mg ☐ 15 mg ☐ 20 mg

Reason: ☐ Clinical trial patient on a stable dose

☐ Established international patient now treated in USA

***Certified Healthcare Provider Signature:**	***Date (MM/DD/YYYY):**

Note: MYQORZO REMS support staff may fill out this form on behalf of the certified healthcare provider of record. The certified healthcare provider of record is responsible for reviewing and submitting this form, as well as ensuring compliance with the REMS requirements. This includes overseeing the monitoring, evaluation, and management of each patient under their care.

If you have any questions about the MYQORZO REMS, please call the MYQORZO REMS Call Center at 1-844-285-7367. For MYQORZO REMS Call Center hours, visit www.MYQORZOREMS.com.

PHONE: 1-844-285-7367 FAX: 1-844-285-7399 www.MYQORZOREMS.com

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Reference ID: 5715575

MYQORZO™ REMS

Pharmacy Enrollment Form

MYQORZO™ (aficamten) 5·10·15·20 mg tablets

Instructions:

1. Designate at least one, and up to two, Authorized Representatives to complete the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
2. Have each Authorized Representative:
   - Review the Prescribing Information, **REMS Overview**, and the **Education Program for Healthcare Providers and Pharmacies**.
   - Successfully complete and submit the **Pharmacy Enrollment Form** to the REMS:
     - Online at **www.MYQORZOREMS.com**, or
     - By fax to 1-844-285-7399

Complete all required fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify pharmacies of successful certification within 2 business days.

Pharmacy Information (Fields marked * are REQUIRED)

*Pharmacy Name:		
*Pharmacy NPI #:	*Pharmacy DEA #:	
*Pharmacy Address:		
*City:	*State:	*ZIP Code:
*Phone Number: Area Code/Telephone Number	*Fax Number: Area Code/Fax Number	

Authorized Representative Information

*First Name:	Middle Initial:	*Last Name:
*Title/Position:		
*Phone Number: Area Code/Telephone Number	*Fax Number: Area Code/Fax Number	
*Email:		
*Preferred Method of Contact: (please select one): ☐ Email ☐ Phone ☐ Fax		

Secondary Pharmacy Contact

First Name:	Middle Initial:	Last Name:
Title/Position:		
Phone Number: Area Code/Telephone Number	Fax Number: Area Code/Fax Number	
Email:		

Reference ID: 5715575

MYQORZO™ REMS

Pharmacy Enrollment Form

MYQORZO™ (aficamten) 5·10·15·20 mg tablets

Pharmacy Agreement

By completing, signing, and submitting this form, I agree and acknowledge that:

As the Pharmacy Authorized Representative, I must:

- Review the Prescribing Information, **REMS Overview**, and **Education Program for Healthcare Providers and Pharmacies**.
- Enroll in the REMS by completing and submitting the **Pharmacy Enrollment Form** to the REMS.
- Train all relevant staff involved in dispensing MYQORZO using the **REMS Overview**, and **Education Program for Healthcare Providers and Pharmacies**.

Before dispensing, all pharmacy staff must:

- Obtain authorization to dispense each prescription from the MYQORZO REMS to verify that the healthcare provider is certified, the patient is enrolled, the healthcare provider has authorized the patient to receive MYQORZO, and the requested dose is an allowable dose.
- Dispense no more than a 30 days' supply for patient initiating treatment, undergoing a dose adjustment, or re-initiating dose titration.
- Dispense no more than a 90 days' supply for patients on a maintenance dose.

At all times, my pharmacy must:

- Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc.
- Not distribute, transfer, loan, or sell MYQORZO, except to a certified pharmacy.
- Maintain records of dispensing information and provide such data during audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc.
- Maintain records of completion of the REMS training by relevant staff.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll by completing and submitting the **Pharmacy Enrollment Form** to the REMS.

Provide Signature Below

By signing below, I acknowledge the above agreements and my obligations as a MYQORZO pharmacy to comply with MYQORZO REMS requirements, and I understand my personally identifiable information provided above will be shared with Cytokinetics, Inc., its agents, contractors, and affiliates and entered into a pharmacy database for the MYQORZO REMS. I agree that I may be contacted in the future by mail, email, fax, and/or phone concerning MYQORZO, the MYQORZO REMS, and other MYQORZO programs and services.

***Authorized Representative Signature:**	***Date (MM/DD/YYYY):**

If you have any questions about the MYQORZO REMS, please call the MYQORZO REMS Call Center at 1-844-285-7367. For MYQORZO REMS Call Center hours, visit www.MYQORZOREMS.com.

PHONE: 1-844-285-7367 FAX: 1-844-285-7399 www.MYQORZOREMS.com

Cytokinetics®

Reference ID: 5715575

MYQORZO™ REMS

Education Program for Healthcare Providers and Pharmacies

Reference ID: 5715575

Cytokinetics

Welcome to the MYQORZO REMS **Education Program for Healthcare Providers and Pharmacies**

To prescribe MYQORZO (aficamten), healthcare providers must become certified in the MYQORZO Risk Evaluation and Mitigation Strategy (REMS), which includes reviewing this **Education Program for Healthcare Providers and Pharmacies**.

- Only certified healthcare providers are eligible to prescribe MYQORZO.
- MYQORZO can only be dispensed by certified pharmacies.
- Patients must be enrolled in the MYQORZO REMS to receive MYQORZO.

Reference ID: 5715575

MYQORZO Indication and Mechanism of Action

Indication:

MYQORZO is a cardiac myosin inhibitor indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM).

Mechanism of Action:

Aficamten is an allosteric and reversible inhibitor of cardiac myosin motor activity. Aficamten reduces the force generated by myosin at the cardiac sarcomere, which contributes to the pathophysiology of HCM. In HCM patients, myosin inhibition with aficamten reduces cardiac contractility and left ventricular outflow tract (LVOT) obstruction.

See full Prescribing Information.

Healthcare providers must report adverse events of heart failure due to systolic dysfunction associated with MYQORZO to Cytokinetics at 1-833-633-2986.

Reference ID: 5715575

MYQORZO REMS
Risk Information

MYQORZO Boxed Warning

WARNING: RISK OF HEART FAILURE

MYQORZO reduces left ventricular ejection fraction (LVEF) and can cause heart failure due to systolic dysfunction.

Echocardiogram assessments are required prior to and during treatment with MYQORZO to monitor for systolic dysfunction. Initiation of MYQORZO in patients with LVEF <55% is not recommended. Decrease the dose of MYQORZO if LVEF is <50% and ≥40%. Interrupt the dose of MYQORZO if LVEF <40% or if the patient experiences heart failure symptoms or worsening clinical status due to systolic dysfunction.

Because of the risk heart failure due to systolic dysfunction, MYQORZO is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MYQORZO REMS Program.

Risk of Heart Failure Due to Systolic Dysfunction

Assess the patient's cardiovascular status and appropriateness of initiating or continuing treatment and adjust the MYQORZO dose accordingly

- Patients who experience a serious intercurrent illness (e.g., serious infection) or arrhythmia (e.g., new or uncontrolled atrial fibrillation) may be at greater risk of developing systolic dysfunction and heart failure.
- Asymptomatic LVEF reduction, intercurrent illnesses, and arrhythmias require additional monitoring considerations.
- New or worsening arrhythmia, dyspnea, chest pain, fatigue, leg edema, or elevations in N-terminal pro-B-type natriuretic peptide (NT-proBNP) may be signs and symptoms of heart failure and should prompt an evaluation of cardiac function.
- Initiation of MYQORZO in patients with LVEF <55% is not recommended.

Reference ID: 5715575

Recommended Dosage and Administration

Initiation or up-titration of MYQORZO in patients with LVEF <55% is not recommended.

- The recommended starting dose of MYQORZO is 5 mg orally once daily
- Increase the dose every 2 to 8 weeks by 5 mg increments until a maintenance dose or the maximum recommended dose of 20 mg once daily is achieved
  - The maintenance dose of MYQORZO is individualized based on the patient's LVEF and left ventricular outflow tract (LVOT) gradient
- Recommendations for dosing based on LVEF and LVOT gradient criteria are in Table 1 (right)

Table 1: Dose Adjustment of MYQORZO

LVEF	Valsalva LVOT Gradient	Dose Adjustment
≥55%	≥30 mm Hg	Increase dose by 5 mg (up to the maximum dose of 20 mg once daily)
≥55%	<30 mm Hg	Maintain Dose
<55% and ≥50%	Any	Maintain Dose
<50% and ≥40%	Any	Decrease dose by 5 mg* Interrupt treatment for 7 days for 5 mg dose
<40%	Any	Interrupt treatment for at least 7 days

*Decrease as follows: 20 mg to 15 mg; 15 mg to 10 mg; 10 mg to 5 mg.

Reference ID: 5715575

Recommended Dosage and Administration

The Use of Echocardiography in MYQORZO Dosing and Administration

Regular LVEF and Valsalva LVOT gradient assessment is required for titration to achieve an appropriate target Valsalva LVOT gradient, while maintaining LVEF ≥50%.

- An echocardiographic assessment should be **performed between 2 to 8 weeks**
  - after initiation of treatment,
  - after any dose adjustment, or
  - after treatment interruption
- After a treatment interruption, resume treatment at the starting dose of 5 mg when LVEF ≥55% and re-initiate dose titration
- After the maintenance dose has been established:
  - assess LVEF and Valsalva LVOT gradient every 6 months, or
  - every 3 months in patients with LVEF <55% to ≥50%
- Consider monitoring LVEF and adjust dose per Table 1 of the Prescribing Information, as needed, in patients during intercurrent illness (e.g., severe infection), new arrhythmia (e.g., new or uncontrolled atrial fibrillation or other uncontrolled tachyarrhythmia), or any other conditions that may impair systolic function
  - Do not increase dose until intercurrent illness or new arrhythmia has resolved or stabilized

Reference ID: 5715575

MYQORZO REMS Overview

MYQORZO REMS Overview

A REMS is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines to ensure that the benefits of a drug outweigh its risks.

Because of the risk of heart failure due to systolic dysfunction, MYQORZO is only available through a restricted program called the MYQORZO REMS.

The objective of the MYQORZO REMS is:

- Healthcare providers monitor left ventricular ejection fraction (LVEF) by echocardiogram during treatment according to the frequency described in the Prescribing Information to detect heart failure due to systolic dysfunction.

Reference ID: 5715575

Healthcare Provider Requirements

Healthcare Provider Requirements

MYQORZO can only be prescribed by certified healthcare providers.

How Does a Healthcare Provider Become Certified in the MYQORZO REMS?

To become certified in the MYQORZO REMS, healthcare providers must:

1. **Review** the MYQORZO Prescribing Information, **REMS Overview**, and **Education Program for Healthcare Providers and Pharmacies** (this presentation)
2. **Successfully complete** the **Healthcare Provider Knowledge Assessment** and submit it to the REMS.
3. **Enroll** by completing and submitting the **Healthcare Provider Enrollment Form** to the REMS.

   Complete certification:
   - Online at www.MYQORZOREMS.com, or
   - By faxing the completed forms to 1-844-285-7399

Upon completion of these steps, healthcare providers will be notified within 2 business days when they are certified in the MYQORZO REMS.

The healthcare provider certification confirmation will also include instructions for the healthcare provider to gain access to the REMS portal where they can enter patient monitoring information and add REMS support staff.

Reference ID: 5715575

Healthcare Provider Requirements

What Are the Healthcare Provider Requirements of the MYQORZO REMS?

To prescribe MYQORZO, certified healthcare providers must:

Before treatment initiation (first dose):

- Counsel the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide** and provide a copy to the patient.
- Assess the patient's cardiovascular status and the appropriateness of initiating treatment based on an echocardiogram.
  - Document and submit confirmation of an echocardiogram and authorization for treatment to the REMS using the **Patient Enrollment Form**.
  - Enroll the patient by completing and submitting the **Patient Enrollment Form** to the REMS.

During treatment, between 2 to 8 weeks after treatment initiation and each dose change, then every 3 or 6 months thereafter (depending on echocardiogram results):

- Counsel the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide**.
- Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram.
- Document and submit confirmation of review of the patient's echocardiogram results and authorization for treatment to the REMS using the **Patient Monitoring Form**.

At all times:

- Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc.

Reference ID: 5715575

Healthcare Provider Requirements

Patient Enrollment Form Submission

The **Patient Enrollment Form** is used to document and confirm the following:

- Patient has been counselled on the risk of heart failure due to systolic dysfunction
- Healthcare provider has reviewed the patient's echocardiogram results and has authorized treatment including the starting dose

Treatment Initiation & Dispense Limits

Treatment with MYQORZO **must** begin within **3 months** of submitting the **Patient Enrollment Form**.

- Note: If treatment is not initiated within 3 months, the patient will be moved to a deactivated status, and a new **Patient Enrollment Form** must be submitted to proceed.

Single dispense limits are **capped** at a **30-day supply** during initiation and titration phases.

- Note: The REMS system will deny any dispense request that exceeds the applicable supply limit.

Reference ID: 5715575

Healthcare Provider Requirements

Patient Monitoring Form Completion

The **Patient Monitoring Form** is used to document and confirm the following:

- Certified healthcare provider has reviewed the patient's echocardiogram results in accordance with the Prescribing Information
- The patient's most recent LVEF
- If the patient has experienced a clinical heart failure event requiring clinical intervention or hospitalization since the last submitted form
- Action that will be taken to the patient's dose based on the clinical visit
- If the patient is authorized to continue treatment

Patient Monitoring Form Submission Timing

Treatment Initiation

- Within 60 days of initiating the first dose

Titration/Dose Changes

- Within 60 days following any dose change

Maintenance Dose

- For patients with LVEF ≥55% every 6 months from the most recent **Patient Monitoring Form**
- For patients with LVEF <55% and ≥50% every 3 months from the most recent **Patient Monitoring Form**

Maintenance Phase Dispense Limits

Single dispense limits are **capped** at a **90-day supply**.

Important: Submit the **Patient Monitoring Form** as soon as possible after completing the echocardiogram. Failure to submit the **Patient Monitoring Form** according to the required schedule may result in dispensing holds and potentially treatment interruptions.

Reference ID: 5715575

Healthcare Provider Requirements

Patient Monitoring Form Completion for Patients With Documented LVEF <40%

Treatment should be interrupted for at least 7 days per the Prescribing Information.

The REMS enforces the following additional **Patient Monitoring Form** submission requirement and dispensing limitations:

- **Recovery Confirmation:** Before treatment can be reinitiated, a new **Patient Monitoring Form** documenting LVEF ≥55% must be submitted to the REMS
- **Dispensing Limitation:** No REMS Dispense Authorization (RDA) will be issued until recovery to LVEF ≥55% is confirmed via **Patient Monitoring Form**
- **Restart Protocol:** Treatment must be reinitiated at the starting dose of 5 mg once daily, with an echocardiogram required within 2 to 8 weeks

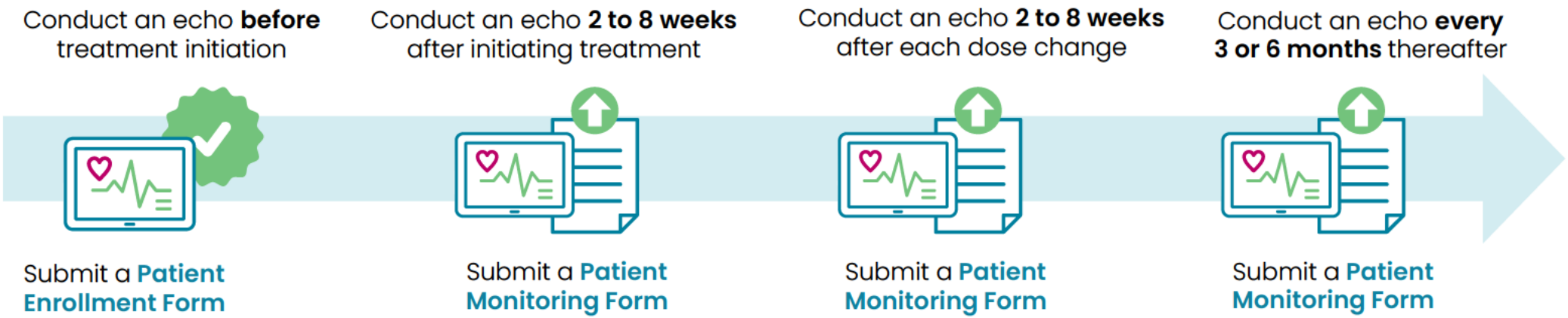
Reference ID: 5715575

Healthcare Provider Requirements

Echocardiogram & Patient Form Submission Timing Illustration

When prescribing MYQORZO, echocardiograms are required prior to initiation of treatment, after treatment initiation, after a dose change, and for routine monitoring. As depicted in the illustration below,

- An echocardiogram and **Patient Enrollment Form** are required prior to the patient initiating treatment.
- An echocardiogram is required 2 to 8 weeks after treatment initiation and any dose change, then every 3 or 6 months thereafter. A **Patient Monitoring Form** is required after each echocardiogram to confirm the patient's cardiovascular status has been assessed and the appropriateness of continuing treatment.



Reference ID: 5715575

Healthcare Provider Requirements

REMS Support Staff

To allow for flexibility in documentation management common within the healthcare delivery system and normal medical practice, the REMS allows for certified healthcare providers to designate up to four (4) REMS support staff per affiliated healthcare setting to complete certain REMS required documentation.

The certified healthcare provider of record is responsible for compliance with the REMS requirements, including monitoring, evaluation, and management of each patient under their care.

- REMS support staff can be added by the certified healthcare provider:
  - When completing and submitting the **Healthcare Provider Enrollment Form**
  - On the online portal accessible from www.MYQORZOREMS.com
  - By calling the REMS Call Center at 1-844-285-7367
- REMS support staff can be removed by the certified healthcare provider:
  - On the online portal accessible from www.MYQORZOREMS.com
  - By calling the REMS Call Center at 1-844-285-7367

Reference ID: 5715575

Healthcare Provider Requirements

REMS Healthcare Provider Delegate

To allow for flexibility in patient management common within the healthcare delivery system and normal medical practice, the REMS allows for certified healthcare providers to designate other certified healthcare providers as healthcare provider delegates to complete REMS-required documentation on their behalf.

Delegates must be enrolled and certified in REMS and attest to the requirements of the REMS.

- REMS healthcare provider delegates can be added or removed by the certified healthcare provider:
  - On the online portal accessible from www.MYQORZOREMS.com
  - By calling the REMS Call Center at 1-844-285-7367

Reference ID: 5715575

Healthcare Provider Requirements

REMS Responsibilities

Once appointed by a certified healthcare provider, REMS support staff and delegates can complete certain activities on behalf of the certified healthcare provider of record online or by hard copy as shown in the table below.

REMS Responsibilities	Certified Healthcare Provider	Healthcare Provider Delegate	Support Staff
Become REMS-certified	Yes	Yes	No
Counsel the patient on the risk of heart failure due to systolic dysfunction using the **Patient Brochure**	Yes	Yes	No
Assess the patient's cardiovascular status and the appropriateness of initiating or continuing treatment by obtaining an echocardiogram	Yes	Yes	No
Enter patient data on a **Patient Enrollment Form** and **Patient Monitoring Form** up to, but not including, signature	Yes	Yes	Yes
Sign the **Patient Enrollment Form** and **Patient Monitoring Form**	Yes	Yes	No

The certified healthcare provider of record or their delegate is responsible for reviewing, signing, and submitting REMS forms, as well as ensuring compliance with the REMS requirements; this includes overseeing the monitoring, evaluation, and management of each patient under their care.

Reference ID: 5715575

Healthcare Provider Requirements

Managing Healthcare Provider Changes for REMS-Enrolled Patients

When enrolled patients need to transition to a new healthcare provider, whether they are no longer under their original provider's care or are planning a switch, the transition can be facilitated through the REMS website or the REMS Call Center. The new healthcare provider must be certified in the REMS program before patient care can be transferred, ensuring continuity of care and compliance with REMS requirements.

- Patient reassignments can be initiated by current or new certified healthcare providers:
  - On the online portal accessible from www.MYQORZOREMS.com
  - By calling the REMS Call Center at 1-844-285-7367

Upon successful reassignment, the REMS will send a notification to both healthcare providers, confirming that the patient is now associated with the new healthcare provider.

Reference ID: 5715575

Pharmacy Requirements

MYQORZO will be dispensed by a limited number of specialty pharmacies.
All pharmacies that dispense MYQORZO must be certified in the REMS.

Pharmacy Requirements

How Does a Pharmacy Become Certified in the MYQORZO REMS?

To become certified to dispense, pharmacies must:

1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
2. Have the Authorized Representative review the Prescribing Information, **REMS Overview**, and **Education Program for Healthcare Providers and Pharmacies** (this document).
3. Have the Authorized Representative enroll by completing and submitting the **Pharmacy Enrollment Form** to the REMS.
4. Train all relevant staff involved in dispensing MYQORZO using the **REMS Overview** and **Education Program for Healthcare Providers and Pharmacies**.

Reference ID: 5715575

Pharmacy Requirements

Eligible specialty pharmacies can complete certification:

- Online at www.MYQORZOREMS.com, or
- By faxing the completed form to 1-844-285-7399

Each pharmacy can designate up to 2 Authorized Representatives.

Pharmacies will be notified within two business days if they are certified to dispense MYQORZO.

The pharmacy certification confirmation will also include instructions for the Authorized Representative to gain access to the REMS portal where they can verify REMS requirements, obtain authorization to dispense MYQORZO, and add pharmacy staff.

Each certified Authorized Representative will have the ability to add staff on the online portal accessible from www.MYQORZOREMS.com, granting them access to the REMS portal. Any certified pharmacy staff member responsible for dispensing MYQORZO will receive unique login credentials.

Reference ID: 5715575

Pharmacy Requirements

What Are the Requirements of the MYQORZO REMS for Certified Pharmacies?

Before dispensing, all pharmacy staff must:

- Obtain authorization to dispense each prescription from the MYQORZO REMS online or by phone to verify that:
  - The healthcare provider is certified,
  - The patient is enrolled,
  - The healthcare provider has authorized the patient to receive MYQORZO, and
  - The requested dose is an allowable dose.
- Dispense no more than a 30 days' supply for patients initiating treatment, undergoing a dose adjustment, or re-initiating dose titration.
- Dispense no more than a 90 days' supply for patients on a maintenance dose.
- Each certified pharmacy will have the ability to obtain a REMS Dispense Authorization (RDA) for each prescription by:
  - Accessing a secure REMS verification portal through the REMS website, or
  - Contacting the REMS Call Center via phone at 1-844-285-7367

Reference ID: 5715575

Pharmacy Requirements

At all times, the pharmacy must:

- Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc.
- Not distribute, transfer, loan, or sell MYQORZO, except to a certified pharmacy.
- Maintain records of dispensing information and provide such data during audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc.
- Maintain records of completion of the REMS training by relevant staff.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc. to ensure that all processes and procedures are in place and are being followed.

To maintain certification to dispense, any new Authorized Representative must:

- Enroll by completing and submitting the **Pharmacy Enrollment Form** to the REMS.

If the pharmacy opts to have a second Authorized Representative enroll, that Authorized Representative must complete and submit the **Pharmacy Enrollment Form** to the REMS.

Reference ID: 5715575

This concludes the MYQORZO REMS Education Program for Healthcare Providers and Pharmacies.

For more information or to obtain any REMS materials, visit www.MYQORZOREMS.com or call 1-844-285-7367. For MYQORZO REMS Call Center hours, visit www.MYQORZOREMS.com.

Report all adverse events, including those of heart failure due to systolic dysfunction, that occur in patients receiving MYQORZO to Cytokinetics, Inc. at 1-833-633-2986.

Phone: 1-844-285-7367 Fax: 1-844-285-7399 www.MYQORZOREMS.com

Reference ID: 5715575

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MYQORZO™ REMS

REMS Overview

This overview describes the requirements of the MYQORZO REMS and the responsibilities of healthcare providers, pharmacists, and patients.

WHAT IS THE MYQORZO REMS?

A **R**isk **E**valuation and **M**itigation **S**trategy (**REMS**) is a strategy to manage known or potential risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure the benefits of a drug outweigh its risks.

Because of the risk of heart failure due to systolic dysfunction, MYQORZO is available only through a restricted program called the MYQORZO REMS.

MYQORZO may increase the risk of heart failure due to systolic dysfunction; patients may experience heart failure at any time during treatment with MYQORZO.

What are the requirements of the MYQORZO REMS?

In order for patients to receive MYQORZO, healthcare providers, pharmacies, and patients must comply with the requirements of the MYQORZO REMS.

Healthcare Provider Requirements

Only healthcare providers certified in the MYQORZO REMS can prescribe MYQORZO.

Healthcare providers must:

Become Certified (One Time)	**To become certified to prescribe:** 1. Review the drug's Prescribing Information, **REMS Overview** (this document), and the **Education Program for Healthcare Providers and Pharmacies**. 2. Successfully complete the **Healthcare Provider Knowledge Assessment** and submit it to the REMS 3. Enroll by completing and submitting the **Healthcare Provider Enrollment Form** to the REMS. Upon completion of these steps, the REMS will notify the healthcare provider of successful certification within 2 business days.
Enroll Patients	**Before treatment initiation (first dose):** 5. Counsel the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide**. Provide a copy of the material to the patient. 6. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit confirmation of an echocardiogram and authorization for treatment to the REMS using the **Patient Enrollment Form**. 7. Enroll the patient by completing and submitting the **Patient Enrollment Form** to the REMS.

Monitor Patients	**During treatment, between 2 to 8 weeks after treatment initiation and each dose change, then every 3 or 6 months thereafter (depending on echocardiogram results):** 8. Counsel the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide**. 9. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. 10. Document and submit confirmation of review of the patient's echocardiogram results and authorization for treatment to the REMS using the **Patient Monitoring Form**. The MYQORZO REMS will send reminders to the certified healthcare provider to submit the **Patient Monitoring Form**. Completed forms should be submitted to the MYQORZO REMS online at www.MYQORZOREMS.com or via fax to 1-844-285-7399. Failure to submit the **Patient Monitoring Form** at the required intervals could result in a delay in dispensing of MYQORZO to the patient.
At All Times	Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc.

Pharmacy Requirements

Only pharmacies certified in the MYQORZO REMS can dispense MYQORZO.

Pharmacies must:

Become Certified	**To become certified:** 1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy. 2. Have the authorized representative review the Prescribing Information, **REMS Overview** (this document), and **Education Program for Healthcare Providers and Pharmacies**. 3. Have the authorized representative enroll by completing and submitting the **Pharmacy Enrollment Form** to the REMS. 4. Train all relevant staff involved in dispensing MYQORZO using the **REMS Overview** and **Education Program for Healthcare Providers and Pharmacies**.
Prior to Dispense	**Before dispensing, all pharmacy staff must:** 5. Obtain authorization to dispense each prescription from the MYQORZO REMS to verify that the healthcare provider is certified, the patient is enrolled, the healthcare provider has authorized the patient to receive the drug, and the requested dose is an allowable dose. 6. Dispense no more than a 30 days' supply for patient initiating treatment, undergoing a dose adjustment, or re-initiating dose titration. 7. Dispense no more than a 90 days' supply for patients on a maintenance dose.

At All Times	**My pharmacy must:** 8. Report adverse events of heart failure due to systolic dysfunction to Cytokinetics, Inc. 9. Not distribute, transfer, loan, or sell MYQORZO, except to a certified pharmacy. 10. Maintain records of dispensing information and provide such data during audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc. 11. Maintain records of completion of the REMS training by relevant staff. 12. Comply with audits conducted by Cytokinetics, Inc. or a third party acting on behalf of Cytokinetics, Inc. to ensure that all processes and procedures are in place and are being followed.
Maintain Certification to Dispense	**To maintain certification to dispense:** 13. Have any new Authorized Representative enroll by completing and submitting the **Pharmacy Enrollment Form** to the REMS.

Patient Requirements

Only patients enrolled in the MYQORZO REMS can receive MYQORZO.

Patients must:

Be Enrolled	**Before treatment initiation (first dose):** 1. Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction (where the heart cannot pump with enough force) using the **Patient Guide**. 2. Get an echocardiogram to check their heart. 3. Enroll in the REMS by completing the **Patient Enrollment Form** with the healthcare provider. Enrollment information will be provided to the REMS.
Be Monitored	**During treatment, between 2 to 8 weeks after treatment initiation and each dose change, then every 3 or 6 months thereafter (depending on echocardiogram results):** 4. Receive counseling from the healthcare provider on the risk of heart failure due to systolic dysfunction (where the heart cannot pump with enough force) using the **Patient Guide**. 5. Get an echocardiogram to check their heart.
At All Times	6. Inform the healthcare provider or seek other medical attention if there are new or worsening symptoms of heart failure.

Resources

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The resources listed below are available for download at www.MYQORZOREMS.com.

Healthcare Provider

- Prescribing Information
- **REMS Overview**
- **Education Program for Healthcare Providers and Pharmacies**
- **Healthcare Provider Knowledge Assessment**
- **Healthcare Provider Enrollment Form**
- **Patient Guide**
- **Patient Enrollment Form**
- **Patient Monitoring Form**

Pharmacy

- Prescribing Information
- **REMS Overview**
- **Education Program for Healthcare Providers and Pharmacies**
- **Pharmacy Enrollment Form**

Patient

- Medication Guide
- **Patient Guide**
- **Patient Enrollment Form**

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For more information about the MYQORZO REMS, visit www.MYQORZOREMS.com or call the MYQORZO REMS at 1-844-285-7367. For MYQORZO REMS Call Center hours, visit www.MYQORZOREMS.com.

Please see Important Safety Information, including BOXED WARNING, and US Full Prescribing Information for MYQORZO here: cytokinetics.com/pi_myqorzo.pdf.

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MYQORZO™ REMS

Healthcare Provider Knowledge Assessment

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Instructions:

1. Complete and submit this **Healthcare Provider Knowledge Assessment** to the REMS:
   - Online at **www.MYQORZOREMS.com**, or
   - Print and complete this form and submit by fax to 1-844-285-7399

   A passing score of 100% is needed to successfully pass the knowledge assessment.
2. To complete certification, enroll by completing and submitting the **Healthcare Provider Enrollment Form**.

You will be notified of successful certification within 2 business days once the **Healthcare Provider Enrollment Form** has also been submitted.

Healthcare Provider Information (Fields marked * are REQUIRED)		
*First Name:	Middle Initial:	*Last Name:
*Healthcare Provider NPI #:		
*Phone Number: Area Code/Telephone Number	*Fax Number: Area Code/Fax Number	
*Email:		

For questions 1–10, select the correct answer. You must answer ALL questions correctly to become certified in the REMS.

Question 1: The risk being mitigated by the MYQORZO REMS is:

- ☐ A. Liver function test elevations (>3 times the upper limit of normal)
- ☐ B. Neutropenia
- ☐ C. Heart failure due to systolic dysfunction
- ☐ D. Severe skin reactions

Question 2: Which of the following is an objective of the MYQORZO REMS?

- ☐ A. Monitoring for detection of heart failure due to systolic dysfunction with routine echocardiograms
- ☐ B. Screening for neutropenia prior to and during treatment with MYQORZO
- ☐ C. Both A & B
- ☐ D. None of the above

Question 3: Initiation of MYQORZO in patients with LVEF <55% is not recommended.

- ☐ A. True
- ☐ B. False

Question 4: What is the recommended starting dose of MYQORZO?

- ☐ A. 5 mg once daily
- ☐ B. 10 mg once daily
- ☐ C. 15 mg once daily

MYQORZO™ REMS

Healthcare Provider Knowledge Assessment

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Question 5: Before treatment initiation with MYQORZO, you must counsel the patient, using the **Patient Guide**, on:

- ☐ A. The risk of heart failure due to systolic dysfunction
- ☐ B. The need to screen patients for severe skin reaction
- ☐ C. All of the above

Question 6: Echocardiograms are required at each of the following time points while on MYQORZO, **except:**

- ☐ A. 2 to 8 weeks after initiation of treatment
- ☐ B. 2 to 8 weeks after dose adjustment
- ☐ C. Every 3 months in patients with LVEF <55% and ≥50%
- ☐ D. Once a year starting in the first year

Question 7: **Patient Monitoring Forms**, confirming the patient's cardiovascular status has been assessed by echocardiogram, must be received by the REMS:

- ☐ A. Within 60 days of initiating the first dose
- ☐ B. Within 60 days following any dose change
- ☐ C. After the maintenance dose has been established: every 6 months (in patients with LVEF ≥55%) or every 3 months (in patients with LVEF <55% and ≥50%) from the most recent **Patient Monitoring Form**
- ☐ D. All of the above

Question 8: Patients do not need to enroll in the REMS to receive treatment with MYQORZO.

- ☐ A. True
- ☐ B. False

Question 9: A prescription for MYQORZO must be sent to a certified pharmacy to be dispensed.

- ☐ A. True
- ☐ B. False

Question 10: If LVEF is <50% and ≥40%, you should:

- ☐ A. Decrease the dose if patient is on 10 mg, 15 mg or 20 mg dose
- ☐ B. Interrupt treatment for 7 days if the patient is on 5 mg dose
- ☐ C. Maintain current dose and conduct an echocardiogram in 6 months
- ☐ D. Both A & B

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MYQORZO™ REMS

Patient Guide

What Is MYQORZO (aficamten)?

MYQORZO is a prescription medicine used to treat adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM).

What Is the Most Serious Risk of Treatment With MYQORZO?

In some patients, MYQORZO can cause heart failure, which is where the heart cannot pump with enough force.

- Heart failure is a serious condition that can lead to death.
- People may have a greater risk of heart failure during treatment with MYQORZO if they develop:
  - A serious infection, or
  - A new or worsening heart rhythm problem.

What Is the MYQORZO REMS?

A **R**isk **E**valuation and **M**itigation **S**trategy (REMS) is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are greater than the risks. FDA must approve these steps as part of the REMS.

MYQORZO has a REMS because of the risk of heart failure due to systolic dysfunction.

What Should I Know About Treatment With MYQORZO?

To receive MYQORZO, you must have tests called echocardiograms on a regular basis so your healthcare provider can see how your heart is responding to MYQORZO. Your healthcare provider will order these tests for you.

When you are taking MYQORZO, tell your healthcare provider or get medical help right away if you develop any of the following new or worsening symptoms:

- Shortness of breath
- Swelling in your legs
- Fatigue
- Chest pain

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What Do I Need to Do Before Starting MYQORZO?

BEFORE TAKING MYQORZO (FIRST DOSE)

1. Receive counseling from your healthcare provider on the risk of heart failure due to systolic dysfunction (where the heart cannot pump with enough force) using this **Patient Guide**. Discuss with your healthcare provider and understand the following:
   - Risk of heart failure due to systolic dysfunction, which is where your heart cannot pump with enough force.
   - New or worsening symptoms of heart failure.
   - Need to report new or worsening symptoms of heart failure to your healthcare provider or to seek other medical attention.
   - Need to get echocardiograms before starting treatment with MYQORZO and routinely during treatment based on the MYQORZO Prescribing Information.
   - Especially tell your healthcare provider if you:
     - Develop a severe infection.
     - Develop a new or worsening heart rhythm problem.
2. Get an echocardiogram to check your heart and see if you are eligible for treatment with MYQORZO.
3. Enroll in the REMS by completing the **Patient Enrollment Form** with your healthcare provider. Enrollment information will be provided to the REMS.

What Do I Need to Do While Taking MYQORZO?

WHILE TAKING MYQORZO

4. Discuss with your healthcare provider and, using this **Patient Guide**, understand the:
   - Risk of heart failure due to systolic dysfunction, where your heart cannot pump with enough force.
   - New or worsening symptoms of heart failure.
   - Need to report new or worsening symptoms of heart failure to your healthcare provider or to seek other medical attention.
5. Get an echocardiogram to check your heart and see if you are eligible to continue treatment with MYQORZO (2 to 8 weeks after treatment initiation and each dose change, and then every 3 or 6 months thereafter, depending on echocardiogram results).

AT ALL TIMES

6. Inform your healthcare provider or seek other medical attention if there are new or worsening symptoms of heart failure.

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Where Will I Get My MYQORZO?

MYQORZO is only dispensed by pharmacies that are certified to participate in the MYQORZO REMS.

The pharmacy will contact you to fill your prescription and ship it to your home.

Where Can I Get More Information on MYQORZO?

You can find additional information at www.MYQORZOREMS.com or call the MYQORZO REMS at 1-844-285-7367.

- For MYQORZO REMS Call Center hours, visit www.MYQORZOREMS.com

PHONE: 1-844-285-7367 FAX: 1-844-285-7399 www.MYQORZOREMS.com

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MYQORZO™ REMS

Patient Monitoring Form

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This completed form must be reviewed and submitted by a certified healthcare provider or their delegate.

Instructions:

Submit this form to the REMS either:

- Online at **www.MYQORZOREMS.com**, or
- By faxing the completed form to the MYQORZO REMS to **1-844-285-7367**

This form must be submitted in its entirety on the appropriate REMS schedule for your patient to receive MYQORZO. Failure to submit a Patient Monitoring Form may result in delay in patient access to MYQORZO.

After a patient has started taking MYQORZO, echocardiograms must be done:

2-8 weeks after initiating treatment

2-8 weeks after dose adjustment

Every 3 or 6 months thereafter (depending on echocardigram results)

After completing the echocardiogram, this form should be submitted per the following schedule:

- Treatment Initiation:
  - Within 60 days of initiating the first dose
- Titration / Dose Change:
  - Within 60 days of the dose change
- Maintenance Dose:
  - For patients with LVEF ≥55% every 6 months from the most recent **Patient Monitoring Form**
  - For patients with LVEF <55% and ≥50% every 3 months from the most recent **Patient Monitoring Form**

Important: While you have up to the timeframes listed above, please submit this form as soon as possible after completing the echocardiogram.

Note: MYQORZO REMS support staff may fill out this form on behalf of the certified healthcare provider of record. The certified healthcare provider or their delegate is responsible for reviewing and submitting this form, as well as ensuring compliance with the REMS requirements; this includes overseeing the monitoring, evaluation, and management of each patient under their care.

Healthcare Provider Information (Fields marked * are REQUIRED)	
*Healthcare Provider First Name:	*Last Name:
*Healthcare Provider NPI #:	*Phone:
*Fax:	*Email:

Reference ID: 5715575

MYQORZO™ REMS

Patient Monitoring Form

MYQORZO™ (aficamten) 5·10·15·20 mg tablets

Patient Information

*Patient First Name:	Middle Initial:	*Last Name:
*Birthdate (MM/DD/YYYY):	*Phone:	

Patient Monitoring

***Is the above-named patient still under your care?**

☐ Yes (If **yes**, answer questions 1-5 below) ☐ No (If **no**, complete Patient Transition of Care section below†)

1. *I have reviewed the patient's echocardiogram results in accordance with the Prescribing Information.

☐ Yes ☐ No (If **no**, the patient cannot receive MYQORZO)

2. *What is the patient's LVEF?

☐ a. ≥55%

☐ b. <55% and ≥50%

☐ c. <50% and ≥40% (decrease dose by 5 mg if at 20 mg, 15 mg or 10 mg; interrupt treatment for 7 days if at 5 mg)

☐ d. <40% (treatment should be interrupted for at least 7 days; a new **Patient Monitoring Form** documenting LVEF ≥55% is required to resume treatment at 5 mg)

3. *Has the patient experienced a clinical heart failure event requiring clinical intervention or hospitalization since the last submitted form?

☐ Yes ☐ No

4. *Is the patient authorized to continue treatment?

☐ Yes ☐ No

5. *After this clinical visit, what will be the patient's next MYQORZO dose?

☐ 5 mg ☐ 10 mg ☐ 15 mg ☐ 20 mg or ☐ 0 mg (dose interruption)

Healthcare Provider Agreement

I acknowledge that I have counseled the patient on the risk of heart failure due to systolic dysfunction using the **Patient Guide** and assessed the patient's cardiovascular status and the appropriateness of continuing treatment.

***Certified Healthcare Provider Signature:**	***Date (MM/DD/YYYY):**

†Patient Transition of Care (Only complete this section if patient is no longer under your care)

If known, please indicate the name of the healthcare provider now responsible for this patient's care:

Healthcare Provider Name: _____

Healthcare Provider Phone Number: _____

☐ Patient's Current Healthcare Provider Is Unknown

Report all adverse events to Cytokinetics, Inc. at 1-833-633-2986 or the FDA at 1-800-FDA-1088 (1-800-332-1088) or www.FDA.gov/medwatch.

If you have any questions about the MYQORZO REMS, please call the MYQORZO REMS Call Center at 1-844-285-7367. For MYQORZO REMS Call Center hours, visit www.MYQORZOREMS.com.

PHONE: 1-844-285-7367 FAX: 1-844-285-7399 www.MYQORZOREMS.com

Cytokinetics®

Reference ID: 5715575

Contents

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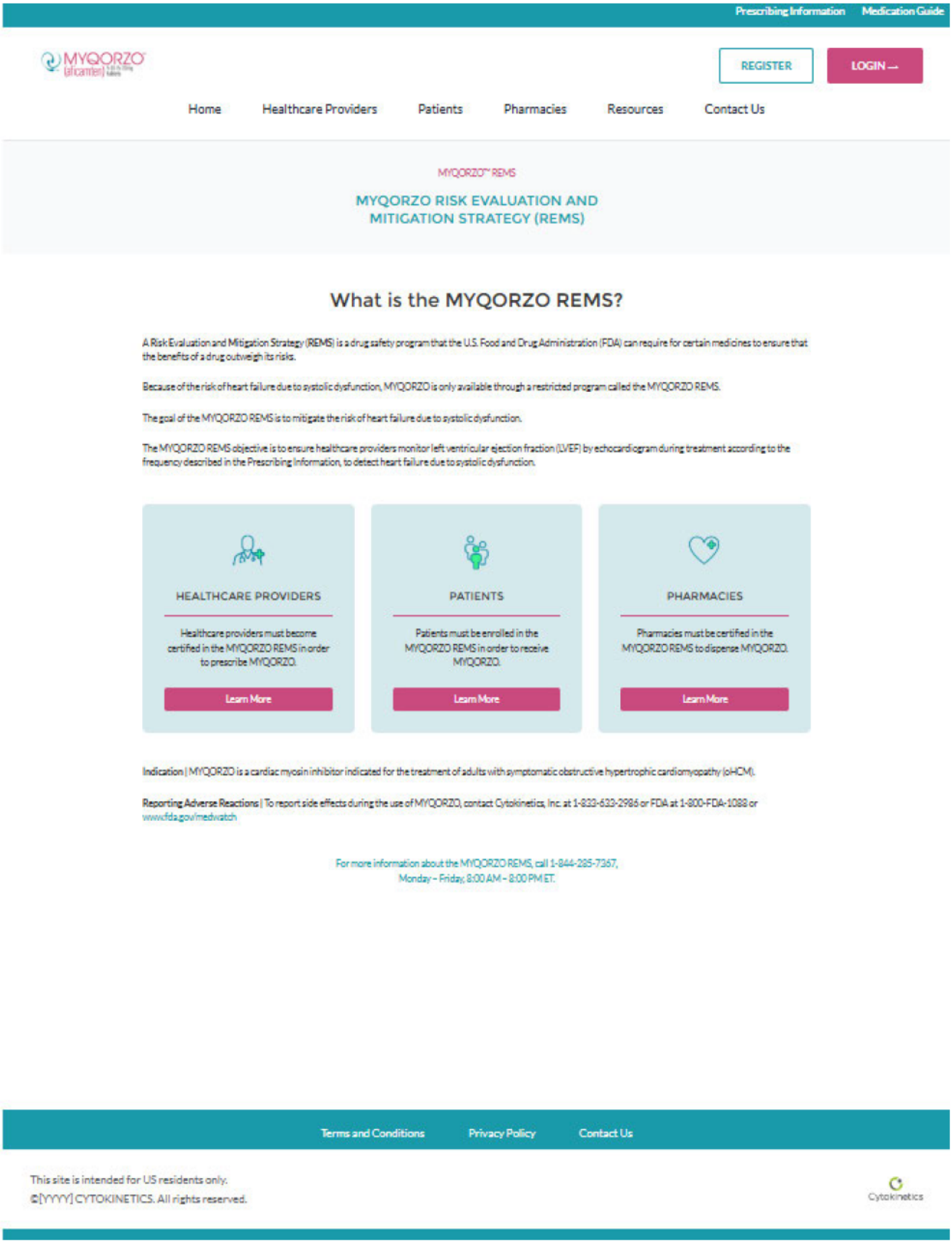
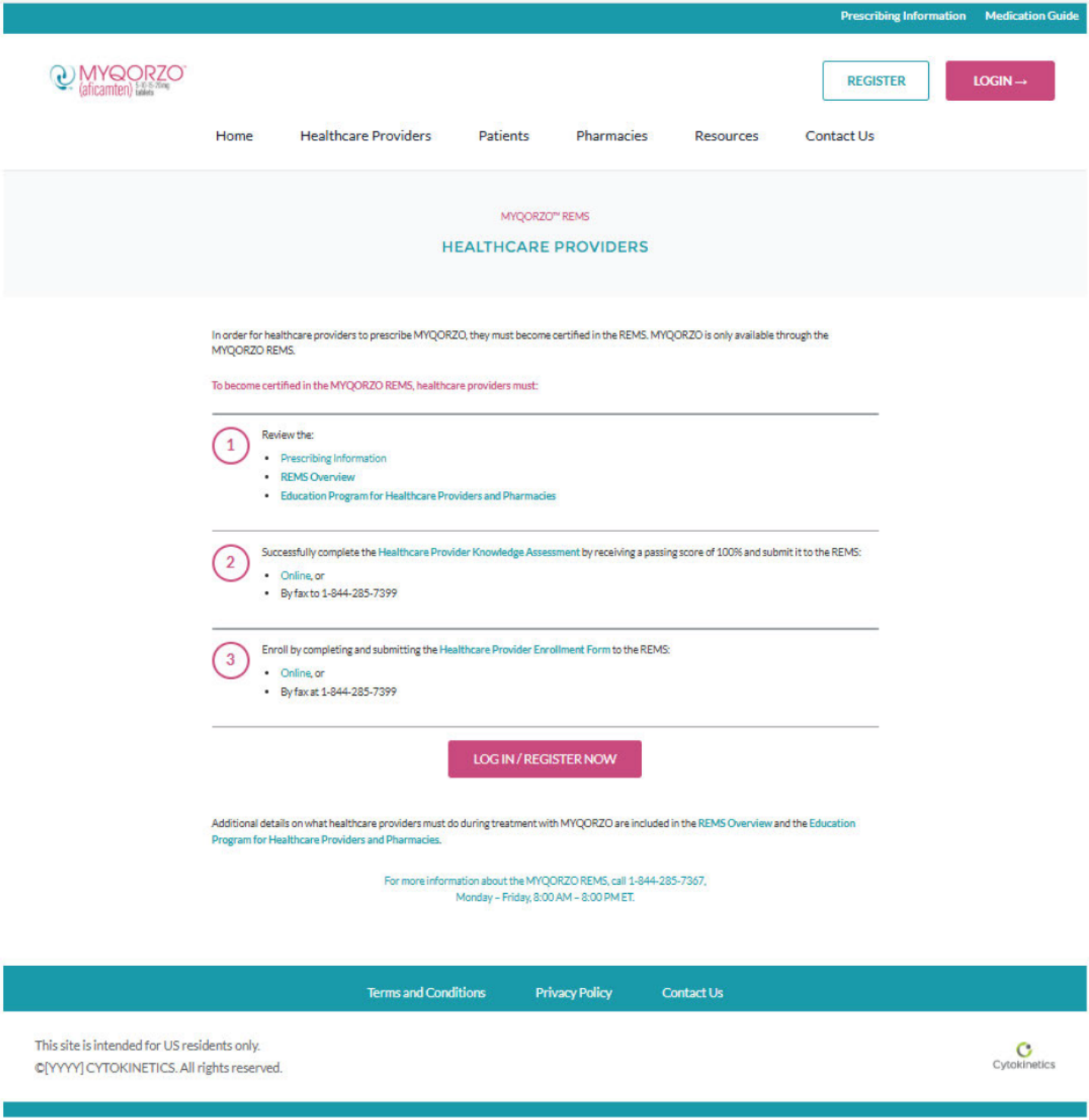
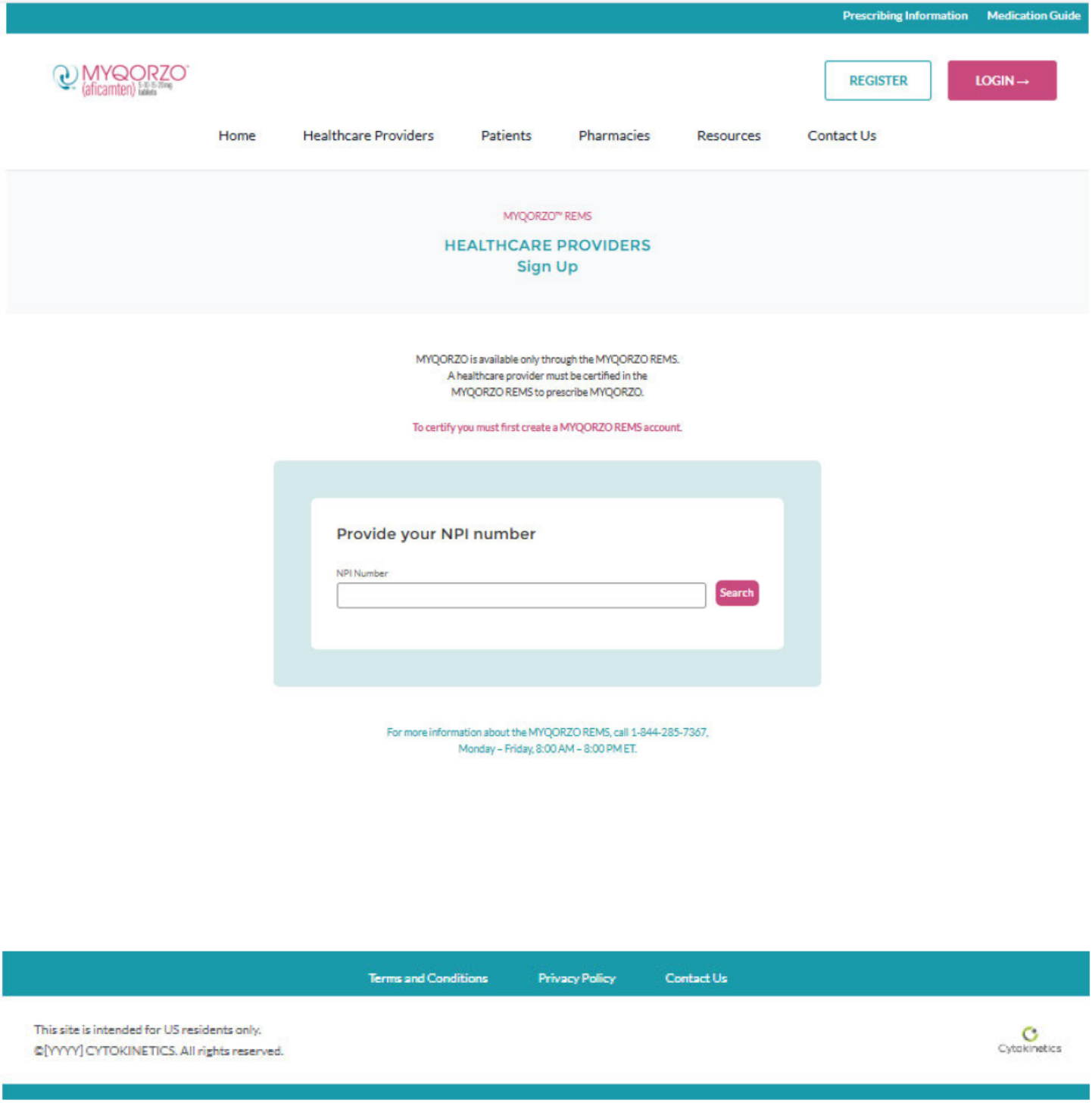


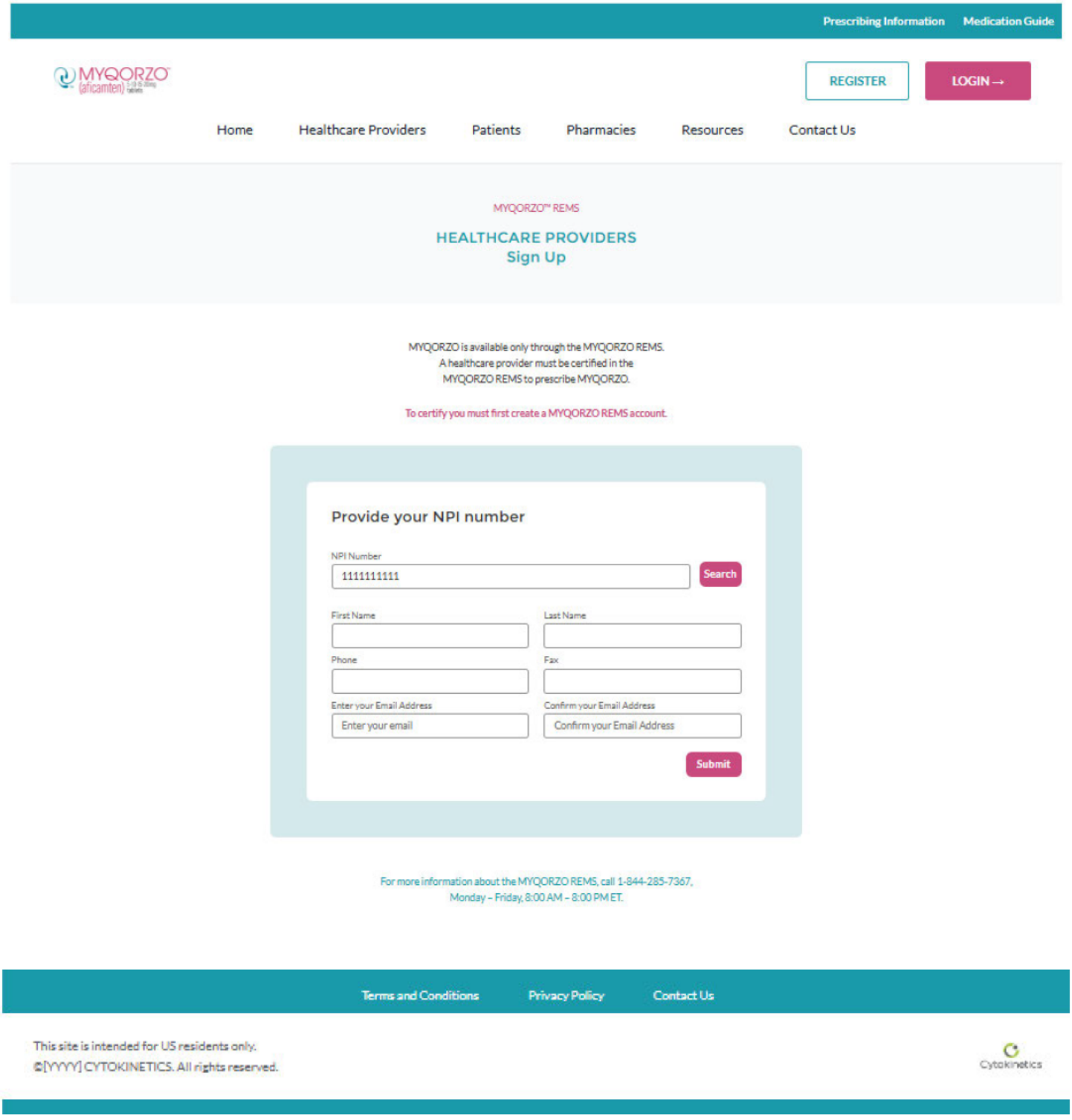
2. Healthcare Providers Landing Page



3. Healthcare Provider — Sign Up (Step 1)



4. Healthcare Provider — Sign Up (Step 2)



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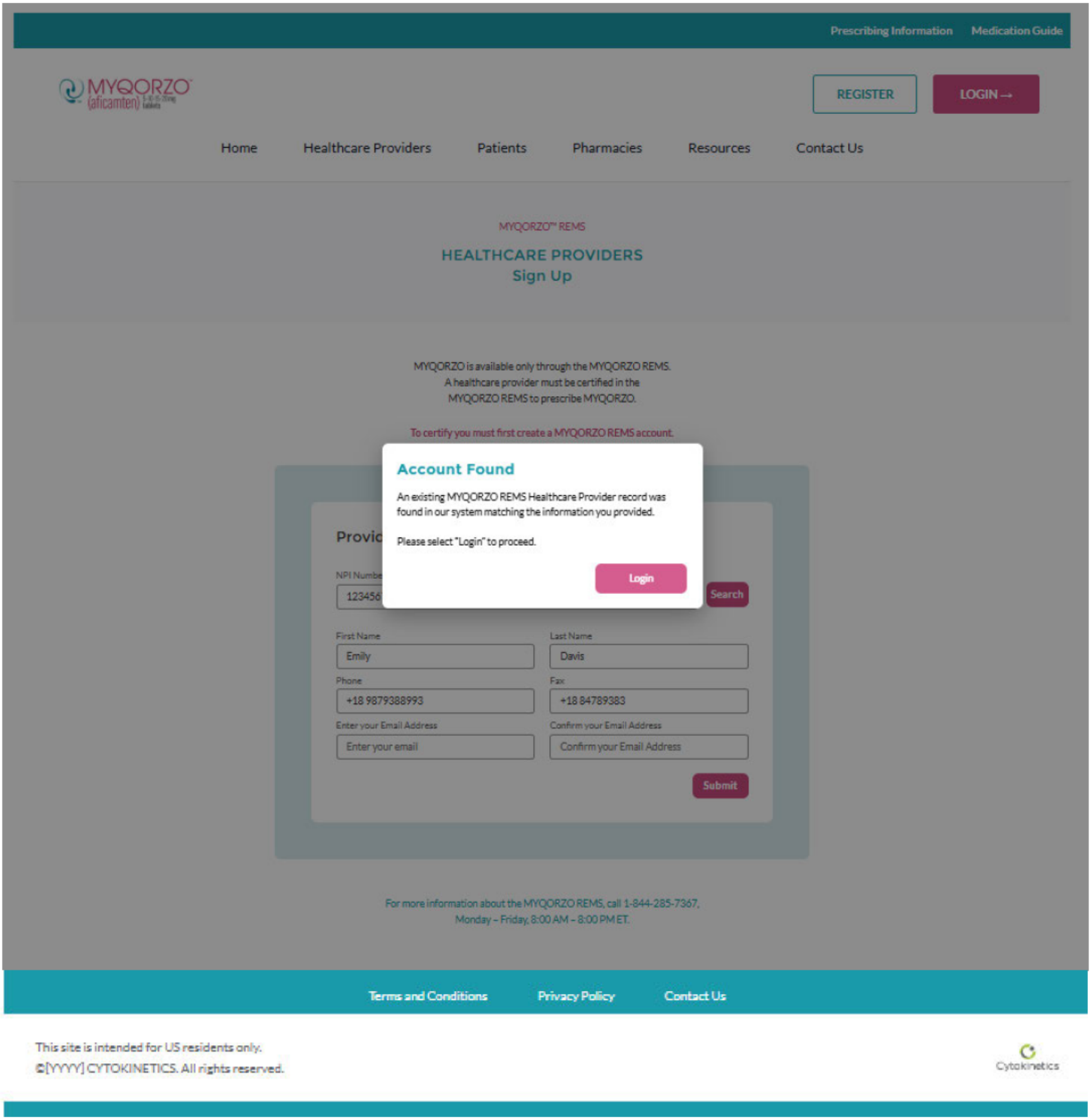
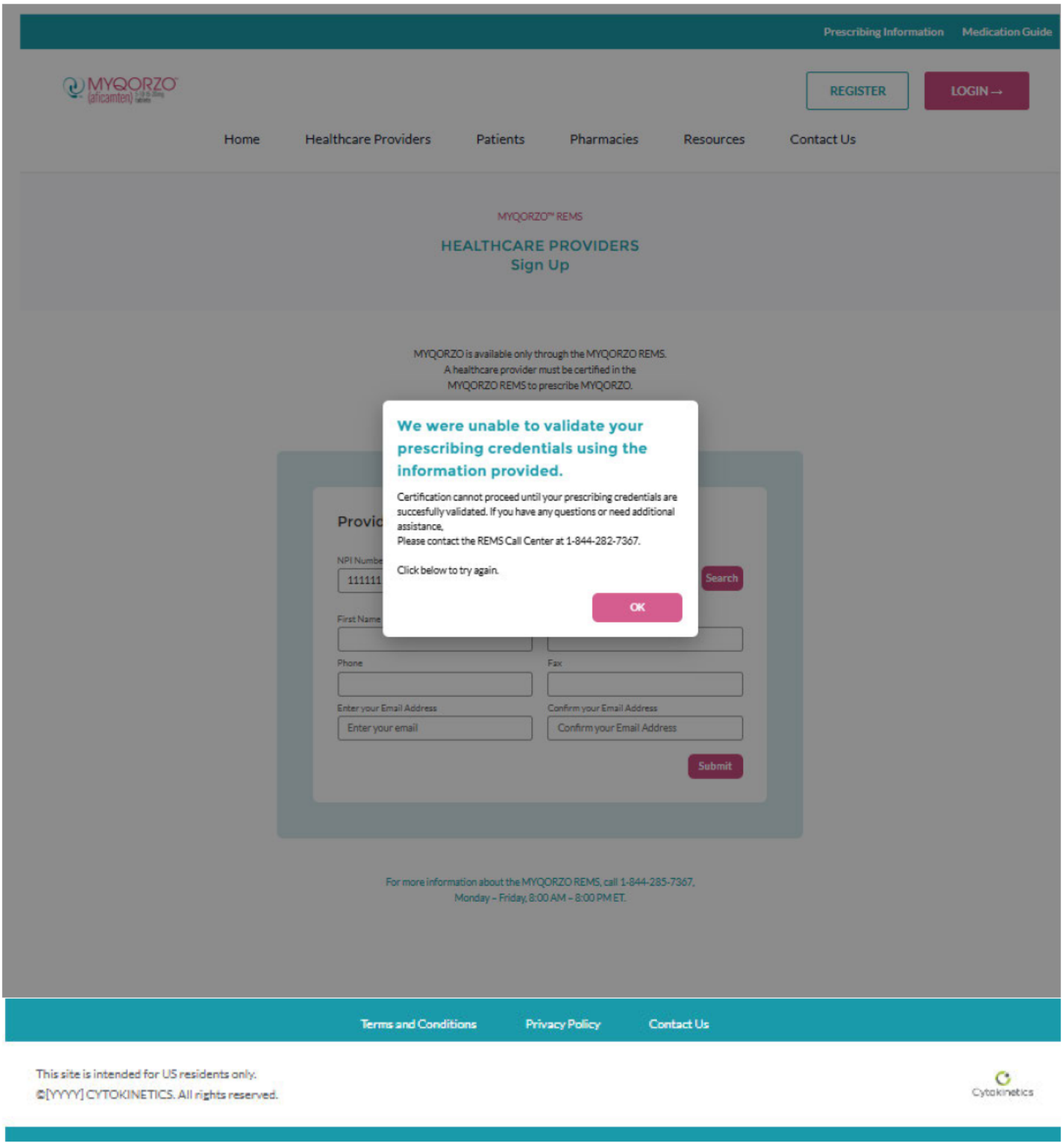
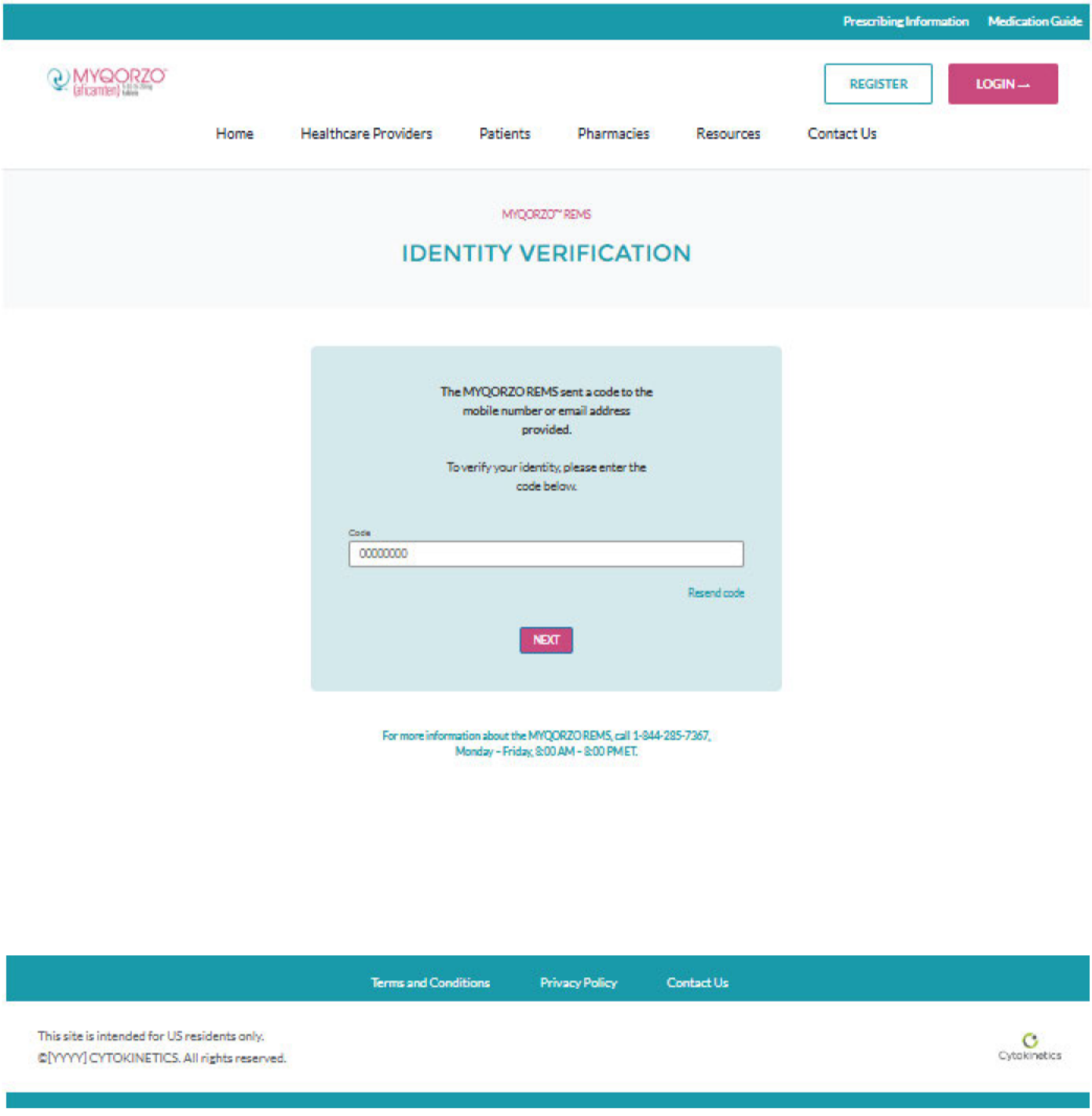


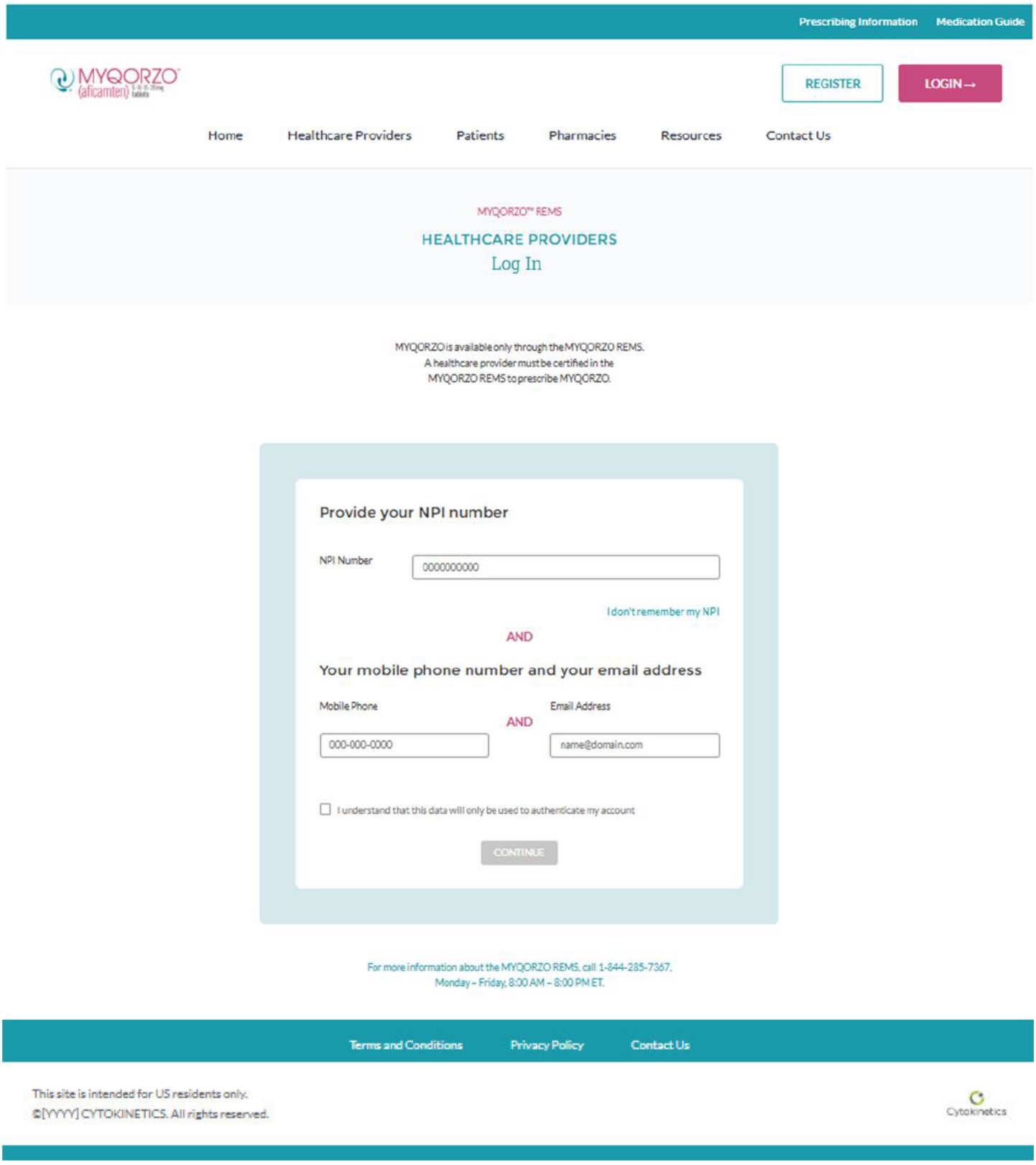
6. Healthcare Provider — Unsuccessful NPI Verification



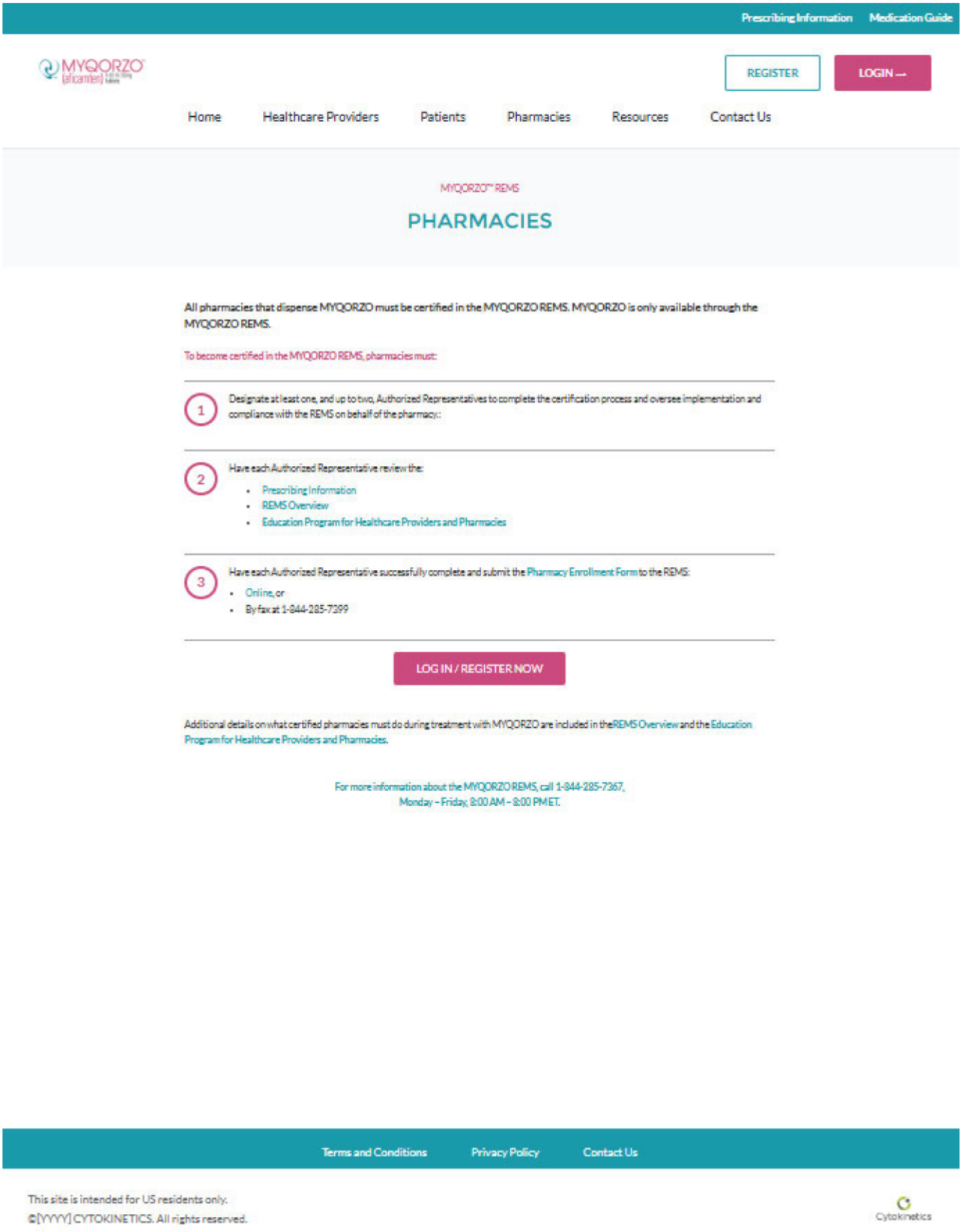
7. Healthcare Provider — Identity Verification



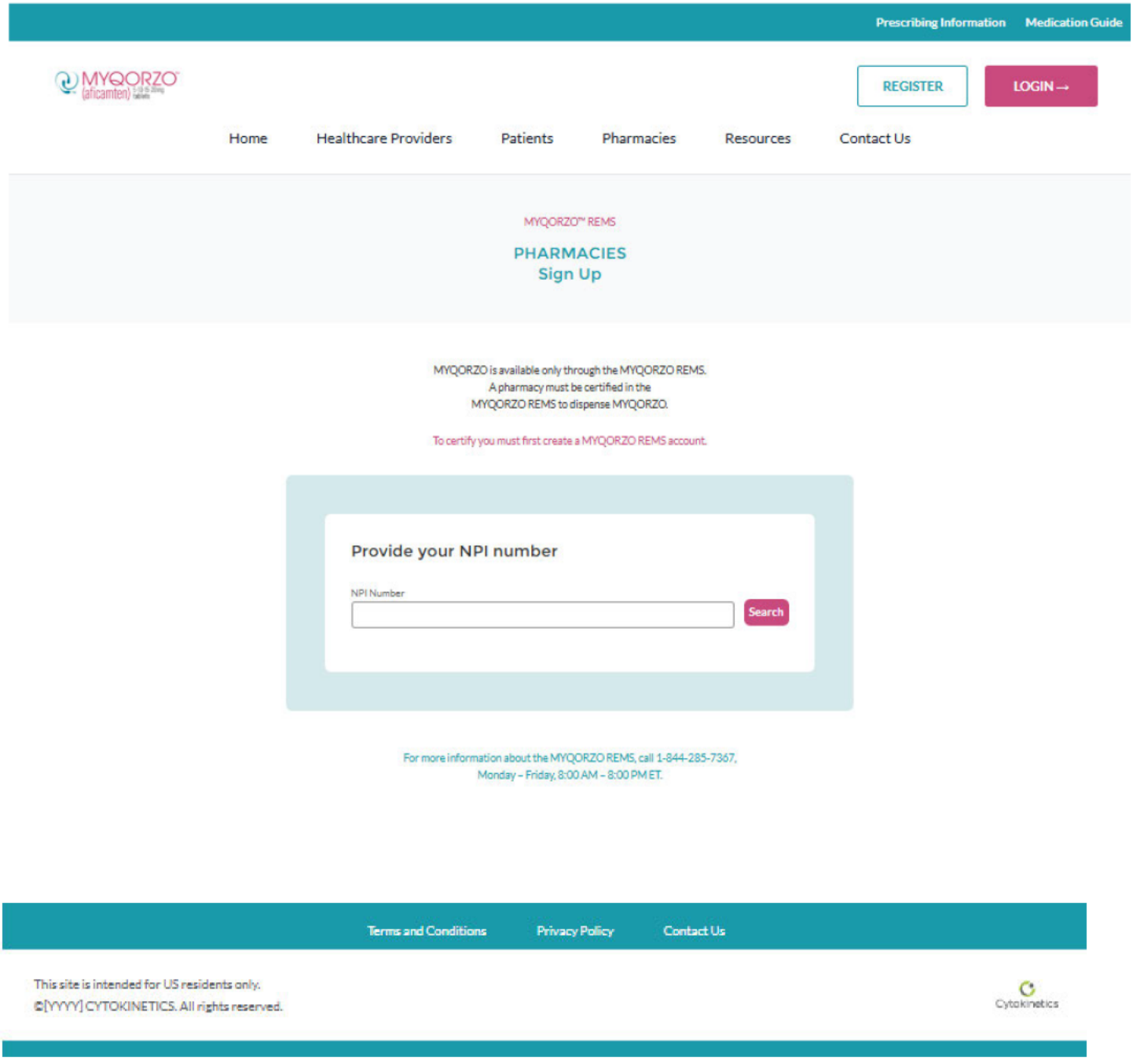
8. Healthcare Provider — Log In



9. Pharmacies Landing Page



10. Pharmacy — Sign Up (Step 1)



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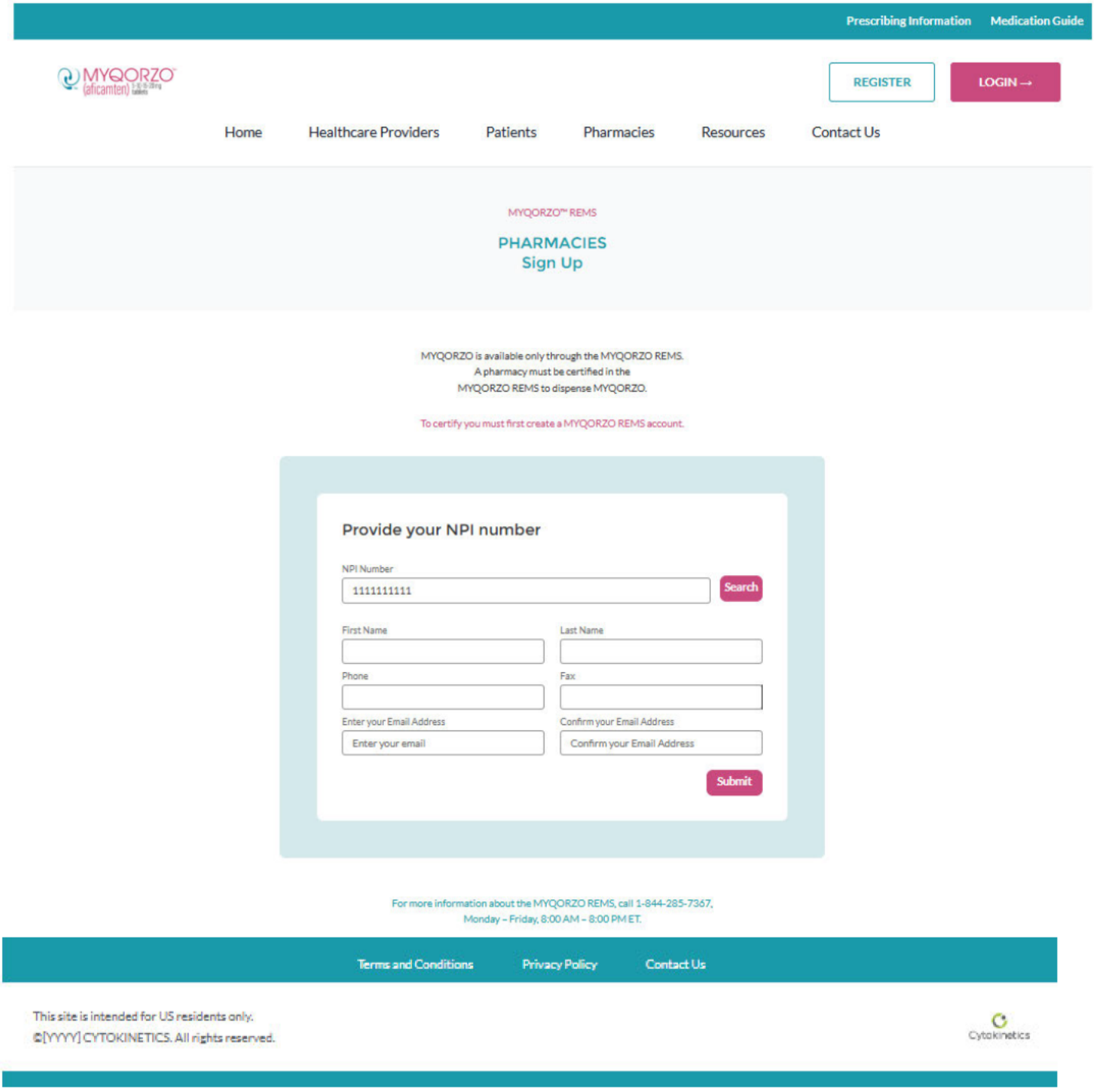
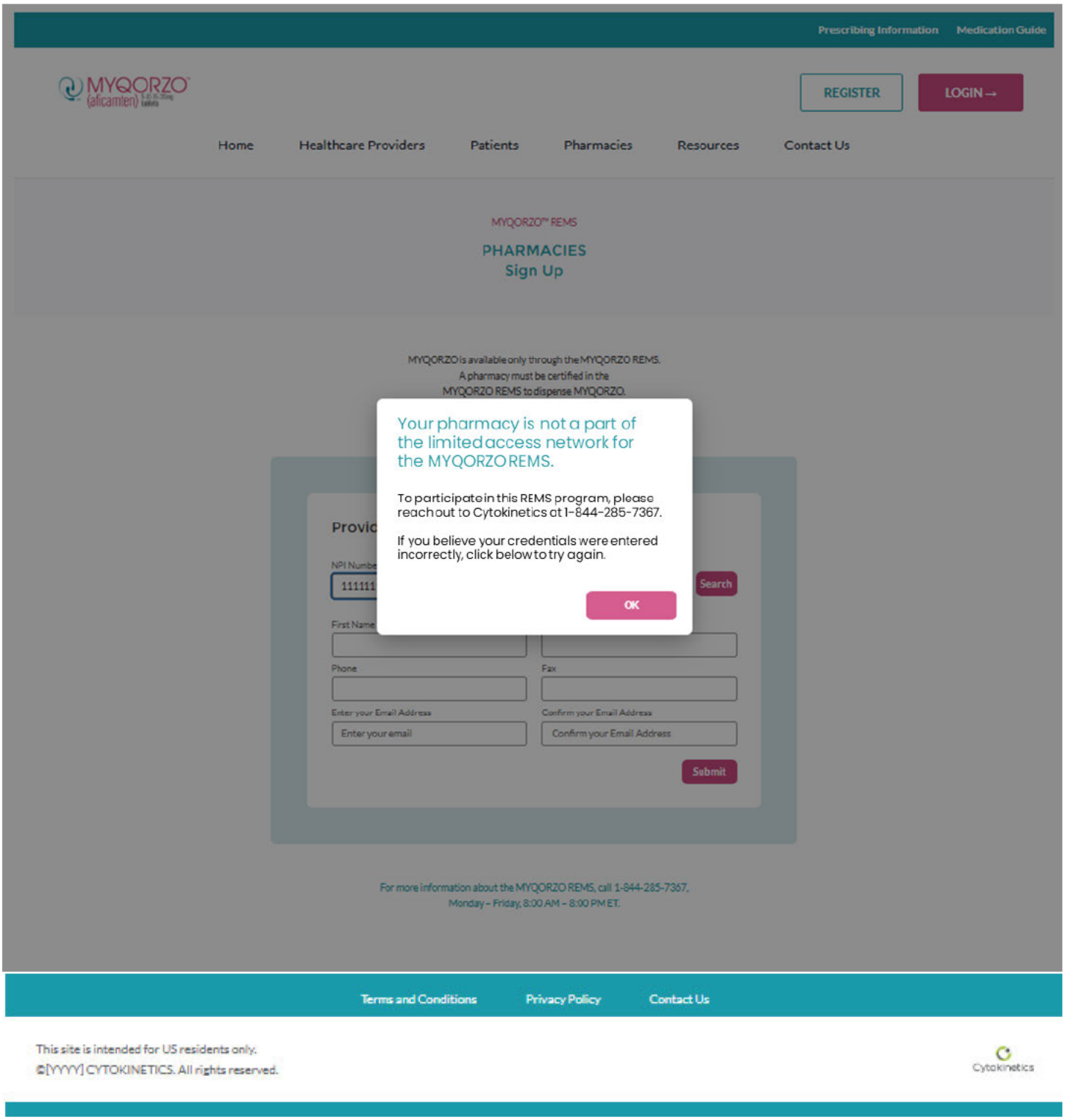
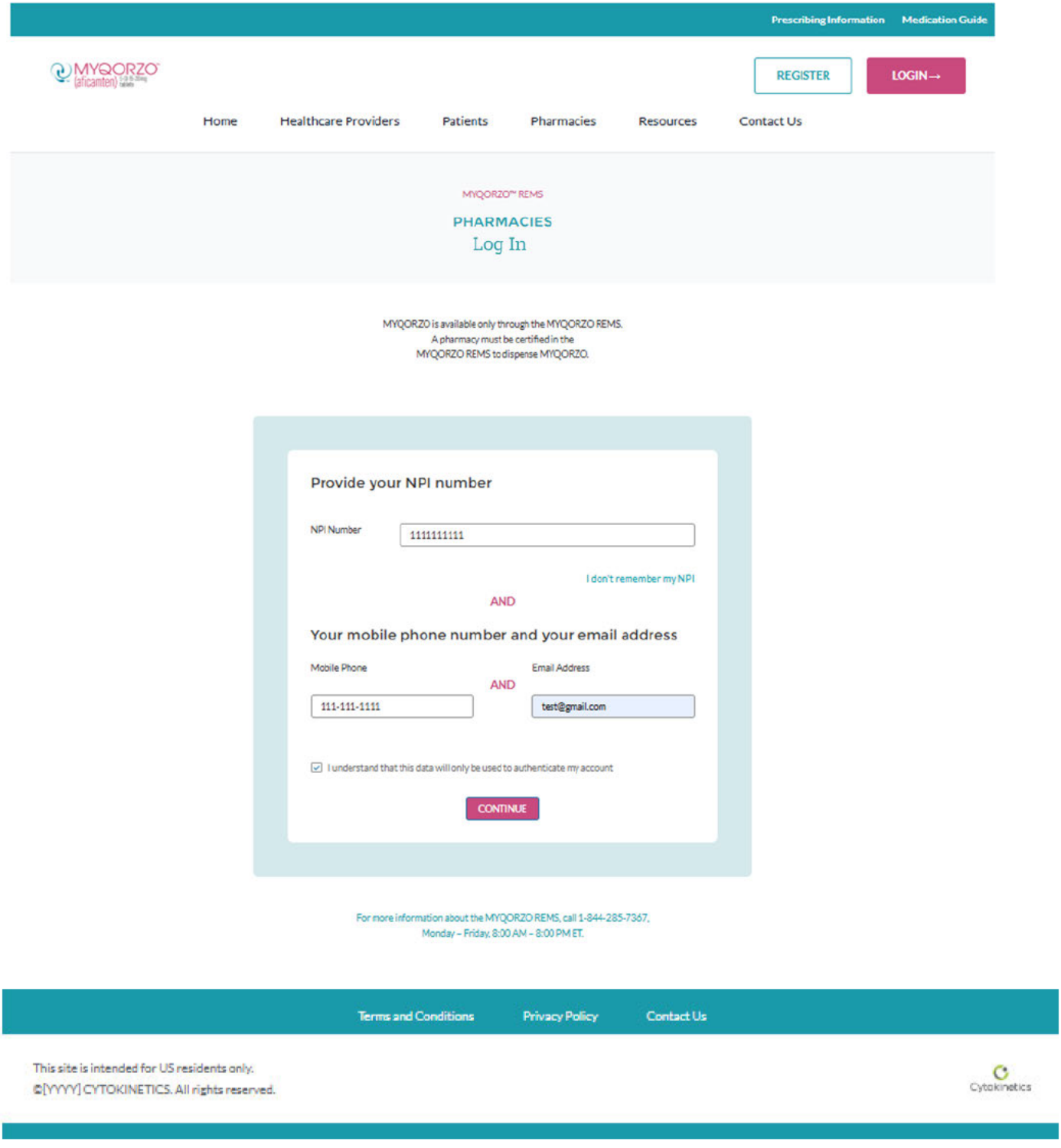


12. Pharmacy – Unsuccessful NPI Verification



13. Pharmacy – Log In



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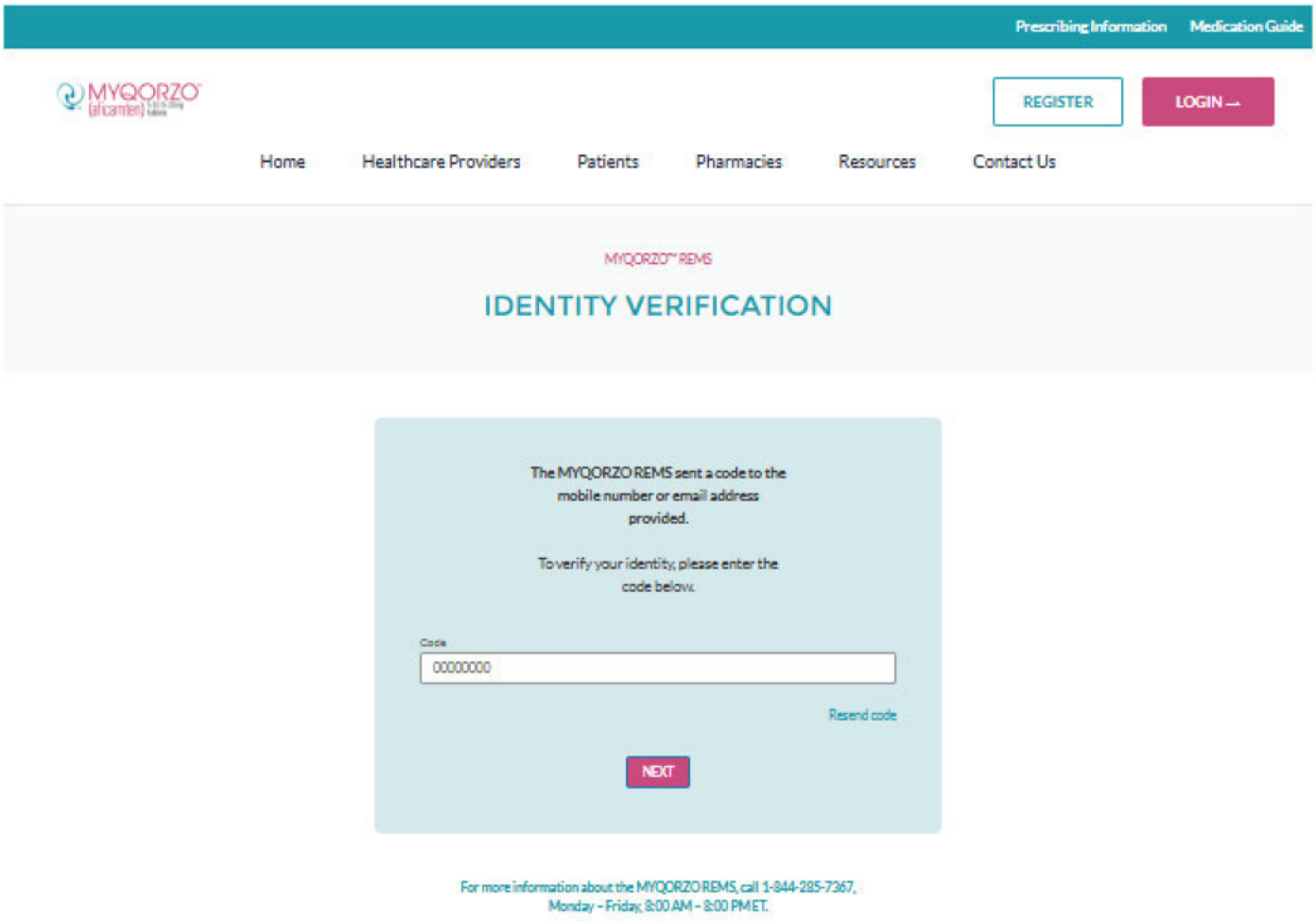
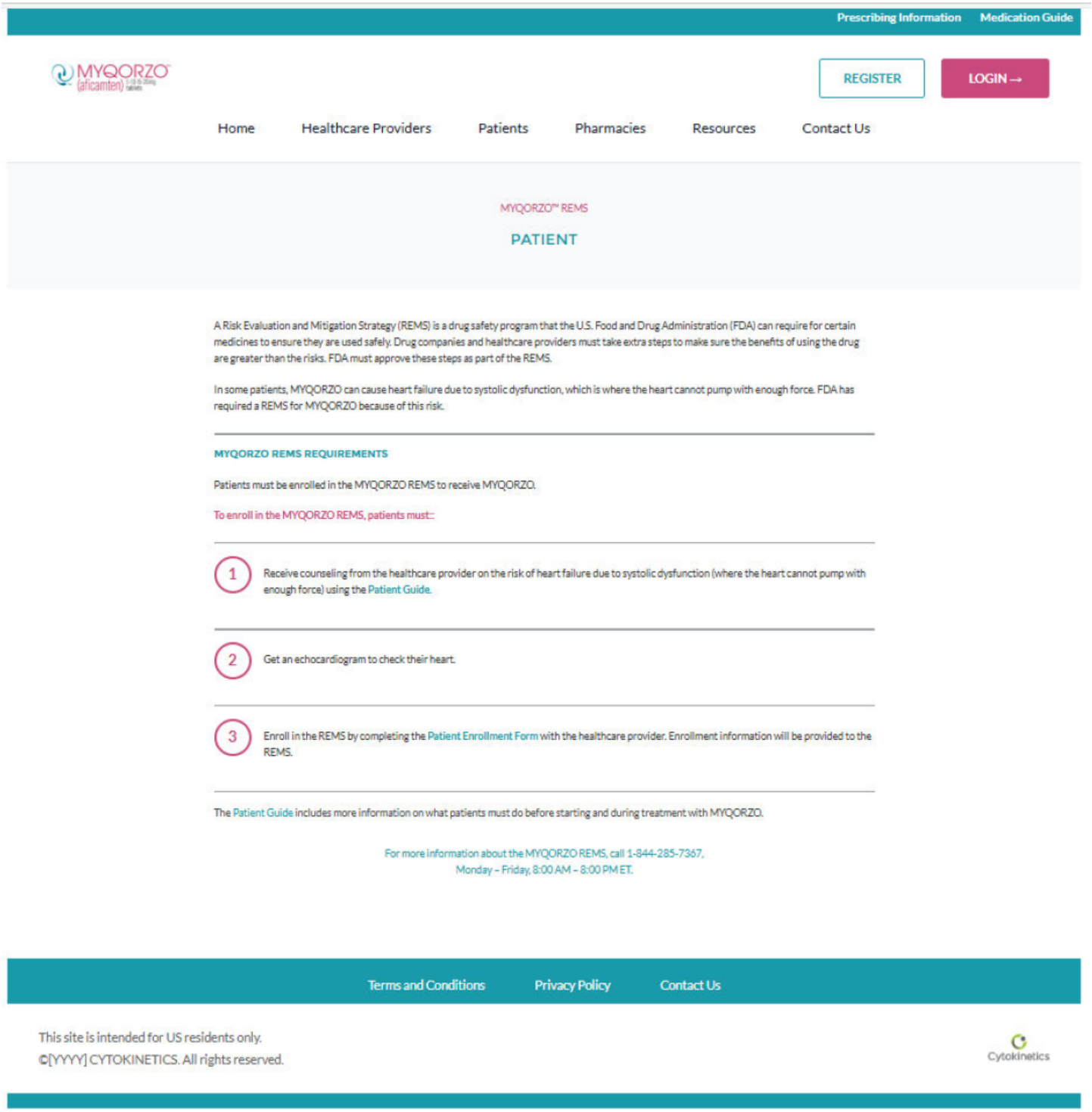
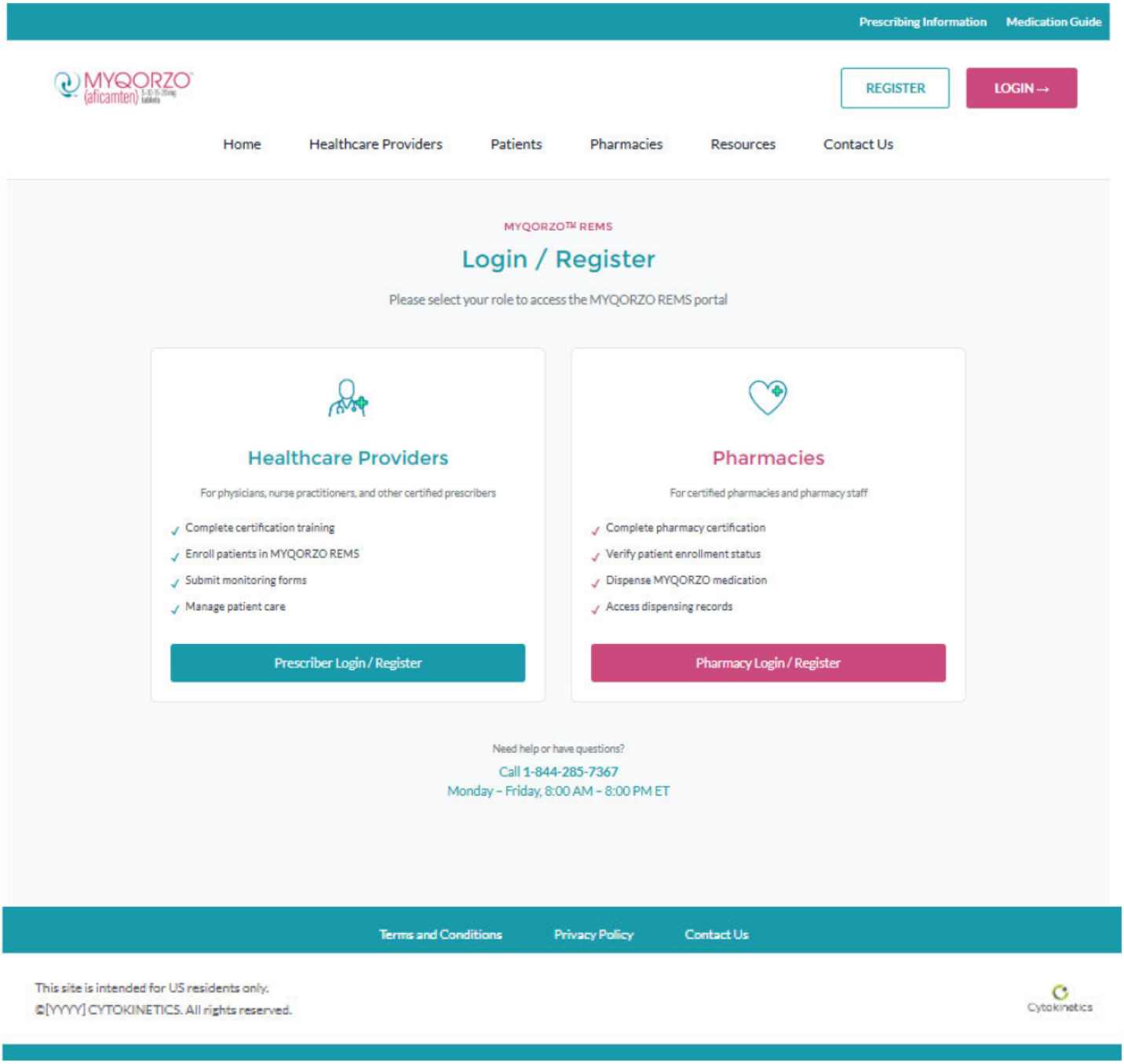


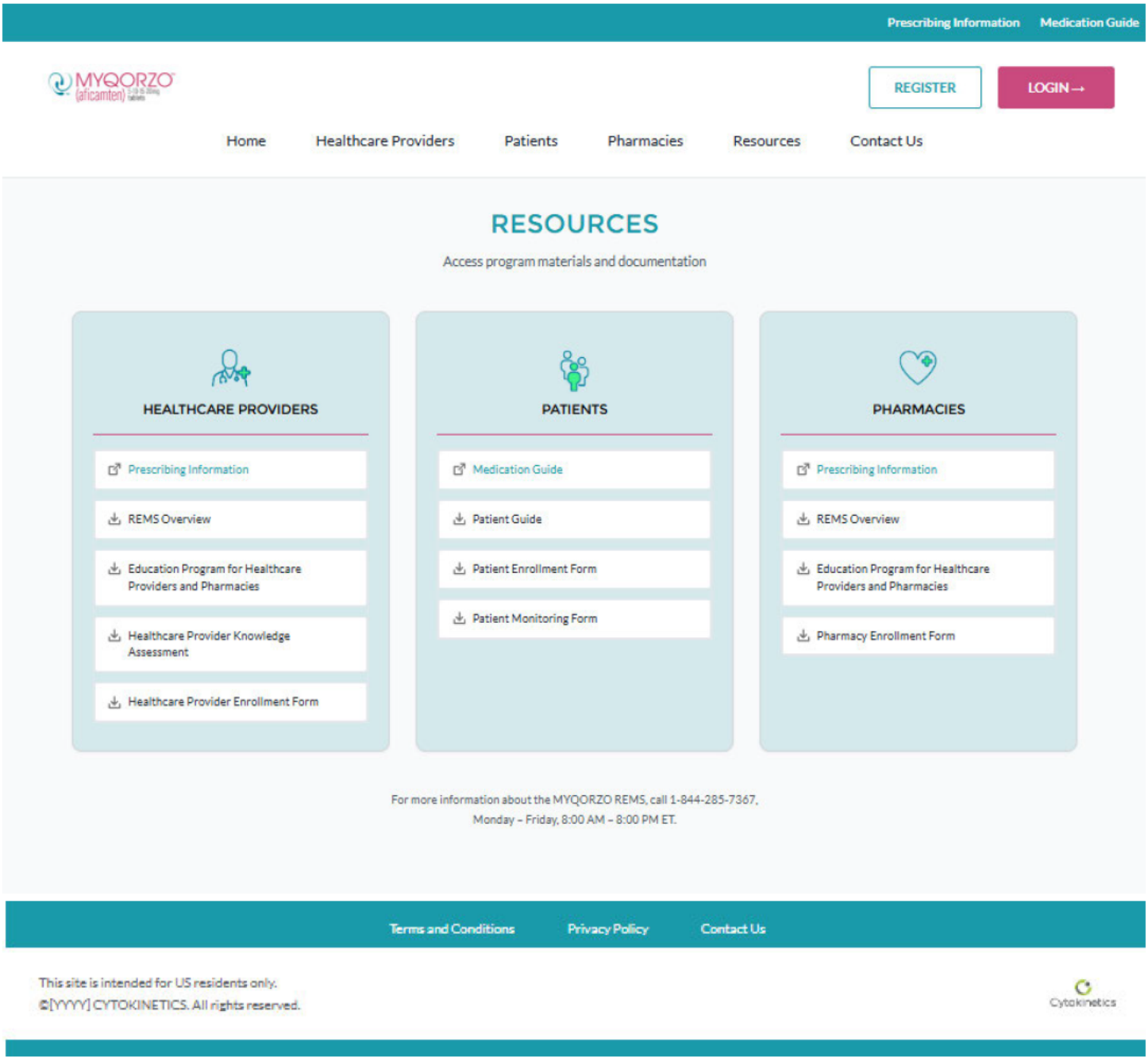
15. Patients Landing Page



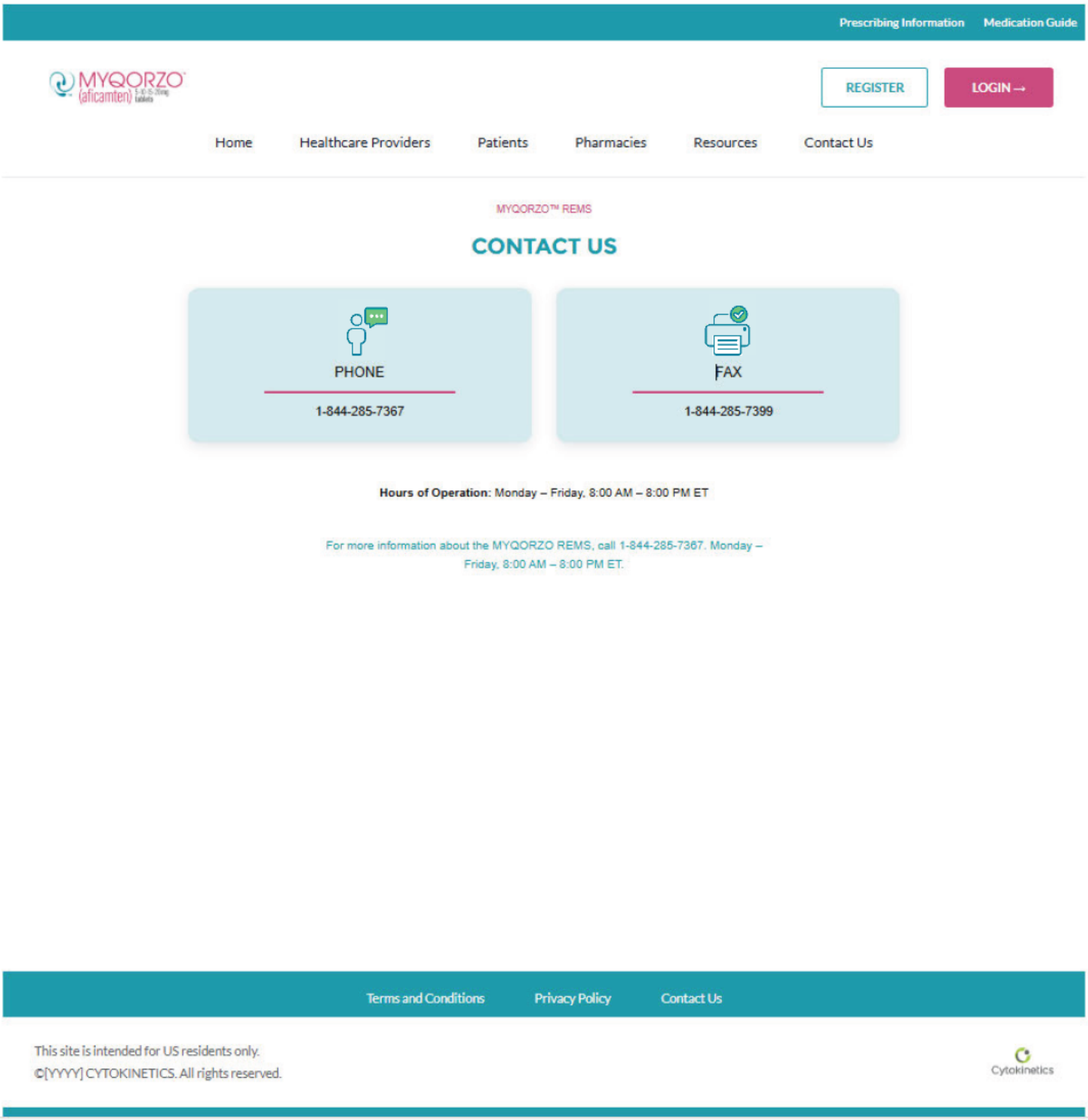
16. Log In / Register



17. Resources



18. Contact Us



This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

HYLTON V JOFFE
12/19/2025 12:22:15 PM