What is the FINTEPLA REMS (Risk Evaluation and Mitigation Strategy)?

The FINTEPLA REMS is a safety program to manage risk of valvular heart disease and pulmonary arterial hypertension. The REMS is required by the U.S. Food and Drug Administration (FDA) to ensure the potential benefits of FINTEPLA outweigh its risks.

FINTEPLA REMS Overview
- Only certified healthcare providers can prescribe FINTEPLA.
- Only certified pharmacies can dispense FINTEPLA.
- Educate patients on the risks of developing problems with the heart valves or high blood pressure in the arteries of the lungs.
- Enroll all patients in the REMS.

To learn more about the serious risks associated with FINTEPLA, please refer to the Prescribing Information, Prescriber Training, Pharmacy Guide, and REMS Program Overview.

To report adverse reactions or side effects, contact:
Zogenix Inc. at 1-866-964-3649 or
FDA at 1-800-FDA-1088
(www.FDA.gov/medwatch)

For FINTEPLA REMS Information contact:
Phone: 877-964-3649
Fax: 833-568-6198
Prescriber Requirements

How do I become certified to prescribe FINTEPLA?

1. Review the following educational materials on FINTEPLA to understand the risk of valvular heart disease and pulmonary arterial hypertension associated with FINTEPLA:
   - Review the Prescribing Information
   - Review the Prescriber Training and REMS Program Overview

2. Successfully complete the Prescriber Knowledge Assessment and submit it to the REMS:
   - Online
   - Fax
   - By Mail

3. Enroll in the REMS by completing the Prescriber Enrollment form and submitting it to the REMS:
   - Online
   - Fax
   - By Mail

How do I enroll a patient in the FINTEPLA REMS?

1. Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide.

2. Provide the patient with the Patient Guide.

3. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS:
   - Online
   - Fax
   - By Mail

4. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit the results and authorization for treatment to the REMS, using the Patient Status Form:
   - Online
   - Fax
   - By Mail

To ensure compliance with FINTEPLA REMS requirements, healthcare providers must:

During treatment: Every 6 months

1. Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment using the Patient Guide.

2. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document and submit the results and appropriateness of continued treatment to the REMS using the Patient Status Form.

After treatment discontinuation: 3 to 6 months

1. Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS using the Patient Status Form.

At all times

1. Report adverse events suggestive of valvular heart disease and/or pulmonary arterial hypertension on the Cardiovascular Adverse Event Reporting Form to the REMS.

2. Report treatment discontinuation or transfer of care to the REMS.
# FINTEPLA REMS Prescriber Enrollment Form

## Instructions

1. Review the FINTEPLA Prescribing Information, Prescriber Training, and REMS Program Overview
2. Successfully complete and submit the Prescriber Knowledge Assessment and this Prescriber Enrollment Form online at www.FinteplaREMS.com or fax to 1-833-568-6198 or mail to 1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134
3. 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

## PRESCRIBER INFORMATION

<table>
<thead>
<tr>
<th>First Name*:</th>
<th>Practice/Facility Name*:</th>
</tr>
</thead>
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<tr>
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<tr>
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<td>City*:</td>
</tr>
<tr>
<td>National Provider Identifier (NPI)*:</td>
<td>State*:</td>
</tr>
<tr>
<td>State License Number:</td>
<td>ZIP Code*:</td>
</tr>
<tr>
<td>Prescriber Email*:</td>
<td>Primary Contact at Office First Name:</td>
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<td>Specialty*:</td>
<td>Primary Contact at Office Last Name:</td>
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<td>Primary Contact Title:</td>
<td>Are primary contact phone and fax numbers different from practice/facility phone and fax numbers?</td>
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<tr>
<td>Preferred Method of Communication:</td>
<td>No Yes</td>
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<td>Primary Contact Fax Number:</td>
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</table>

## PRESCRIBER AGREEMENT

By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

- Review the FINTEPLA Prescribing Information (PI), Prescriber Training, and REMS Program Overview
- Successfully complete the Prescriber Knowledge Assessment and submit it to the REMS
- Enroll in the REMS by completing this form

### Before treatment initiation, to prescribe FINTEPLA to a patient, I will:

- Give the patient a copy of the Patient Guide
- Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide
- Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS
- Assess the patient’s cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit the results and authorization for treatment to the REMS using the Patient Status Form

### During treatment, every 6 months, I will:

- Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment and once 3 to 6 months after treatment discontinuation using the Patient Guide
- Assess the patient’s cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document and submit the results and appropriateness of continued treatment to the REMS using the Patient Status Form

### After treatment discontinuation, within 3 to 6 months, I will:

- Assess the patient’s cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS using the Patient Status Form

### At all times, I will:

- Report cardiovascular adverse events suggestive of valvular heart disease and pulmonary arterial hypertension to the REMS
- Report treatment discontinuation or transfer of care to the REMS

Reference ID: 4631810
Login

User Name

Password

Forgot password?

Login

New Prescriber User? Click here to Create Login
New Pharmacy User? Click here to Create Login
FINTEPLA is available only through the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) program. If you have any questions, please contact the FINTEPLA REMS Program at 877-964-3649 Monday through Friday between 7AM - 7PM Central Time.

To submit this form, please complete all required fields below. Required fields are denoted by***.

**Prescriber Information**

- National Provider Identifier (NPI) Number *
  - [Look up NPI](#)

- First Name *
  - [Submit](#)

- Last Name *
  - [Submit](#)

- Prescriber Email *
  - [Submit](#)

- Re-enter Prescriber Email *
  - [Submit](#)

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

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Hello, UserName@email.com  Change Password  |  Logout

PRESCRIBERS  PHARMACIES  PATIENTS  CONTACT US  RESOURCES

Tools

- REMS Prescriber Knowledge Assessment Certification

Documents

- Prescriber Training
- REMS Program Overview
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form
- Patient Enrollment Form
- Patient Guide
- Patient Status Form
- Cardiovascular Adverse Event Reporting Form
- Letter for Healthcare Providers
- Prescribing Information

This allows the prescriber to access online forms after login to the website.
FINTEPLA is available only through the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS).
If you have any questions or need additional information, please call 1-877-964-3649, Monday through Friday 7 AM - 7 PM Central Time.

Instructions
1. Review the FINTEPLA's Prescribing Information, the Prescriber Training and REMS Program Overview.
2. Successfully complete and submit this Prescriber's Knowledge Assessment at www.FinteplaREMS.com or fax to 1-833-568-6198 or mail to 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134.
3. Complete all required fields on this form to avoid delay in the enrollment process.

Prescriber Knowledge Assessment

Answer the following questions by selecting the 1 best answer. You must answer ALL questions correctly to become certified in the REMS.

You will have 3 tries to successfully complete the Prescriber Knowledge Assessment.
If you do not successfully complete the Prescriber Knowledge Assessment you will need to review the Prescriber Training and REMS Program Overview.

To submit this form, please complete all required fields below. Required fields are denoted by*.*

Prescriber Information

National Provider Identifier (NPI) Number *

First Name *

Phone *

Last Name *

Email *

SAVE and START Test
Prescriber Knowledge Assessment

Answer the following questions by selecting the 1 best answer. You must answer all 9 questions correctly to become certified in the FINTEPLA REMS.

Question 1:
The goal of the REMS is to mitigate the risk of valvular heart disease and pulmonary arterial hypertension.
- True
- False

Question 2:
In order to receive FINTEPLA, patients must enroll in REMS.
- True
- False

Question 3:
FINTEPLA is indicated for the treatment of seizures associated with Dravet syndrome in patients 2 years of age and older.
- True
- False

Question 4:
The signs and symptoms for valvular heart disease and pulmonary arterial hypertension may include:
- Shortness of breath
- Fatigue
- Dizziness or fainting
- Swelling of ankles and feet
- Rapid heartbeat
- All of the above

Question 5:
A patient must obtain an echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation.
- True
- False

Question 6:
I don’t need to document the results of the echocardiogram for each patient on the Patient Status Form in order to prescribe FINTEPLA.
- True
- False

Question 7:
I may be contacted by the REMS program for further information regarding any reports of valvular heart disease and pulmonary arterial hypertension.
- True
- False

Question 8:
Only pharmacies certified in the REMS may dispense FINTEPLA to patients.
- True
- False

Question 9:
An echocardiogram can identify evidence of valvular heart disease or pulmonary arterial hypertension prior to a patient becoming symptomatic.
- True
- False

Click to Submit and continue to Certification
FINTEPLA REMS Prescriber Knowledge Assessment Results

Prescribers who successfully complete the Prescriber Knowledge Assessment will receive:

You have successfully completed the Prescriber Knowledge Assessment.
You must complete the Prescriber Enrollment and submit to the REMS before prescribing FINTEPLA.
Enrollment and certification in the REMS will be confirmed within 2 business days.

Continue to Certification

Prescribers who did not achieve 100% will be presented the message below:

You did not achieve 100%; you must retake the Prescriber Knowledge Assessment.
You must successfully complete the Prescriber Knowledge Assessment within 3 attempts or you must review
the Prescriber Training and REMS Program Overview in order to retake the Prescriber Knowledge Assessment.

Review The Documents  Retake The Test
By completing, signing, and submitting this form, I agree to comply with the following REMS requirements:

1. Review the FINTEPLA Prescribing Information, Prescriber Training, and REMS Program Overview.
2. Successfully complete and submit the Prescriber Knowledge Assessment and Prescriber Enrollment Form online at www.FinteplaREMS.com or fax to 1-833-568-6198 or mail to 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134.
3. 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 upon successful certification within 2 business days.

Before treatment initiation, to prescribe FINTEPLA to a patient, I will:

1. Give the patient a copy of the Patient Guide.
2. Counsel the patient on the risks of valvular heart disease and pulmonary arterial hypertension, including how to recognize and respond to signs and symptoms of valvular heart disease and pulmonary arterial hypertension, and the need for cardiac monitoring via echocardiogram at baseline (treatment initiation), every 6 months during treatment, and once 3 to 6 months after treatment discontinuation using the Patient Guide.
3. Enroll the patient by completing and submitting the Patient Enrollment Form to the REMS.
4. Assess the patient's cardiovascular status and the appropriateness of initiating treatment by obtaining an echocardiogram. Document and submit the results and authorization for treatment to the REMS using the Patient Status Form.

During treatment, every 6 months, I will:

1. Counsel the patient on the need for cardiac monitoring via echocardiogram every 6 months during treatment and once 3 to 6 months after treatment discontinuation using the Patient Guide.
2. Assess the patient's cardiovascular status and the appropriateness of continuing treatment by obtaining an echocardiogram. Document and submit the results and appropriateness of continued treatment to the REMS using the Patient Status Form.

After treatment discontinuation, within 3 to 6 months, I will:

1. Assess the patient's cardiovascular status by obtaining an echocardiogram. Document and submit the results to the REMS using the Patient Status Form.
2. Report any cardiovascular adverse events suggestive of valvular heart disease and pulmonary arterial hypertension to the REMS.
3. Report treatment discontinuation or transfer of care to the REMS.

At all times, I will:

1. Report any cardiovascular adverse events suggestive of valvular heart disease and pulmonary arterial hypertension to the REMS.
2. Report any cardiorespiratory adverse events suggestive of valvular heart disease and pulmonary arterial hypertension to the REMS.
3. Report any treatment discontinuation or transfer of care to the REMS.

If you have any questions about this form, please call 1-877-799-9969.

To submit this form, please complete all required fields below. Required fields are denoted by "*".
*The site is intended for US residents only

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**Patient Agreement**

I have reviewed, read, and understood the Patient Guide that my healthcare provider has given me. Before my treatment begins:

- I will Enroll in the REMS by completing this Patient Enrollment Form with my healthcare provider.
- I will get an echocardiogram (ECHO) to check my heart.

My healthcare provider has counseled me on:

- The risk of developing heart valve problems and high blood pressure in my lung arteries.
- Recognizing the signs and symptoms associated with these risks.
- Importance of getting a test called an echocardiogram (ECHO) before starting FINTEPLA, every 6 months during treatment, and once 3 to 6 months after I stop treatment.

During treatment, every 6 months:

- I will receive counseling from my healthcare provider on the importance of getting an echocardiogram (ECHO).
- I will get an echocardiogram (ECHO) to check my heart.

After stopping treatment, 3 to 6 months after my final dose:

- I will get one last echocardiogram (ECHO) to check my heart.

At all times:

- I will let all my healthcare providers know that I am taking FINTEPLA.
- I will also tell my healthcare provider if I am having any of these signs or symptoms:
  - Shortness of breath
  - Rapid heartbeat
  - Fatigue
  - Swelling of ankles and feet
  - Dizziness or fainting spells
  - Chest pressure or pain

I understand that:

- Zogenix, Inc. and its agents may contact me via phone, mail, fax, or email to support administration of the REMS.
- Zogenix, Inc. and its agents may use and share my personal health information, including echocardiogram (ECHO) results and prescription data collected as part of the REMS for the purpose of operations, analysis, and reporting of the REMS including enrolling me into, administering, and evaluating the REMS, coordinating the dispensing of FINTEPLA, and releasing my personal health information to the Food and Drug Administration (FDA), as necessary.
- In order to receive FINTEPLA, I am required to be enrolled in the REMS, and my information will be stored in a database of all participants who receive FINTEPLA in the United States.

---

**Prescriber Agreement**

By signing below, I acknowledge that I have reviewed the risks of FINTEPLA and the requirements of the FINTEPLA REMS with this patient.
Patient Status Form

Prior to starting and during treatment, patients must undergo an echocardiogram (ECHO) to evaluate for cardiac abnormalities. The prescriber must consider the benefits versus the risks of initiating or continuing treatment with FINTEPLA if any of the following signs are observed on an echocardiogram:

- Valvular heart disease (VHD) as indicated by mild or greater aortic regurgitation or moderate or greater mitral regurgitation
- Pulmonary arterial hypertension (PAH) as indicated by elevated right heart/pulmonary artery pressure [PASP > 35mm Hg]

Instructions

This form must be regularly completed for all patients treated with FINTEPLA:

- Before the start of FINTEPLA treatment.
- With completion of each echocardiogram every 6 months for the duration of FINTEPLA treatment.
- With completion of echocardiograms performed 3 to 6 months after the final dose of FINTEPLA.

This form must be regularly completed for all patients treated with FINTEPLA:

- Before the start of FINTEPLA treatment.
- With completion of each echocardiogram every 6 months for the duration of FINTEPLA treatment.
- With completion of echocardiograms performed 3 to 6 months after the final dose of FINTEPLA.

To submit this form, please complete all required fields below. Required fields are denoted by *.

Patient Information

First Name *
Last Name *
REMS ID
Street Address, line 1 *
Street Address, line 2
City * State *
Zip *
Date of Birth (MM/DD/YYYY) *

Prescriber Information

First Name *
Last Name *
REMS ID
National Provider Identifier (NPI) *
Street Address, line 1 *
Street Address, line 2
City * State *
Zip *
Telephone Number *
Fax Number *
E-mail

FINTEPLA Dosing Information

Current Dose of FINTEPLA: mg/kg/day Total mg/day Current Duration of treatment with FINTEPLA:

Echocardiogram Results

Date of ECHO (MM/DD/YYYY) *

Regurgitation

- Select -

NYHA
- Select -

MOD
d - Select -

Severe
- Select -

PAH: Yes No

Any new abnormality reported on baseline echocardiogram (only applicable to baseline echocardiogram assessment)

Any new abnormality on echocardiogram (not previously reported)

Authorization for Treatment

If this patient is not authorized to receive FINTEPLA, please provide the reason(s) (please select all that apply): *

- Select -

Submitted by *

- Select -

Signature *

Submit
Cardiovascular Adverse Event Reporting Form

My patient’s most recent echocardiogram observed signs of valvular heart disease (VHD), pulmonary arterial hypertension (PAH) or other cardiac findings in the echocardiogram.

Instructions
Within 3 business days of receipt, complete this form and submit the completed form online at www.FiniteplaREMS.com, via fax to 1-833-568-6198, or via mail to 1710 N Shelby Oaks Dr, Ste 3, Memphis, TN 38134.

If you have any questions or need additional information, please visit www.FiniteplaREMS.com or call 1-877-964-3649, Monday through Friday between 7 AM–7 PM Central Time.
FINTEPLA is available only through the FINTEPLA Risk Evaluation and Mitigation Strategy (REMS) program. If you have any questions, please contact the FINTEPLA REMS Program at 877-964-3649 Monday through Friday between 7AM - 7PM Central Time.

To submit this form, please complete all required fields below. Required fields are denoted by "***".

**Pharmacy Information**

Pharmacy Name *** Pharmacy National Provider Information (NPI): ***

**Authorized Representative Information**

First Name *** Last Name *** Email ***

Confirm Email ***

Create Login
Outpatient Pharmacy Requirements

How do I become certified to dispense FINTEPLA?
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 Pharmacy Guide and REMS Program Overview.
3. Have the authorized representative enroll the Pharmacy in the REMS by completing the Outpatient Pharmacy Enrollment Form and submitting it to the REMS.
   - Online
   - Fax
   - By Mail
4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.

To Ensure Compliance with the FINTEPLA REMS Requirements, Pharmacies must:

Before dispensing FINTEPLA
1. Obtain authorization to dispense by contacting the REMS to verify that the prescriber is certified, and the patient is enrolled, and authorized to receive the drug.

To maintain certification to dispense
1. Have the new authorized representative enroll in the REMS by completing the Outpatient Pharmacy Enrollment Form if the authorized representative changes.

At all times
1. Not distribute, transfer, loan, or sell FINTEPLA, except to certified pharmacies.
2. Maintain records of dispensing information.
3. Maintain records that all processes and procedures are in place and being followed.
4. Maintain records documenting staff’s completion of REMS training.
5. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.

Inpatient Pharmacy Requirements:

How do I become certified to dispense FINTEPLA?
1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS requirements on behalf of the pharmacy.
2. Have the authorized representative review the Pharmacy Guide and REMS Program Overview.
3. Have the authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the REMS.
   - Online
   - Fax
   - By Mail
4. Train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.

To Ensure Compliance with the REMS Requirements Pharmacies must:

Before dispensing FINTEPLA
1. For patients initiating treatment: Obtain authorization to dispense each prescription by contacting the REMS to verify that the prescriber is certified, and the patient is enrolled and authorized to receive the drug.
2. For patient continuing treatment: Obtain authorization to dispense each prescription by contacting the REMS to verify that the patient is enrolled and authorized to receive the drug.

At discharge
1. Dispense no more than 15 days’ supply.

To maintain certification to dispense
1. Have the new authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form if the authorized representative changes.

At all times
1. Not distribute, transfer, loan, or sell FINTEPLA.
2. Maintain records of dispensing information.
3. Maintain records that all processes and procedures are in place and being followed.
4. Maintain records documenting staff’s completion of REMS training.
5. Comply with audits carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.
To become a FINTEPLA REMS certified pharmacy, enroll by following these steps:

**STEP 1: REVIEW**
- Designate an Authorized Representative.
- Authorized Representative review the Pharmacy Guide and REMS Program Overview.

**STEP 2: COMPLETE AND SIGN**
- The Authorized Representative must complete and sign this Outpatient Pharmacy Enrollment Form.
- If the Authorized Representative changes, the new Authorized Representative must complete and sign a new Outpatient Pharmacy Enrollment Form.

**STEP 3: SUBMIT**
- Submit the Form via:
  - Online at www.FinteplaREMS.com or
  - Via fax to 1-833-568-4998 or
  - Via mail to 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134

To submit this form, please complete all required fields below. Required fields are denoted by "*".

**Authorized Pharmacy Representative Agreement:**

I am the Authorized Representative designated by my outpatient pharmacy to coordinate the activities of the REMS.

By completing, signing, and submitting this form on behalf of myself and my outpatient pharmacy, I attest that:
- I have reviewed the Pharmacy Guide and REMS Program Overview.
- I am enrolling in the REMS.
- I agree to train all relevant staff involved in dispensing FINTEPLA on the REMS requirements using the Pharmacy Guide.
- I will ensure that, before dispensing, all pharmacy staff obtain authorization to dispense each prescription by contacting the FINTEPLA REMS to verify the prescriber is certified and the patient is enrolled and authorized to receive FINTEPLA.
- I will maintain records of dispensing information.
- I will maintain records documenting staff's completion of REMS training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will ensure that all pharmacy staff comply with audit carried out by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and are being followed.

If the authorized representative changes, this pharmacy will have the new authorized representative enroll in the REMS by completing the Outpatient Pharmacy Enrollment Form.

To submit this form, please complete all required fields below. Required fields are denoted by "*".

**Pharmacy Name **
Street Address, line 1 *
Street Address, line 2 *
City * State * Zip *
Telephone Number * Fax Number * E-mail *
National Provider Identifier (NPI) *
Pharmacy DEA Number *
National Provider Identifier (NPI) *
Pharmacy DEA Number *

**Authorized Representative Information**

First Name * Last Name *
Credentials *
- R.PH
- PharmD
- BCPS
- Other (please specify) *
Preferred Method of Communication:
- Phone
- Fax
- E-mail

**Preferred Method of Communication:**

Select Signing Reason?
- Select *

Signature *
Inpatient Pharmacy Enrollment Form

To become a FINTEPLA REMS certified pharmacy, enroll by following these steps:

STEP 1: REVIEW
- Designate an Authorized Representative.
- The Authorized Representative review the Pharmacy Guide and REMS Program Overview.

STEP 2: COMPLETE AND SIGN
- The Authorized Representative must complete and sign this Inpatient Pharmacy Enrollment Form.
- If the Authorized Representative changes, the new Authorized Representative must complete and sign a new Inpatient Pharmacy Enrollment Form.

STEP 3: SUBMIT
- Submit this form online:
  - Online at www.FinteplaREMS.com
  - Via fax at 1-833-568-6198
  - Via mail to: Zogenix, Inc., Attn: Rems Pharmacy, 1710 N Shelby Oaks Dr, Suite 3, Memphis, TN 38134

To submit this form, please complete all required fields below. Required fields are denoted by *.

Authorized Representative Information

First Name * Last Name *
Credentials *
- R.PH
- PharmD
- BCPS
- Other (please specify):

Phone Number * Fax Number * Email *
Preferred method of contact:
- Phone
- Fax
- Email

Authorized Pharmacy Representative Agreement:

I am an authorized representative designated by my inpatient pharmacy to coordinate the activities of the REMS. I certify, by completing, signing, and submitting this form on behalf of myself and my inpatient pharmacy, that:

1. I have reviewed the Pharmacy Guide and REMS Program Overview.
2. I am enrolled in the REMS.
3. I agree to train all relevant staff involved in dispensing FINTEPLA in the REMS requirements using the Pharmacy Guide.
4. For patients initiating treatment: before dispensing, all pharmacy staff must obtain authorization to dispense each prescription by contacting the FINTEPLA REMS to verify the prescriber is certified, and the patient is enrolled and authorized to receive FINTEPLA.
5. For patients continuing treatment: before dispensing, all pharmacy staff must obtain authorization to dispense each prescription by contacting the REMS to verify that the patient is under the care of a certified prescriber, and the patient is enrolled and authorized to receive FINTEPLA.
6. I will not dispense more than 15 days’ supply at discharge.
7. I agree to ensure that all pharmacy staff do not distribute, transfer, loan or sell FINTEPLA.
8. I will maintain records of dispensing information.
9. I will maintain records documenting staff’s completion of REMS training.
10. I will maintain records that all REMS processes and procedures are in place and being followed.
11. I will ensure that all pharmacy staff comply with any audits conducted by Zogenix, Inc. or a third party acting on behalf of Zogenix, Inc. to ensure that all processes and procedures are in place and being followed.
12. If the authorized representative changes, this pharmacy will have the new authorized representative enroll in the REMS by completing the Inpatient Pharmacy Enrollment Form.

Select Signing Reason
- Select -

* Signature

SUBMIT
## Prescriber List

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<thead>
<tr>
<th>HCP ID</th>
<th>First Name</th>
<th>Last Name</th>
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<td>SMITH</td>
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</table>

**Reference ID:** 4631810
Patient Authorized to Receive FINTEPLA

Do you want a Dispense Authorization number for the selected Patient?

Yes  No

If the Pharmacy checks YES they will go on to page 22.
Dispense Authorization Number

Patient and Provider Information

Patient First Name: Anee
Patient Last Name: e
DOB: 05/20/1999
Patient Echo Due Date: 06/18/2020

Provider First Name: THOMAS
Provider Last Name: OUELLETTE
NPI: 1231231231
Certification Expiration Date: 07/12/2021

Patient Dispense Authorization Information

Patient Status: [ ]
Authorization Number: 17890659

A unique authorization number will be generated for each authorization to dispense, which FINTEPLA REMS will record in the patient's file. The pharmacy is not required to maintain record of the authorization number.

Do you want to authorize another patient?

[ ] Yes  [ ] No
Patient First Name

MRN

Search

Reset

Patient NOT Authorized to Receive FINTEPLA.
Patient is Enrolled in REMS but does not have a valid Echo, please contact REMS Administrator, 877-964-3649

OK
Prescriber Not Certified

Prescriber is not certified, please contact REMS Administrator, 877-964-3649

Prescriber's Certification is pending
<table>
<thead>
<tr>
<th>HCP ID</th>
<th>First Name</th>
<th>Last Name</th>
<th>State of License</th>
<th>NPI</th>
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<tr>
<td>15</td>
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<td>MI</td>
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<td>18</td>
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<td>GA</td>
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<td>Freeman</td>
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<td>1124132768</td>
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<td>1982577951</td>
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<td>Asim</td>
<td>Shahid</td>
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Prescriber not found, please try new search or contact REMS Administrator, 877-964-3649.

Reference ID: 4631810
Patient Authorized to Receive FINTEPLA. Patient has a valid Echo to obtain an Authorization number for the dispense.
Patient not found, please try new search or contact REMS Administrator, 877-964-3649

<table>
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<th>HubID</th>
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<th>Patient Last Name</th>
<th>Patient DOB</th>
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<tr>
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<td>02/02/2017</td>
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<td>16</td>
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<td>Ann</td>
<td>Galesite</td>
<td>02/15/2019</td>
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<td>Bob</td>
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<td>02/04/2018</td>
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<td>17</td>
<td></td>
<td>Catherine</td>
<td>Test-Twentyfive</td>
<td>03/10/2013</td>
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</table>
PATIENTS

How do I receive FINTEPLA?

• Review the Patient Guide.
• Talk to your healthcare provider about the information in this Patient Guide.
• Complete the Patient Enrollment Form. Your healthcare provider will help you with this.
• Get an ECHO before you start taking FINTEPLA. The ECHO will check for signs of heart valve problems or high blood pressure in the arteries of the lungs. An ECHO can identify heart valve problems or high blood pressure in the arteries of the lungs before having any symptoms which may help prevent serious medical problems. Therefore, it is very important to get an ECHO prior to taking FINTEPLA and at regular intervals while on the medicine.
• After you and your healthcare provider have discussed your ECHO results and decided to begin or continue FINTEPLA, the REMS will notify the pharmacy of your decision and you will be contacted regarding next steps for obtaining FINTEPLA.

What do I need to do during the time I am on FINTEPLA?

• You will have an ECHO every 6 months as long as you are taking FINTEPLA.

What do I need to do if I stop taking FINTEPLA?

• If you stop taking FINTEPLA, you will have an ECHO one last time 3 to 6 months after your final dose.

What do I need to do if I stop taking FINTEPLA?

• If you stop taking FINTEPLA, you will have an ECHO one last time 3 to 6 months after your final dose.

FINTEPLA ECHO Monitoring Timeline

It is important that you read the Medication Guide that comes with your medicine for more information about FINTEPLA. The REMS just covers the risk of heart valve problems and high blood pressure in the arteries of the lungs from the medication. The Medication Guide explains how to take FINTEPLA and has other information about other serious risks and potential side effects.

Where can I find more information about the REMS?

• If you have questions about the REMS, you can visit www.FinteplaREMS.com or call the REMS at 1-877-964-3649 (7 am to 7 pm Central Time)

To report side effects, contact Zogenix, Inc. at 1-866-964-3649, or the FDA at 1-800-FDA-1088 (www.fda.gov/medwatch).
CONTACT US

For FINTEPLA REMS Information contact:

FINTEPLA REMS
1710 Shelby Oaks Drive North Suite #3
Memphis, TN  38134

Phone: 877-964-3649
Fax: 833-568-6198
www.FinteplaREMS.com
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/

NICHOLAS A KOZAUER
06/25/2020 06:43:49 PM