

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

The ZULRESSO REMS is a safety program to manage the **risk of serious harm resulting from excessive sedation and sudden loss of consciousness** during the ZULRESSO infusion.

The REMS is required by the U.S. Food and Drug Administration (FDA) to ensure the potential benefits of ZULRESSO outweigh its risks.

## ZULRESSO REMS Overview

- Only administer ZULRESSO to patients in a medically supervised setting that provides monitoring during administration.
- Only certified Pharmacies and Healthcare Settings can dispense ZULRESSO.
- Educate patients on the risks of serious harm from excessive sedation and loss of consciousness and the need for monitoring while ZULRESSO is administered.
- Enroll all patients in a registry.



**Healthcare Settings**

[CERTIFY IN THE ZULRESSO REMS >](#)

[HOW TO ADMINISTER ZULRESSO >](#)



**Pharmacies**

1. Designate an Authorized Representative
2. Review the Program Overview for Pharmacies
3. Complete the Pharmacy Enrollment Form

[ENROLL IN THE ZULRESSO REMS >](#)



**Patients**

1. Understand the risks associated with ZULRESSO
2. Learn how to enroll in the ZULRESSO REMS

[HOW TO RECEIVE ZULRESSO >](#)



**Healthcare Professionals**

1. Review education materials

[LEARN ABOUT ZULRESSO >](#)



**Forms and Resources**

Downloadable forms and educational resources to learn about and enroll in the ZULRESSO REMS.

[VIEW RESOURCES >](#)

ZULRESSO is indicated for the treatment of postpartum depression (PPD) in adults.

Please see **Prescribing Information**, including **BOXED WARNING**.



If you have questions about the ZULRESSO REMS Program or need help, call **844-472-4379** Monday - Friday 8AM-8PM ET.

To report any **SUSPECTED ADVERSE REACTIONS**, contact Sage Therapeutics, Inc. at **844-472-4379** or FDA at **800-FDA-1088** or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

# ZULRESSO REMS Healthcare Setting Enrollment

Healthcare Settings must be certified in the ZULRESSO REMS to administer ZULRESSO.

To enroll and become certified in the program, the Healthcare Setting must complete the following steps:



**STEP 1**

## Designate and Maintain

Identify an Authorized Representative. The Authorized Representative will carry out the certification process, and oversee implementation and compliance with the ZULRESSO REMS on behalf of the Healthcare Setting.

The Authorized Representative will complete the following steps:



**STEP 2**

## Review

The Authorized Representative should review the Training for Healthcare Settings through the module on this site as well as the Prescribing Information.

**Download**



TRAINING FOR HEALTHCARE SETTINGS



PRESCRIBING INFORMATION

**Online**



LOGIN/REGISTER



**STEP 3**

## Complete

Complete the ZULRESSO REMS Healthcare Setting Knowledge Assessment. All questions must be answered correctly to become certified.

**Email/Fax/Mail**



HEALTHCARE SETTING KNOWLEDGE ASSESSMENT

**Online**



LOGIN/REGISTER



**STEP 4**

## Complete

Complete the ZULRESSO REMS Healthcare Setting Enrollment Form.

**Email/Fax/Mail**



HEALTHCARE SETTING ENROLLMENT FORM

**Online**



LOGIN/REGISTER



**STEP 5**

## Submit

If you haven't completed the forms online, submit the completed ZULRESSO REMS Healthcare Setting Knowledge Assessment and ZULRESSO REMS Healthcare Enrollment Form.

Completed forms not submitted online can be sent to the ZULRESSO REMS via email at [information@zulressorems.com](mailto:information@zulressorems.com), via fax at 833-584-7243, or mailed to the ZULRESSO REMS at 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.



**STEP 6**

## Implement

Implement the necessary processes and procedures to comply with the ZULRESSO REMS.

Please see [Prescribing Information](#), including **BOXED WARNING**.



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# ZULRESSO REMS Healthcare Setting Administration

Healthcare Settings must be certified in the ZULRESSO REMS to administer ZULRESSO.

## Before Administering ZULRESSO



### STEP 1 Counsel

Counsel the patients using the [Patient Information Guide](#) and provide a copy to the patient.



[PATIENT INFORMATION GUIDE](#)



### STEP 2 Enroll

Enroll the patient in the ZULRESSO REMS by ensuring trained staff complete the [ZULRESSO REMS Patient Enrollment Form](#) with the patient. Retain a copy of the completed form in the patient's record.



[PATIENT ENROLLMENT FORM](#)



### STEP 3 Submit

Submit the completed [ZULRESSO REMS Patient Enrollment Form](#).

Completed forms can be faxed to the ZULRESSO REMS at 833-564-7243, emailed to the ZULRESSO REMS at [information@zulressorems.com](mailto:information@zulressorems.com), or mailed to the ZULRESSO REMS at 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.



## POST ADMINISTRATION REQUIREMENTS

### Post Infusion Form

The Post Infusion Form must be submitted to the ZULRESSO REMS after the completion of the infusion, if the patient receives any part of the infusion, or if the infusion has been canceled. If the infusion has been rescheduled, the form should be completed at that time.

### Adverse Event Form

If a patient experiences an event of excessive sedation or loss of consciousness this should be indicated on the Post Infusion Form. Fill out an Excessive Sedation and Loss of Consciousness Adverse Event Form. You will be contacted for further information on reported events by the ZULRESSO REMS.

### How to Submit

- Submit the Post Infusion Form and, if need be, the Excessive Sedation and Loss of Consciousness Adverse Event Form to the ZULRESSO REMS within 3 business days of the patient completing the infusion or the scheduled infusion start date
- You can only submit an Excessive Sedation and Loss of Consciousness Adverse Event Form with a completed Post Infusion Form

The Post Infusion Form and the Excessive Sedation and Loss of Consciousness Adverse Event Form can be completed via securely logging into this website, faxed to the ZULRESSO REMS at 833-564-7243 or emailed to [information@zulressorems.com](mailto:information@zulressorems.com).

### By Fax/Email



[POST INFUSION FORM](#)



[EXCESSIVE SEDATION AND LOSS OF CONSCIOUSNESS ADVERSE EVENT FORM](#)

### Online



[LOGIN/REGISTER](#)

To report any other adverse events contact Sage Therapeutics at 844-472-4379 or FDA at 800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Contact the ZULRESSO REMS at 844-472-4379 to obtain contact information for certified Pharmacies and for distributors who are authorized to ship to certified inpatient Pharmacies.

Please see [Prescribing Information](#) including BOXED WARNING.



If you have questions about the ZULRESSO REMS or need help, call **844-472-4379** Monday - Friday 8AM-8PM ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at **844-472-4379** or FDA at **800-FDA-1088** or <http://www.fda.gov/medwatch>.



# ZULRESSO REMS Pharmacy Enrollment

Pharmacies must be enrolled in the ZULRESSO REMS to be able to prepare and ship ZULRESSO.

Pharmacies outside the Healthcare Setting that are preparing ZULRESSO for administration must enroll in the program and complete the following steps:



## STEP 1 Designate

Designate an Authorized Representative to carry out the enrollment process and oversee implementation and compliance with the ZULRESSO REMS on behalf of the pharmacy.

The Authorized Representative will complete the following steps:



## STEP 2 Review

The Pharmacy should review the [ZULRESSO REMS Program Overview for Pharmacies](#).



PROGRAM OVERVIEW FOR PHARMACIES



## STEP 3 Enroll

Enroll in the ZULRESSO REMS by completing and submitting the **Pharmacy Enrollment Form**.

Completed forms not submitted online can be sent to the ZULRESSO REMS via email at [information@zulressorems.com](mailto:information@zulressorems.com), via fax at 833-564-7243, or mailed to the ZULRESSO REMS at 7751 Brier Creek Parkway, Suite 200, Raleigh, NC 27617.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.

### Email/Fax/Mail



PHARMACY ENROLLMENT FORM

### Online



PHARMACY ENROLLMENT FORM



## STEP 4 Establish

Establish processes and procedures to ensure ZULRESSO is dispensed only to a certified Healthcare Setting enrolled in the ZULRESSO REMS Program.

[HEALTHCARE SETTINGS LIST](#)



## STEP 5 Train

Train all relevant staff involved in dispensing of ZULRESSO on the relevant processes and procedures.

Please see [Prescribing Information](#), including BOXED WARNING.



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## ZULRESSO™ REMS Pharmacy Enrollment Form

Complete and submit this form by clicking "Submit" below.

**If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.**

1. Review REMS Program Overview
2. Review and complete this Pharmacy Enrollment Form
3. Submit the completed form by clicking "Continue" below

\* Indicates Required Field

### PHARMACY INFORMATION

\* National Provider Identifier (NPI#)

CONTINUE

Please see [Prescribing Information](#) including BOXED WARNING.



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call **844-472-4379** Monday - Friday 8AM-8PM ET.

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# ZULRESSO™ REMS Pharmacy Enrollment Form

Complete and submit this form by clicking "Submit" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.

1. Review REMS Program Overview
2. Review and complete this Pharmacy Enrollment Form
3. Submit the completed form by clicking "Continue" below

\* Indicates Required Field

**PHARMACY INFORMATION**

\* National Provider Identifier (NPI#)

---

\* Pharmacy Name

\* Pharmacy Type  
 Specialty  Specialty Infusion  Compounding  Other

\* National Council for Prescription Drug Program ID (NCPDP)

\* Pharmacy DEA Number

\* Address 1  Address 2

\* City  \* State  \* ZIP

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Click below to enroll an additional Pharmacy location (optional)

[+ ADDITIONAL PHARMACY LOCATION](#)

Your Pharmacy information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Pharmacy to purchase product.

**AUTHORIZED REPRESENTATIVE INFORMATION**

\* First Name  MI  \* Last Name  \* Title

\* Credentials  \* Reason for Form  
 New Enrollment  New Representative

\* Phone Number  \* Fax Number  \* Email Address

\* Address 1  Address 2

\* City  \* State  \* ZIP

**PHARMACY ATTESTATIONS**

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the *Program Overview*.
- I must complete the *Pharmacy Enrollment Form* and submit it to the ZULRESSO REMS
- I agree to train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting.
- I agree to put processes and procedures in place to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS.
- I agree not to distribute, transfer, loan or sell ZULRESSO.
- I will maintain records documenting staff's completion of training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
- I will comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

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\* Signature:

CANCEL
CONTINUE

Please see [Prescribing Information](#) including BOXED WARNING.



If you have questions about the ZULRESSO REMS or need help, call **844-472-4379** Monday - Friday 8AM-8PM ET.

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# ZULRESSO™ REMS Pharmacy Enrollment Form

Complete and submit this form by clicking "Submit" below.

**If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.**

1. Review REMS Program Overview
2. Review and complete this Pharmacy Enrollment Form
3. Submit the completed form by clicking "Continue" below

\* Indicates Required Field

**PHARMACY INFORMATION**

\* National Provider Identifier (NPI#)

---

\* Pharmacy Name

\* Pharmacy Type  
 Specialty  Specialty Infusion  Compounding  Other

\* National Council for Prescription Drug Program ID (NCPDP)

\* Pharmacy DEA Number

\* Address 1  Address 2

\* City  \* State  \* ZIP

---

\* National Provider Identifier (NPI#)  
 CONTINUE

---

Click below to enroll an additional Pharmacy location (optional)

+ ADDITIONAL PHARMACY LOCATION

Your Pharmacy information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Pharmacy to purchase product.

---

**AUTHORIZED REPRESENTATIVE INFORMATION**

\* First Name  MI  \* Last Name  \* Title

\* Credentials  \* Reason for Form  
 New Enrollment  New Representative

\* Phone Number  \* Fax Number  \* Email Address

\* Address 1  Address 2

\* City  \* State  \* ZIP

---

**PHARMACY ATTESTATIONS**

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the *Program Overview*.
- I must complete the *Pharmacy Enrollment Form* and submit it to the ZULRESSO REMS
- I agree to train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting.
- I agree to put processes and procedures in place to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS.
- I agree not to distribute, transfer, loan or sell ZULRESSO.
- I will maintain records documenting staff's completion of training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
- I will comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

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\* Signature:

CANCEL
CONTINUE

Please see **Prescribing Information** including **BOXED WARNING**.



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# ZULRESSO™ REMS Pharmacy Enrollment Form

Complete and submit this form by clicking "Submit" below.

**If your Healthcare Setting and Pharmacy are within the same institution, enroll as a Healthcare Setting only.**

1. Review REMS Program Overview
2. Review and complete this Pharmacy Enrollment Form
3. Submit the completed form by clicking "Continue" below

\* Indicates Required Field

**PHARMACY INFORMATION**

\* National Provider Identifier (NPI#)

---

\* Pharmacy Name

\* Pharmacy Type  
 Specialty  Specialty Infusion  Compounding  Other

\* National Council for Prescription Drug Program ID (NCPDP)

\* Pharmacy DEA Number

\* Address 1  Address 2

\* City  \* State  \* ZIP

---

\* National Provider Identifier (NPI#)  
 CONTINUE

Pharmacy Location Name

\* Pharmacy Type  
 Specialty  Specialty Infusion  Compounding  Other

\* National Council for Prescription Drug Program ID (NCPDP)

\* Pharmacy DEA Number

\* Address 1  Address 2

\* City  \* State  \* ZIP

X REMOVE PHARMACY

---

Click below to enroll an additional Pharmacy location (optional)

+ ADDITIONAL PHARMACY LOCATION

Your Pharmacy information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Pharmacy to purchase product.

**AUTHORIZED REPRESENTATIVE INFORMATION**

\* First Name  MI  \* Last Name  \* Title

\* Credentials  \* Reason for Form  
 New Enrollment  New Representative

\* Phone Number  \* Fax Number  \* Email Address

\* Address 1  Address 2

\* City  \* State  \* ZIP

**PHARMACY ATTESTATIONS**

As the Authorized Pharmacy Representative, I attest that:

- I have reviewed the *Program Overview*.
- I must complete the *Pharmacy Enrollment Form* and submit it to the ZULRESSO REMS
- I agree to train all relevant staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting.
- I agree to put processes and procedures in place to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS.
- I agree not to distribute, transfer, loan or sell ZULRESSO.
- I will maintain records documenting staff's completion of training.
- I will maintain records that all REMS processes and procedures are in place and being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, and number of vials.
- I will comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics to ensure that all processes and procedures are in place and are being followed.

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\* Signature:

CANCEL
CONTINUE

Please see [Prescribing Information](#) including BOXED WARNING.



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Healthcare Settings

Pharmacies

Patients

Healthcare Professionals

Forms and Resources

Healthcare Setting Locator

LOG IN

# ZULRESSO™ REMS Pharmacy Enrollment Form

Pharmacy Enrollment Submitted Successfully.

Thank you for submitting your information to enroll in the ZULRESSO REMS.

Please see [Prescribing Information](#) including BOXED WARNING.



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## ZULRESSO REMS Patient Enrollment

Work with your certified Healthcare Setting to enroll in the ZULRESSO REMS so you can start treatment.



### STEP 1

## Discuss

Discuss risks of treatment with ZULRESSO with your Healthcare Provider, including that ZULRESSO can cause excessive sedation (extreme sleepiness) and sudden loss of consciousness (passing out).



### STEP 2

## Receive and review

Receive and review the ZULRESSO [Patient Information Guide](#) with your Healthcare Provider.



**PATIENT INFORMATION GUIDE**



### STEP 3

## Complete

Complete the ZULRESSO REMS Patient Enrollment Form at your certified Healthcare Setting.

Please see [Prescribing Information](#), including BOXED WARNING.



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## ZULRESSO REMS Information for Healthcare Providers

Patients can only be treated with ZULRESSO at a REMS certified Healthcare Setting.



### Please review the materials below

Healthcare Providers must be affiliated with a REMS certified Healthcare Setting in order to prescribe ZULRESSO. Please review the materials below.



LETTER FOR  
HEALTHCARE  
PROVIDERS



PRESCRIBING  
INFORMATION



PATIENT  
INFORMATION  
GUIDE

If you are affiliated with a REMS certified Healthcare Setting, follow your institution's REMS procedures for ZULRESSO. Otherwise, to locate a REMS certified Healthcare Setting use this [directory](#) or call the ZULRESSO REMS at 844-472-4379.

Please see [Prescribing Information](#), including BOXED WARNING.



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# ZULRESSO REMS Program Forms and Resources

Below are downloadable resources to support the ZULRESSO REMS.



## Materials for Healthcare Settings

To learn more about these documents please visit the [Healthcare Settings page](#)

### Certification Materials

- TRAINING FOR HEALTHCARE SETTINGS
- HEALTHCARE SETTING KNOWLEDGE ASSESSMENT
- HEALTHCARE SETTING ENROLLMENT FORM
- PRESCRIBING INFORMATION

### Administration Materials

- PATIENT INFORMATION GUIDE
- PATIENT ENROLLMENT FORM
- POST INFUSION FORM
- EXCESSIVE SEDATION AND LOSS OF CONSCIOUSNESS ADVERSE EVENT FORM



## Materials for Pharmacies

To learn more about these documents please visit the [Pharmacy page](#).

- REMS PROGRAM OVERVIEW FOR PHARMACIES
- PHARMACY ENROLLMENT FORM



## Materials for Patients

To learn more about these documents please visit the [Patients page](#).

- PATIENT INFORMATION GUIDE



## Materials for Healthcare Providers

To learn more about these documents please visit the [Healthcare Providers page](#).

- LETTER FOR HEALTHCARE PROVIDERS
- PRESCRIBING INFORMATION
- PATIENT INFORMATION GUIDE

Please see [Prescribing Information](#), including **BOXED WARNING**.



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# Healthcare Setting Locator

Search for Healthcare Settings that are enrolled and certified in the ZULRESSO REMS and able to administer ZULRESSO.

**FULL HEALTHCARE SETTING LISTING**  
View, filter and download all locations

To search for a specific location, please complete the following:

Please enter a street address, city, state, or ZIP Code you would like to search for.

Find a Healthcare Setting near  Within 25 miles SEARCH

**HEALTHCARE SETTING** 3.2 miles  
**NAME**  
100 Main St  
Blue Bell, PA 19042  
555 555-1212 Directions

**HEALTHCARE SETTING** 3.2 miles  
**NAME**  
100 Main St  
Blue Bell, PA 19042  
555 555-1212 Directions

**HEALTHCARE SETTING** 3.2 miles  
**NAME**  
100 Main St  
Blue Bell, PA 19042  
555 555-1212 Directions

**HEALTHCARE SETTING** 3.2 miles  
**NAME**  
100 Main St  
Blue Bell, PA 19042  
555 555-1212 Directions

Healthcare settings included in the Locator tool have completed the requirements to enroll and certify in the ZULRESSO REMS; however, not all healthcare settings listed are accepting new patients. Please call to confirm.

Inclusion of a certified healthcare setting in the Locator tool does not represent an endorsement, referral or recommendation from Sage Therapeutics, Inc. ("Sage") and is not intended as medical advice. Inclusion of a healthcare setting in this Locator tool is based on approval by the Authorized Representative for each healthcare setting and no fees have or will be received in exchange for participation in this Locator tool.

This Locator tool is intended to provide users with the opportunity to locate nearby ZULRESSO REMS-certified healthcare settings and is compiled for informational purposes only. In no event shall Sage or its employees or agents be liable for the actions of any of the healthcare settings listed herein or any damages resulting from or related to this Locator tool. All users agree that use of this Locator tool is at their own risk.

Sage makes no representations as to whether any of the healthcare settings included in this Locator tool are covered by healthcare plans or insurers. Insurance verification is the responsibility of the provider and patient. Users of this Locator tool are solely responsible for interactions with any of the listed healthcare settings, and any information sent is not governed by Sage's Terms of Use and Privacy Policy. Users are responsible for compliance with all state and federal laws and regulations.

Please see [Prescribing Information](#), including **BOXED WARNING**.



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## Healthcare Setting Locations

Listing of Healthcare Settings that are enrolled and certified in the ZULRESSO REMS and able to administer ZULRESSO.

 Download the list to spreadsheet format by clicking on the Excel icon just above the column headers  
This list is updated in real-time and displays the current Healthcare Setting Locations. You may refresh this page at any time for an updated list.

 Search/Filter the list by entering information in the text box below any column header

 Sort the list by clicking on any column header

 Name 	Phone Number 	Fax Number 
<input type="text"/>	<input type="text"/>	<input type="text"/>
Test Healthcare Setting	546-546-4545	564-564-5646

Please see [Prescribing Information](#), including BOXED WARNING.



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[Pharmacies](#)
[Patients](#)
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[Forms and Resources](#)
[Healthcare Setting Locator](#)
[LOG IN](#)

## Login

Login is available to certified Healthcare Settings in the ZULRESSO REMS.

### Login

Please enter your User Name.

Your user name was provided to you following enrollment and/or certification in the ZULRESSO REMS.

[LOG IN](#)
[Forgot Username](#)

OR

### Don't have an online account?

## Register

**Note:** Online registration is required for Healthcare Settings only.

In order to complete the certification process online, an Authorized Representative for the Healthcare Setting must register for an account. To create your account, please enter your Healthcare Setting NPI Number and click "Continue".

\* NPI Number

[CONTINUE](#)

Please see [Prescribing Information](#), including BOXED WARNING.



If you have questions about the ZULRESSO REMS or need help, call **844-472-4379** Monday - Friday 8AM-8PM ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at **844-472-4379** or FDA at 800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).



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This site is intended for residents of the United States only



# Login

Login is available to certified Healthcare Settings in the ZULRESSO REMS.

## Login

Please enter your User Name.

Your user name was provided to you following enrollment and/or certification in the ZULRESSO REMS.

LOGIN

OR

## Don't have an online account?

## Register

**Note:** Online registration is required for Healthcare Settings only.

In order to complete the certification process online, an Authorized Representative for the Healthcare Setting must register for an account. To create your account, please enter your Healthcare Setting NPI Number and click "Continue".

\* NPI Number

\* First Name

\* Last Name

\* Phone Number

\* Email Address

CONTINUE

Please see [Prescribing Information](#), including BOXED WARNING.



If you have questions about the ZULRESSO REMS or need help, call **844-472-4379** Monday - Friday 8AM-8PM ET.

To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at **844-472-4379** or FDA at **800-FDA-1088** or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).




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## ZULRESSO REMS Healthcare Setting Certification

Thank you for submitting your information to create your web account for the ZULRESSO REMS.



### Create Account Submitted Successfully

A confirmation of this submission has been sent to the email address provided. You can expect to receive 2 emails, one contains your username and the second contains your temporary password. Please login with the username provided. You will then be prompted to update your password.

If you do not receive the emails within the next few hours, or would like to update your enrollment information at any time, please contact the ZULRESSO REMS at 844-472-4379.

[LOGIN](#)

Please see full [Prescribing Information](#) including BOXED WARNING.



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**LOG IN**

[Forgot Username](#)

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\* NPI Number

**CONTINUE**

Please see [Prescribing Information](#), including BOXED WARNING.



If you have questions about the ZULRESSO REMS or need help, call **844-472-4379** Monday - Friday 8AM-8PM ET.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



# ZULRESSO<sup>™</sup> REMS Training for Healthcare Settings

Risk Evaluation and Mitigation Strategy (REMS)



v 5.0



## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



# Training for Healthcare Settings

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### What Is ZULRESSO™ (brexanolone) injection?

- ZULRESSO is indicated for the treatment of postpartum depression (PPD) in adults.
- Pregnancy: Based on findings from animal studies of other drugs that enhance GABAergic inhibition, ZULRESSO may cause fetal harm.
- ZULRESSO is intended for dilution and administration as a continuous intravenous infusion.
- ZULRESSO is available only through the ZULRESSO REMS.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### ZULRESSO Has a Boxed Warning

#### **WARNING: EXCESSIVE SEDATION AND SUDDEN LOSS OF CONSCIOUSNESS**

- **Patients are at risk of excessive sedation or sudden loss of consciousness during administration of ZULRESSO.**
- **Because of the risk of serious harm, patients must be monitored for excessive sedation and sudden loss of consciousness and have continuous pulse oximetry monitoring. Patients must be accompanied during interactions with their child(ren).**
- **ZULRESSO is available only through a restricted program called the ZULRESSO REMS.**

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### What Was Observed in the ZULRESSO Clinical Program?

- In premarketing clinical studies, the following observations were noted:
    - ZULRESSO caused sedation and somnolence that required in some patients with PPD dose interruption or reduction during the infusion (5% of ZULRESSO-treated patients compared to 0% of placebo-treated patients).
    - Some patients with PPD were also reported to have loss of consciousness or altered state of consciousness during the ZULRESSO infusion (4% of the ZULRESSO-treated patients compared with 0% of the placebo-treated patients).
    - All patients with loss of or altered state of consciousness recovered with dose interruption; time to full recovery from loss or altered state of consciousness, after dose interruption, ranged from 15 to 60 minutes.
    - Three ZULRESSO-treated patients who had a dosage interruption because of loss of consciousness subsequently resumed and completed treatment after resolution of symptoms; two patients who had dosage interruption because of loss of consciousness did not resume the infusion.
    - There was no clear association between loss or alteration of consciousness and pattern or timing of dose. Not all patients who experienced a loss or alteration of consciousness reported sedation or somnolence before the episode.
    - A healthy 55-year-old man participating in a cardiac repolarization study experienced severe somnolence and <1 minute of apnea while receiving two times the maximum recommended dosage of ZULRESSO (180 mcg/kg/hour).
  - There is limited clinical trial experience regarding human overdose with ZULRESSO. In premarketing clinical studies, two cases of accidental overdose due to infusion pump malfunction resulted in transient loss of consciousness. Both patients regained consciousness approximately 15 minutes after discontinuation of the infusion without supportive measures. After full resolution of symptoms, both patients subsequently resumed and completed treatment. Overdosage may result in excessive sedation, including loss of consciousness and the potential for accompanying respiratory changes.
  - These are not all of the adverse events observed in these trials.\*
- \*Please see Prescribing Information, including Boxed Warning and Medication Guide.**

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# ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



## What Is the ZULRESSO REMS?

- The ZULRESSO Risk Evaluation and Mitigation Strategy (REMS) is a safety program to manage the risk of serious harm resulting from excessive sedation and sudden loss of consciousness during the ZULRESSO infusion.
- A REMS is required by the Food and Drug Administration (FDA) to ensure the potential benefits of a treatment outweigh its risks.

### ZULRESSO REMS Overview:

- Administration of ZULRESSO to patients only in a medically supervised Healthcare Setting that provides monitoring while ZULRESSO is being administered.
- Only certified Pharmacies and Healthcare Settings can dispense ZULRESSO.
- Educate patients on the risk of serious harm from excessive sedation and sudden loss of consciousness and the need for monitoring while ZULRESSO is administered.
- Enroll all patients in a registry to characterize these risks and support safe use.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### How to Become a Certified Healthcare Setting

**STEP 1: Designate and Maintain an Authorized Representative. The Authorized Representative will carry out the certification process and oversee implementation and compliance with the ZULRESSO REMS on behalf of the Healthcare Setting.**

- An Authorized Representative is a responsible individual assigned by the Healthcare Setting and its associated clinic(s).
- Each Healthcare Setting must designate one Authorized Representative who enrolls in the ZULRESSO REMS on behalf of the Healthcare Setting and attests to comply with the REMS requirements included in the Healthcare Setting Enrollment Form.
- A Healthcare Setting must be recertified in the ZULRESSO REMS if a new Authorized Representative is designated.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### How to Become a Certified Healthcare Setting (continued)

The Authorized Representative will complete the following steps:

**STEP 2: Review** this Training and the Prescribing Information.

**STEP 3: Complete** the Healthcare Setting Knowledge Assessment. All questions in the Healthcare Setting Knowledge Assessment must be answered correctly to become certified.

**STEP 4: Complete** the Healthcare Setting Enrollment Form.

**STEP 5: Submit** the completed Healthcare Setting Knowledge Assessment and the Healthcare Setting Enrollment Form.

**STEP 6: Implement** the necessary processes and procedures to administer the ZULRESSO REMS.  
The ZULRESSO REMS will notify the Authorized Representative of successful certification within 2 business days.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### Healthcare Setting Requirements

- A healthcare provider must be available continuously on-site to oversee each patient for the duration of the infusion, and trained on the requirements of the ZULRESSO REMS. As a continuous intravenous (IV) infusion, treatment lasts a total of 60 hours (2.5 days).
- The facility must have a fall precautions protocol in place and be equipped with a programmable peristaltic IV infusion pump with alarm and continuous pulse oximetry with an alarm.
- Staff at the Healthcare Setting must be trained on the processes and procedures to administer ZULRESSO.

The Healthcare Setting must comply with audits by Sage Therapeutics, Inc., the FDA, or a third party acting on behalf of Sage Therapeutics, Inc. to ensure that all training, processes, and procedures are in place and are in compliance with the ZULRESSO REMS. The Authorized Representative of the Healthcare Setting must maintain documentation that all ZULRESSO REMS–required processes and procedures are in place and are being followed.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### Before Administering ZULRESSO

**Counsel** the patients using the Patient Information Guide and provide a copy to the patient.

**Enroll** the patient in the ZULRESSOREMS by providing the Patient Enrollment Form and ask the patient to **complete** and **sign** the form. The ZULRESSOREMS trained healthcare provider assisting the patient with enrollment must also sign the Patient Enrollment Form and include their name and title. Retain a copy of the completed form in the patient's record.

**Submit** the completed Patient Enrollment Form.

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# ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



## Patient Counseling

### Patients need to know that:

- They may experience excessive sedation or loss of consciousness during the ZULRESSO infusion, which could cause serious harm.
- They must alert a healthcare provider during the infusion if they have any symptoms associated with excessive sedation, such as:
  - Feeling extremely sleepy and being unable to stay awake when not planning to sleep
  - Impaired alertness and attention
  - Difficulty following simple instructions
  - Feeling lightheaded, dizzy, or like they are going to pass out
- They must enroll in the ZULRESSO REMS in order to receive ZULRESSO.
- They will be continuously monitored by pulse oximetry during the infusion.
- A healthcare provider will oversee the ZULRESSO infusion.
- They **cannot** be the primary caregiver for their child(ren) during the infusion. They must be accompanied during interactions with their child(ren) while receiving the infusion because of the risk of serious harm from excessive sedation and sudden loss of consciousness.
- Taking certain other medications or alcohol together with ZULRESSO can make these side effects more likely to occur.
- They should not engage in potentially hazardous activities requiring mental alertness, such as driving, after the infusion until any sedative effects of ZULRESSO have dissipated.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### During the Administration of ZULRESSO

The infusion must be administered using an intravenous programmable infusion pump with alarms to alert if the pump malfunctions and started early enough during the day in order to monitor for excessive sedation.

#### Patient Monitoring:

- A healthcare provider must monitor the patient every 2 hours during the ZULRESSO infusion during planned, non-sleep periods.
- Patients must be continuously monitored for hypoxia by pulse oximetry with an alarm during the infusion.
- Immediately stop the infusion if pulse oximetry indicates hypoxia. If hypoxia occurs the infusion should not be restarted.
- Immediately stop the infusion if there are signs or symptoms of excessive sedation. After symptoms resolve, the infusion may be resumed at the same or lower dose as clinically appropriate.
- Staff at the Healthcare Setting should report all adverse events by contacting Sage Therapeutics, Inc. at 844-472-4379 or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 800-FDA-1088.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### After the Administration of ZULRESSO

#### After treatment discontinuation, and prior to discharge:

- Assess the patient's level of sedation.

#### Submit the Post Infusion Form:

- The Post Infusion Form must be submitted to the ZULRESSO REMS after the completion of the infusion, if the patient receives any part of the infusion, or if the infusion has been cancelled. If the infusion has been rescheduled, the form should be completed at that time.
- Submit the Post Infusion Form to the ZULRESSO REMS within 3 business days from the date of the patient completing the infusion or the scheduled infusion completion date.
- The Post Infusion Form is available at the ZULRESSO REMS website ([www.zulressorems.com](http://www.zulressorems.com)).

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### How to Report an Event of Excessive Sedation or Loss of Consciousness

#### Reporting Procedures:

If a patient experiences an event of excessive sedation or loss of consciousness:

- 1) Indicate the event on the **Post Infusion Form**.
  - 2) Complete the **Excessive Sedation and Loss of Consciousness Adverse Event Form**.
  - 3) Submit both forms to the ZULRESSO REMS.
- The Post Infusion Form and Excessive Sedation and Loss of Consciousness Adverse Event Form are available at [www.zulressoems.com](http://www.zulressoems.com).
  - You may be contacted for further information on reported events by the Sage Therapeutics, Inc. Drug Safety Department.
  - For the purposes of this REMS and event reporting, the events are further characterized below:
    - Excessive sedation: impaired alertness and attention or difficulty following simple instructions, which precludes the patient from completing daily tasks. Patient is frequently drowsy and may fall asleep during activities (e.g., conversation, eating).
    - Loss of consciousness: total loss of awareness of the patient's self and surroundings manifest by lack of responsiveness to loud or noxious stimuli. Patient is not rousable to loud voice or with firm physical contact, including shaking. This is in contrast to sleep which is physiologic and intrinsically reversible with sufficient stimuli.

**To report any SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### REMS Requirements Specific for Pharmacies within the Certified Healthcare Setting

#### Pharmacies within the certified Healthcare Setting must:

- Maintain records of all prepared and dispensed ZULRESSO.
- Maintain records documenting that all ZULRESSO REMS-required processes and procedures are in place and being followed, including records of staff training.
- Not distribute, transfer, loan, or sell ZULRESSO.
- Comply with audits carried out by Sage Therapeutics, Inc., or a third party acting on behalf of Sage Therapeutics, Inc. to ensure all processes and procedures are in place and being followed.

**Any Pharmacy not part of the certified Healthcare Setting must be certified before they can dispense ZULRESSO. For more information, see Program Overview for Pharmacies.**

# ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



## Ordering Instructions

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



### How to Order Product

#### To order vials of ZULRESSO:

- Contact the ZULRESSO REMS at **844-472-4379** for a current list of enrolled distributors.

#### To order ZULRESSO prepared for administration:

- If product will be prepared within the certified Healthcare Setting, follow the protocol and procedures established by the Authorized Representative.
- If product will be prepared outside the Healthcare Setting, contact an enrolled Pharmacy to place an order for ZULRESSO. Contact the ZULRESSO REMS at **844-472-4379** for a current list of enrolled Pharmacies.

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



# Resources

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# ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



## ZULRESSO REMS Resources

For more information about the ZULRESSO REMS, visit [www.zulressoems.com](http://www.zulressoems.com) or call the ZULRESSO REMS at 844-472-4379. The resources below are available for download at [www.zulressoems.com](http://www.zulressoems.com).

### Healthcare Settings

- ZULRESSO Prescribing Information
- ZULRESSO Medication Guide
- ZULRESSO REMS Training
- ZULRESSO REMS Healthcare Setting Enrollment Form
- ZULRESSO REMS Healthcare Setting Knowledge Assessment
- ZULRESSO REMS Patient Enrollment Form
- ZULRESSO REMS Post Infusion Form
- ZULRESSO REMS Patient Information Guide
- Excessive Sedation and Loss of Consciousness Adverse Event Form

### Patients

- ZULRESSO REMS Patient Information Guide
- ZULRESSO Medication Guide
- ZULRESSO REMS Patient Enrollment Form

### Pharmacies

- ZULRESSO Prescribing Information
- ZULRESSO Medication Guide
- Program Overview for Pharmacies

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## ZULRESSO REMS Healthcare Setting Certification

Review the ZULRESSO REMS Training.



Please see ZULRESSO Prescribing Information, including Boxed Warning and Medication Guide, for additional Important Safety Information.

See the Prescribing Information for ZULRESSO for more information on the risk of excessive sedation and sudden loss of consciousness.



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## ZULRESSO REMS Healthcare Setting Certification

### Next Steps



- Now that you have reviewed the ZULRESSO REMS Training for Healthcare Settings, in order to become certified you must complete the Healthcare Setting Knowledge Assessment
- The next 10 questions are about what you just reviewed. You are expected to achieve 100% on the Healthcare Setting Knowledge Assessment
- You will have 3 tries to successfully complete the Healthcare Setting Knowledge Assessment
- If you do not successfully complete the Healthcare Setting Knowledge Assessment, you will need to rereview the ZULRESSO REMS Training for Healthcare Settings

**CONTINUE**

## ZULRESSO REMS Healthcare Setting Certification

Please complete the following Healthcare Setting Knowledge Assessment and click "Submit".



## ZULRESSO™ REMS Healthcare Setting Knowledge Assessment

You are required to answer all questions correctly in order to pass the assessment.

You have **3** attempt(s) to answer all questions correctly.

If you do not answer all 10 questions correctly in 3 attempts, you will be instructed to rereview the ZULRESSO REMS Training for Healthcare Settings. Once reviewed, you will have an opportunity to retake the Healthcare Setting Knowledge Assessment.

### Question 1:

The approved indication for ZULRESSO is for adults with:

- Migraine
- Liver failure
- Postpartum depression
- Relapsing multiple sclerosis
- Bipolar depression

### Question 2

A Healthcare Setting can administer ZULRESSO to a patient before certifying in the ZULRESSO REMS.

- True
- False

### Question 3:

To become a certified Healthcare Setting in the ZULRESSO REMS, the Authorized Representative for the Healthcare Setting should (check all that apply):

- Develop processes and procedures to enroll patients in the ZULRESSO REMS prior to administration of ZULRESSO
- Develop processes and procedures to ensure staff are trained to administer ZULRESSO
- Ensure any new Authorized Representative is enrolled in the ZULRESSO REMS and completes the Healthcare Setting Knowledge Assessment

### Question 4:

The Healthcare Providers at the certified Healthcare Setting administering ZULRESSO should counsel patients on which of the following before administering ZULRESSO? (check all that apply):

- There is a risk for harm resulting from excessive sedation and sudden loss of consciousness
- Patients will be monitored for excessive sedation and sudden loss of consciousness for the duration of the infusion
- Patients will be monitored using continuous pulse oximetry
- Patients must be accompanied during interactions with their child(ren) while receiving the infusion

### Question 5

During the administration of ZULRESSO, staff at the Healthcare Setting must (check all that apply):

- Continuously monitor pulse oximetry
- Perform urinalysis every 24 hours
- Provide monitoring of the patient every 2 hours

### Question 6:

A Healthcare Provider administering ZULRESSO should immediately stop the infusion pump for the following reasons (check all that apply):

- The patient is sleeping, in the evening (planned)
- Pulse oximeter indicates hypoxia
- The patient has excessive sedation
- The patient has loss of consciousness

### Question 7

If a patient loses consciousness during the administration of ZULRESSO, the Healthcare Provider must (check all that are true):

- Complete only the Excessive Sedation and Loss of Consciousness Adverse Event Form
- Complete only the Post Infusion Form
- Complete both the Post Infusion Form and the Excessive Sedation and Loss of Consciousness Adverse Event Form

### Question 8:

The ZULRESSO REMS Post Infusion Form should (check all that are true):

- Not be completed if the patient only received 8 hours of the infusion
- Be completed if the patient receives any of the infusion or is not infused
- Indicate if a loss of consciousness or excessive sedation event occurred
- Capture the start and end date and time of the infusion if the infusion was administered

### Question 9

After treatment with ZULRESSO, the Post Infusion Form must be sent to the ZULRESSO REMS within how many business days?

- 3 business days
- 7 business days
- 15 business days
- Not necessary to return

### Question 10

It is optional to train all new Healthcare Providers involved in the administration of ZULRESSO on the processes and procedures of the ZULRESSO REMS.

- True
- False

## ZULRESSO REMS Healthcare Setting Certification



You have successfully completed the ZULRESSO REMS Healthcare Setting Knowledge Assessment.

You must complete the ZULRESSO REMS Certified Healthcare Setting Enrollment Form and submit to the ZULRESSO REMS before administering ZULRESSO.

You will receive a notification from the ZULRESSO REMS confirming your certification in the ZULRESSO REMS. Upon receipt of this notification, you may administer ZULRESSO.

[COMPLETE ONLINE ENROLLMENT](#)

## ZULRESSO REMS Healthcare Setting Certification



 You did not achieve 100% on the ZULRESSO REMS Healthcare Setting Knowledge Assessment.

You have **2** attempt(s) to correctly answer all questions. You may click "Review Training Slides" to return to view the necessary resources. At the end of the review, you will be able to retake the assessment. Or, you may immediately retake the assessment by clicking "Retake Assessment".

[REVIEW TRAINING SLIDES](#)

[RETAKE ASSESSMENT](#)

## Healthcare Setting Certification



You did not achieve 100% on the ZULRESSO REMS Healthcare Setting Knowledge Assessment within the last 3 attempts.

You must rereview the ZULRESSO REMS Training for Healthcare Settings before attempting the ZULRESSO REMS Healthcare Setting Knowledge Assessment again.

[REVIEW TRAINING SLIDES](#)

## ZULRESSO REMS Healthcare Setting Certification



### ZULRESSO<sup>TM</sup> REMS Certified Healthcare Setting Enrollment Form

Complete and submit this form by clicking "Continue" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as Healthcare Setting only.

\* Indicates Required Field

#### HEALTHCARE SETTING INFORMATION

\* National Provider Identifier (NPI#)

1234567890

\* Site Type

Hospital  Infusion Center  Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

Click below to enter an additional Associated National Provider Identifier (NPI #)

+ ADD ASSOCIATED NPI #

\* Healthcare Setting Name

\* Healthcare Setting DEA Number



\* Address 1

Address 2



\* City

\* State

\* ZIP




\* Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy

Yes  No

For each additional Healthcare Setting where ZULRESSO will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, you will need to add the Healthcare Setting by clicking the button below.

+ ADD HEALTHCARE SETTING

#### AUTHORIZED REPRESENTATIVE INFORMATION

\* First Name

MI

\* Last Name

\* Title





\* Credentials

Physician  Physician Assistant  
 Nurse Practitioner  Nurse  Pharmacist  
 Other

\* Reason for Form

New Enrollment  New Representative

\* Phone Number

\* Fax Number

\* Email Address




\* Address 1

Address 2



\* City

\* State

\* ZIP




Your Healthcare Setting information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Healthcare Setting to purchase product. Your Healthcare Setting information (name, location, and phone number) will be listed on a location finder, as a certified Healthcare Setting, available to Healthcare Providers and patients seeking treatment with ZULRESSO. If you do not want your information listed, please call ZULRESSO REMS at 844-472-4379

#### HEALTHCARE SETTING ATTESTATIONS

As the Authorized Representative I agree that:

- I have reviewed the *Training Program for Healthcare Settings* and successfully completed the *Healthcare Setting Knowledge Assessment*.
- I agree to train all relevant staff involved in prescribing, dispensing, and administering ZULRESSO on the ZULRESSO REMS requirements using the *Training Program*.
- I will establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering ZULRESSO to ensure they are trained.
- I will establish processes and procedures to enroll the patient in the ZULRESSO REMS by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
- I will establish processes and procedures to counsel the patient and verify the patient is enrolled in the ZULRESSO REMS before administration.
- I will establish processes and procedures to submit the *Post Infusion Form* and if needed the *Excessive Sedation and Loss of Consciousness Adverse Event Form* to the ZULRESSO REMS.
- On behalf of the Healthcare Setting, we will comply with the following REMS requirements:
  - Before dispensing:
    - Enroll the patient by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
  - Before administering:
    - Counsel the patient on the signs and symptoms of excessive sedation, loss of consciousness, and the importance of immediately reporting to a healthcare professional any signs and symptoms of excessive sedation using the *Patient Information Guide*. Provide a copy of the material to the patient.
  - During treatment, (60 hours):
    - Every 2 hours during planned, non-sleep periods:
      - Assess the patient's health status for signs and symptoms of excessive sedation and loss of consciousness.
    - Assess the patient's oxygen saturation using continuous pulse oximetry.
  - After treatment discontinuation, and prior to discharge:
    - Assess the patient's level of sedation.
  - After treatment discontinuation, within 3 business days of scheduled completion date:
    - Document and submit the patient's infusion outcome to the ZULRESSO REMS using the *Post Infusion Form*.
    - Report excessive sedation or loss of consciousness to the ZULRESSO REMS using the *Excessive Sedation and Loss of Consciousness Adverse Event Form*.
- Not distribute, transfer, loan or sell ZULRESSO
- Maintain records documenting staff's completion of training.
- Maintain records that all REMS processes and procedures are in place and are being followed.
- I will maintain records of all shipments of ZULRESSO received and dispensing information including patient name, dose, number of vials, and date administered.
- Comply with audits carried out by Sage Therapeutics, Inc. or third party acting on behalf of Sage Therapeutics, Inc. to ensure that all processes and procedures are in place and being followed.

As a condition of the certification, the Healthcare Setting must:

- Be able to monitor patients continuously for the duration of the infusion
- Have the following onsite: continuous pulse oximetry, fall precaution protocol, intravenous programmable infusion pumps with alarms to alert when the pump malfunctions, Healthcare Providers to be continuously available on site to monitor the patient and intervene as necessary
- Ensure that if the Healthcare Setting designates a new Authorized Representative, the new Authorized Representative will enroll in the ZULRESSO REMS by successfully completing the *Healthcare Setting Knowledge Assessment* and *Healthcare Setting Enrollment Form* and submitting both to the ZULRESSO REMS

\* Signature:

CANCEL

CONTINUE

## ZULRESSO REMS Healthcare Setting Certification



## ZULRESSO<sup>™</sup> REMS Certified Healthcare Setting Enrollment Form

Complete and submit this form by clicking "Continue" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as Healthcare Setting only.

\* Indicates Required Field

### HEALTHCARE SETTING INFORMATION

\*National Provider Identifier (NPI#)  \*Site Type  
 Hospital  Infusion Center  Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

Associated National Provider Identifier (NPI #)  
 X REMOVE

Click below to enter an additional Associated National Provider Identifier (NPI #)

+ ADD ASSOCIATED NPI #

\*Healthcare Setting Name

\*Healthcare Setting DEA Number

\*Address 1

Address 2

\*City

\*State

\*ZIP

\*Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy  
 Yes  No

For each additional Healthcare Setting where ZULRESSO will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, you will need to add the Healthcare Setting by clicking the button below.

+ ADD HEALTHCARE SETTING

### AUTHORIZED REPRESENTATIVE INFORMATION

\*First Name

MI

\*Last Name

\*Title

\*Credentials  
 Physician  Physician Assistant  
 Nurse Practitioner  Nurse  Pharmacist  
 Other

\*Reason for Form  
 New Enrollment  New Representative

\*Phone Number

\*Fax Number

\*Email Address

\*Address 1

Address 2

\*City

\*State

\*ZIP

**Your Healthcare Setting information will be shared with Sage Therapeutics, Inc.'s patient support and distribution partners, to allow your Healthcare Setting to purchase product. Your Healthcare Setting information (name, location, and phone number) will be listed on a location finder, as a certified Healthcare Setting, available to Healthcare Providers and patients seeking treatment with ZULRESSO. If you do not want your information listed, please call ZULRESSO REMS at 844-472-4379**

### HEALTHCARE SETTING ATTESTATIONS

**As the Authorized Representative I agree that:**

- I have reviewed the *Training Program for Healthcare Settings* and successfully completed the *Healthcare Setting Knowledge Assessment*.
- I agree to train all relevant staff involved in prescribing, dispensing, and administering ZULRESSO on the ZULRESSO REMS requirements using the *Training Program*.
- I will establish processes and procedures to identify new staff involved in prescribing, dispensing, and administering ZULRESSO to ensure they are trained.
- I will establish processes and procedures to enroll the patient in the ZULRESSO REMS by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
- I will establish processes and procedures to counsel the patient and verify the patient is enrolled in the ZULRESSO REMS before administration.
- I will establish processes and procedures to submit the *Post Infusion Form* and if needed the *Excessive Sedation and Loss of Consciousness Adverse Event Form* to the ZULRESSO REMS.
- On behalf of the Healthcare Setting, we will comply with the following REMS requirements:
  - Before dispensing:
    - Enroll the patient by completing and submitting the *Patient Enrollment Form* to the ZULRESSO REMS.
  - Before administering:
    - Counsel the patient on the signs and symptoms of excessive sedation, loss of consciousness, and the importance of immediately reporting to a healthcare professional any signs and symptoms of excessive sedation using the *Patient Information Guide*. Provide a copy of the material to the patient.
  - During treatment, (60 hours):
    - Every 2 hours during planned, non-sleep periods:
      - Assess the patient's health status for signs and symptoms of excessive sedation and loss of consciousness.
    - Assess the patient's oxygen saturation using continuous pulse oximetry.
  - After treatment discontinuation, and prior to discharge:
    - Assess the patient's level of sedation.
  - After treatment discontinuation, within 3 business days of scheduled completion date:
    - Document and submit the patient's infusion outcome to the ZULRESSO REMS using the *Post Infusion Form*.
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**As a condition of the certification, the Healthcare Setting must:**

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\*Signature:

CANCEL CONTINUE

## ZULRESSO REMS Healthcare Setting Certification



### ZULRESSO™ REMS Certified Healthcare Setting Enrollment Form

Complete and submit this form by clicking "Continue" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as Healthcare Setting only.

\* Indicates Required Field

#### HEALTHCARE SETTING INFORMATION

\* National Provider Identifier (NPI#)

1234567890

\* Site Type

Hospital  Infusion Center  Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

1111111111

Associated National Provider Identifier (NPI #)

2222222222

REMOVE

Click below to enter an additional Associated National Provider Identifier (NPI #)

+ ADD ASSOCIATED NPI #

\* Healthcare Setting Name

\* Healthcare Setting DEA Number

\* Address 1

Address 2

\* City

\* State

-- Please Select --

\* ZIP

\* Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy

Yes  No

\* National Provider Identifier (NPI#)

CONTINUE

For each additional Healthcare Setting where ZULRESSO will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, you will need to add the Healthcare Setting by clicking the button below.

+ ADD HEALTHCARE SETTING

#### AUTHORIZED REPRESENTATIVE INFORMATION

\* First Name

MI

\* Last Name

\* Title

\* Credentials

Physician  Physician Assistant  
 Nurse Practitioner  Nurse  Pharmacist  
 Other

\* Reason for Form

New Enrollment  New Representative

\* Phone Number

\* Fax Number

\* Email Address

\* Address 1

Address 2

\* City

\* State

-- Please Select --

\* ZIP

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#### HEALTHCARE SETTING ATTESTATIONS

As the Authorized Representative I agree that:

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\* Signature:

CANCEL

CONTINUE

# ZULRESSO REMS Healthcare Setting Certification



## ZULRESSO™ REMS Certified Healthcare Setting Enrollment Form

Complete and submit this form by clicking "Continue" below.

If your Healthcare Setting and Pharmacy are within the same institution, enroll as Healthcare Setting only.

\* Indicates Required Field

### HEALTHCARE SETTING INFORMATION

\*National Provider Identifier (NPI#)  \*Site Type  
 Hospital  Infusion Center  Other

List All Associated National Provider Identifiers (NPI #s)

Associated National Provider Identifier (NPI #)

Associated National Provider Identifier (NPI #)  [X REMOVE](#)

Click below to enter an additional Associated National Provider Identifier (NPI #)

[+ ADD ASSOCIATED NPI #](#)

\*Healthcare Setting Name  \*Healthcare Setting DEA Number

\*Address 1  Address 2

\*City  \*State  \*ZIP

\*Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy  
 Yes  No

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\*Site Type  
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\*City  \*State  \*ZIP

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[X REMOVE HEALTHCARE SETTING](#)

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### AUTHORIZED REPRESENTATIVE INFORMATION

\*First Name  MI  \*Last Name  \*Title

\*Credentials  
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\*Reason for Form  
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\*Signature:

[CANCEL](#) [CONTINUE](#)

## ZULRESSO REMS Healthcare Setting Certification



You have successfully completed and submitted the ZULRESSO REMS Certified Healthcare Setting Enrollment Form.

You are now certified in the ZULRESSO REMS.

**CONTINUE**

**PATIENTS**

DELEGATE/HEALTHCARE SETTING MANAGEMENT

## Patients

Below is a list of patients enrolled at your healthcare setting(s)

- Download the list to spreadsheet format by clicking the Excel icon just above the column headers
- Search/Filter the list by entering information in the textbox below any column header
- Sort the list by clicking on any column header

\*Heathcare Setting

Healthcare Facility 1 ▾



REMS ID ▾	First Name ▾	Last Name ▾	Date of Birth ▾	Healthcare Setting ▾	Status ▾	Action	Patient Authorization
12345	Peggy	Sue	1/1/2000	Healthcare Facility 1	Enrolled	<b>SUBMIT A POST INFUSION FORM</b>	<b>GENERATE PATIENT ENROLLMENT NOTIFICATION</b>



Page 1 of 11 | Total Records: 55

**PATIENTS**

DELEGATE/HEALTHCARE SETTING MANAGEMENT

# Patients

Below is a list of patients enrolled at your healthcare setting(s)

- Download the list to spreadsheet format by clicking the Excel icon just above the column headers
- Search/Filter the list by entering information in the textbox below any column header
- Sort the list by clicking on any column header

**\*Heathcare Setting**

Healthcare Facility 2 ▾



REMS ID	First Name	Last Name	Date of Birth	Healthcare Setting	Status	Action	Patient Authorization
98765	Robert	Peterson	1/1/2000	Healthcare Facility 2	Enrolled	<b>SUBMIT A POST INFUSION FORM</b>	<b>GENERATE PATIENT ENROLLMENT NOTIFICATION</b>

Navigation: << < > >> ↔

Page 1 of 11 | Total Records: 55

## ZULRESSO Post Infusion Form

### INSTRUCTIONS

ZULRESSO is only available through the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS). A Post Infusion Form must be submitted to the ZULRESSO REMS for all patients who are enrolled in the ZULRESSO REMS. Please complete and submit this form within 3 business days of the patient completing the infusion or the scheduled infusion completion date.

Please complete and submit this Post Infusion Form to the ZULRESSO REMS by clicking "Submit" below. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

*\*Indicates required field*

### PATIENT AND HEALTHCARE SETTING INFORMATION

<b>Patient First Name:</b> Peggy	<b>Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered :</b> Professional Associates		
<b>Middle Initial:</b>	Address 1: 123 Main Street		
<b>Patient Last Name:</b> Sue	Address 2:		
<b>Patient Date of Birth (MM/DD/YYYY):</b> 1/1/2000	<b>City:</b> Malvern	<b>State:</b> PA	<b>ZIP:</b> 19542
<b>REMS ID:</b> 1234567890	<b>Phone Number:</b> 555 555-1212		
	<b>Email:</b> abc@abc.com		

### HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

\*First Name

\*Last Name

\*Credentials

MD/DO  NP/PA  Pharmacist  Nurse  Other

\*Specialty

Psychiatry  OB/GYN  Family Practice  Other

\*Did the Patient Receive ZULRESSO?

Yes  No

\*Administering HCP Signature: 

HCP Email (Optional)

\*HCP Phone Number

CANCEL

SUBMIT

If you have any questions, require additional information or need additional copies of any of the ZULRESSO REMS documents, please visit the ZULRESSO REMS website at [www.zulressorems.com](http://www.zulressorems.com) or call 844-472-4379.

**Healthcare Providers must report to the ZULRESSO REMS any event of excessive sedation or loss of consciousness using the Excessive Sedation and Loss of Consciousness Adverse Event Form.**

**To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## ZULRESSO Post Infusion Form

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Patient First Name: Peggy	Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered : Professional Associates
Middle Initial:	Address 1: 123 Main Street
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Patient Date of Birth (MM/DD/YYYY): 1/1/2000	City: Malvern State: PA ZIP: 19542
REMS ID: 1234567890	Phone Number: 555 555-1212
	Email: abc@abc.com

### HEALTHCARE PROFESSIONAL (HCP) INFORMATION

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\*First Name  \*Last Name

\*Credentials  MD/DO  NP/PA  Pharmacist  Nurse  Other

\*Specialty  Psychiatry  OB/GYN  Family Practice  Other

\*Did the Patient Receive ZULRESSO?

Yes  No

\*Date Infusion Started (MM/DD/YYYY)

\*Date Infusion Ended (MM/DD/YYYY)

\*Did the Patient Experience Loss of Consciousness While on ZULRESSO?

Yes  No

\*Did the Patient Experience Excessive Sedation While on ZULRESSO?

Yes  No

\*Administering HCP Signature:

HCP Email (Optional)

\*HCP Phone Number

CANCEL

SUBMIT

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### PATIENT AND HEALTHCARE SETTING INFORMATION

<b>Patient First Name:</b> Peggy <b>Middle Initial:</b> <b>Patient Last Name:</b> Sue <b>Patient Date of Birth (MM/DD/YYYY):</b> 1/1/2000 <b>REMS ID:</b> 1234567890	<b>Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered :</b> Professional Associates <b>Address 1:</b> 123 Main Street <b>Address 2:</b> <b>City:</b> Malvern <b>State:</b> PA <b>ZIP:</b> 19542 <b>Phone Number:</b> 555 555-1212 <b>Email:</b> abc@abc.com
--	--

### HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

<b>*First Name</b> <input type="text"/>	<b>*Last Name</b> <input type="text"/>
<b>*Credentials</b> <input type="checkbox"/> MD/DO <input type="checkbox"/> NP/PA <input type="checkbox"/> Pharmacist <input type="checkbox"/> Nurse <input type="checkbox"/> Other	<b>*Specialty</b> <input type="checkbox"/> Psychiatry <input type="checkbox"/> OB/GYN <input type="checkbox"/> Family Practice <input type="checkbox"/> Other

**\*Did the Patient Receive ZULRESSO?**

Yes  No

**\*Date Infusion Started (MM/DD/YYYY)**

**\*Time Infusion Started (24-Hour Clock HH:MM)**

**\*Date Infusion Ended (MM/DD/YYYY)**

**\*Time Infusion Ended (24-Hour Clock HH:MM)**

**\*Did the Patient Experience Loss of Consciousness While on ZULRESSO?**

Yes  No

**\*Did the Patient Experience Excessive Sedation While on ZULRESSO?**

Yes  No

If You Answer Yes to Either of the Above Questions, Complete the Excessive Sedation and Loss of Consciousness Adverse Event Form\*

### EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS ADVERSE EVENT SECTION

Please complete the following

#### ADDITIONAL PATIENT INFORMATION

<b>*Height (feet/inches)</b>	<b>*Weight (lbs)</b>	<b>*Date of Delivery (MM/DD/YYYY)</b>
<input type="text"/>	<input type="text"/>	<input type="text"/>

**\*Race (Mark One or More)**

American Indian or Alaska Native  Black or African American  Asian  Native Hawaiian or Other Pacific Islander  White

**\*Delivery Information**

Vaginal  Caesarean

**\*Live Birth**

Yes  No

**History of:**

**\*Postpartum Depression (with Prior Pregnancy)**

Yes  No

**\*Major Depressive Disorder**

Yes  No

**\*Hypertension**

Yes  No

**\*Hypotension/Fainting**

Yes  No

**\*Substance/Alcohol Abuse**

Yes  No

**\*Is There Any Other Relevant Medical History?**

Yes  No

**\*Onset of Current Episode PPD Symptoms**

During Pregnancy  After Delivery

**\*Concomitant Medications Currently Being Taken**

Oral Antidepressants  Benzodiazepines  Opioids  
 Hormonal Birth Control  Other

**\*Were Clinical Labs Performed?**

Yes  No

### EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION

**\*Event Type**

Excessive Sedation  Loss of Consciousness (LOC)

**\*Event Onset Date (MM/DD/YYYY)**

**\*Event Onset Time (24-Hour Clock HH:MM)**

**\*Did the Event Resolve?**

Yes  No

**\*If Excessive Sedation or Loss of Consciousness Occurred What Was the Duration of the Event?**

Less than 5 Min  5-15 Min  15-30 Min  30 Min - 1 Hour  >1 Hour

**\*Dose of ZULRESSO at Time of Event (mcg/kh/h)**

**\*Was the Event Witnessed?**

Yes  No

**\*Was Infusion Stopped Due to Event?**

Yes  No

**\*Was Infusion Restarted After the Event Resolved?**

Yes  No

**\*Was There a Desaturation Event Noted on Pulse Oximetry?**

Yes  No

**Vital Signs Prior to Infusion (if Available)**

**Date (MM/DD/YYYY)**

**Time (24-Hour Clock HH:MM)**

**Heart Rate (BPM)**

**BP (mmHg)**

**Respiratory Rate (Breaths/Minute)**

**O<sub>2</sub> Saturation (%)**

**Vital Signs at Time (or Closest to Time) of the Event**

**\*Date (MM/DD/YYYY)**

**\*Time (24-Hour Clock HH:MM)**

**\*Heart Rate (BPM)**

**\*BP (mmHg)**

**\*Respiratory Rate (Breaths/Minute)**

**\*O<sub>2</sub> Saturation (%)**

**\*Did the Event Result in a Fall?**

Yes  No

**\*Did the Event Result in an Injury?**

Yes  No

**\*What Was the Patient's Position at the Time of the Event?**

Supine  Sitting  Standing

**\*What was the Patient's Activity at the Time of the Event?**

Eating/Drinking  Awake  Resting  Sleeping  Other

**\*During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient**

Voice  Light Touch  Deep Touch  Pain  Did Not Respond

**\*Within 2 Hours Prior to the Event Did the Patient Report Symptoms of**

Somnolence  Sedation  Dizziness  Vertigo  Other

**\*Did the Event Need Treatment?**

Yes  No

**\*Did the Patient Have More Than One Event of Excessive Sedation or LOC Event During the Infusion?**

Yes  No

**\*Administering HCP Signature:**

**HCP Email (Optional)**

**\*HCP Phone Number**

CANCEL

SUBMIT

\*If you have any questions, require additional information or need additional copies of any of the ZULRESSO REMS documents, please visit the ZULRESSO REMS website at [www.zulressorems.com](http://www.zulressorems.com) or call 844-472-4379.

**Healthcare Providers must report to the ZULRESSO REMS any event of excessive sedation or loss of consciousness using the Excessive Sedation and Loss of Consciousness Adverse Event Form.**

**To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

ZULRESSO Post Infusion Form

INSTRUCTIONS

ZULRESSO is only available through the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS). A Post Infusion Form must be submitted to the ZULRESSO REMS for all patients who are enrolled in the ZULRESSO REMS. Please complete and submit this form within 3 business days of the patient completing the infusion or the scheduled infusion completion date.

Please complete and submit this Post Infusion Form to the ZULRESSO REMS by clicking "Submit" below. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

\*Indicates required field

PATIENT AND HEALTHCARE SETTING INFORMATION

Patient First Name: Peggy, Middle Initial: Sue, Patient Last Name: Sue, Patient Date of Birth (MM/DD/YYYY): 1/1/2000, REMS ID: 1234567890, Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered: Professional Associates, Address 1: 123 Main Street, Address 2: City: Malvern, State: PA, ZIP: 19542, Phone Number: 555 555-1212, Email: abc@abc.com

HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

\*First Name, \*Last Name, \*Credentials (MD/DO, NP/PA, Pharmacist, Nurse, Other), \*Specialty (Psychiatry, OB/GYN, Family Practice, Other), \*Did the Patient Receive ZULRESSO?, \*Date Infusion Started (MM/DD/YYYY), \*Time Infusion Started (24-Hour Clock HH:MM), \*Date Infusion Ended (MM/DD/YYYY), \*Time Infusion Ended (24-Hour Clock HH:MM), \*Did the Patient Experience Loss of Consciousness While on ZULRESSO?, \*Did the Patient Experience Excessive Sedation While on ZULRESSO?

If You Answer Yes to Either of the Above Questions, Complete the Excessive Sedation and Loss of Consciousness Adverse Event Form\*

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS ADVERSE EVENT SECTION

Please complete the following

ADDITIONAL PATIENT INFORMATION

\*Height (feet/inches), \*Weight (lbs), \*Date of Delivery (MM/DD/YYYY), \*Race (Mark One or More), \*Delivery Information, \*Live Birth, \*History of: \*Postpartum Depression (with Prior Pregnancy), \*Major Depressive Disorder, \*Hypertension, \*Hypotension/Fainting, \*Substance/Alcohol Abuse, \*Is There Any Other Relevant Medical History?, \*Onset of Current Episode PPD Symptoms, \*Concomitant Medications Currently Being Taken, \*Other Concomitant Medication, \*Were Clinical Labs Performed?

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION

\*Event Type, \*Event Onset Date (MM/DD/YYYY), \*Event Onset Time (24-Hour Clock HH:MM), \*Did the Event Resolve?, \*Event Resolution Date (MM/DD/YYYY), \*Event Resolution Time (24-Hour Clock HH:MM), \*If Excessive Sedation or Loss of Consciousness Occurred What Was the Duration of the Event?, \*Dose of ZULRESSO at Time of Event (mcg/kh/h), \*Was the Event Witnessed?, \*Was Infusion Stopped Due to Event?, \*Infusion Stop Date (MM/DD/YYYY), \*Infusion Stop Time (24-Hour Clock HH:MM), \*Was Infusion Restarted After the Event Resolved?, \*Infusion Restart Date (MM/DD/YYYY), \*Infusion Restart Time (24-Hour Clock HH:MM), \*Dose of Zulresso Restarted (mcg/kg/h), \*Did the Patient Complete the Infusion?, \*Was There a Desaturation Event Noted on Pulse Oximetry?

Vital Signs Prior to Infusion (if Available)

Date (MM/DD/YYYY), Time (24-Hour Clock HH:MM), Heart Rate (BPM), BP (mmHg), Respiratory Rate (Breaths/Minute), O2 Saturation (%)

Vital Signs at Time (or Closest to Time) of the Event

\*Date (MM/DD/YYYY), \*Time (24-Hour Clock HH:MM), \*Heart Rate (BPM), \*BP (mmHg), \*Respiratory Rate (Breaths/Minute), \*O2 Saturation (%)

\*Did the Event Result in a Fall?, \*Did the Event Result in an Injury?

\*What Was the Patient's Position at the Time of the Event?, \*What was the Patient's Activity at the Time of the Event?

\*Patient Activity Other

\*During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient

\*Within 2 Hours Prior to the Event Did the Patient Report Symptoms of

\*Symptoms Other

\*Did the Event Need Treatment? If Yes, Please Provide Treatment Information in the Section Below.

Please Include Additional Information Regarding the Event That is Not Captured Above (Including Other Symptoms Preceding the Event, Location/Activities During the Onset of Event, Treatment for the Event [If Applicable], and Any Other Details Thought to Be Relevant or Resulting From the Event [eg, Falls, Injury]).

\*Did the Patient Have More Than One Event of Excessive Sedation or LOC Event During the Infusion?

Please Click "Additional Adverse Event" to Report Each Additional Event. + ADDITIONAL ADVERSE EVENT

The Sage Therapeutics, Inc. Drug Safety Department may follow-up to obtain more information about these events.

\*Administering HCP Signature:

HCP Email (Optional), \*HCP Phone Number

CANCEL SUBMIT

\*If you have any questions, require additional information or need additional copies of any of the ZULRESSO REMS documents, please visit the ZULRESSO REMS website at www.zulressorems.com or call 844-472-4379.

Healthcare Providers must report to the ZULRESSO REMS any event of excessive sedation or loss of consciousness using the Excessive Sedation and Loss of Consciousness Adverse Event Form. To report SUSPECTED ADVERSE REACTIONS, contact Sage Therapeutics, Inc. at 844-472-4379 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

ZULRESSO Post Infusion Form

INSTRUCTIONS

ZULRESSO is only available through the ZULRESSO Risk Evaluation and Mitigation Strategy (REMS). A Post Infusion Form must be submitted to the ZULRESSO REMS for all patients who are enrolled in the ZULRESSO REMS. Please complete and submit this form within 3 business days of the patient completing the infusion or the scheduled infusion completion date.

Please complete and submit this Post Infusion Form to the ZULRESSO REMS by clicking "Submit" below. You may be contacted for further information on any reported events by the ZULRESSO REMS team.

\*Indicates required field

PATIENT AND HEALTHCARE SETTING INFORMATION
Patient First Name: Peggy
Middle Initial:
Patient Last Name: Sue
Patient Date of Birth (MM/DD/YYYY): 1/1/2000
REMS ID: 1234567890
Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered: Professional Associates
Address 1: 123 Main Street
Address 2:
City: Malvern
State: PA
ZIP: 19542
Phone Number: 555 555-1212
Email: abc@abc.com

HEALTHCARE PROFESSIONAL (HCP) INFORMATION
The HCP identified below may be contacted for further information.
\*First Name
\*Last Name
\*Credentials
\*Specialty
\*Did the Patient Receive ZULRESSO?
\*Date Infusion Started (MM/DD/YYYY)
\*Time Infusion Started (24-Hour Clock HH:MM)
\*Date Infusion Ended (MM/DD/YYYY)
\*Time Infusion Ended (24-Hour Clock HH:MM)
\*Did the Patient Experience Loss of Consciousness While on ZULRESSO?
\*Did the Patient Experience Excessive Sedation While on ZULRESSO?
If You Answer Yes to Either of the Above Questions, Complete the Excessive Sedation and Loss of Consciousness Adverse Event Form\*

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS ADVERSE EVENT SECTION

PLEASE COMPLETE THE FOLLOWING
ADDITIONAL PATIENT INFORMATION
\*Height (feet/inches)
\*Weight (lbs)
\*Date of Delivery (MM/DD/YYYY)
\*Race (Mark One or More)
\*Delivery Information
\*Live Birth
History of:
\*Postpartum Depression (with Prior Pregnancy)
\*Major Depressive Disorder
\*Hypertension
\*Hypotension/Fainting
\*Substance/Alcohol Abuse
\*Is There Any Other Relevant Medical History?
Sage Therapeutics, Inc. Drug Safety Department will contact the site to collect additional medical history.
\*Onset of Current Episode PPD Symptoms
\*Concomitant Medications Currently Being Taken
\*Other Concomitant Medication
\*Were Clinical Labs Performed?
Sage Therapeutics, Inc. Drug Safety Department will contact the site to obtain the relevant lab information.

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION
\*Event Type
\*Event Onset Date (MM/DD/YYYY)
\*Event Onset Time (24-Hour Clock HH:MM)
\*Did the Event Resolve?
\*Event Resolution Date (MM/DD/YYYY)
\*Event Resolution Time (24-Hour Clock HH:MM)
\*If Excessive Sedation or Loss of Consciousness Occurred What Was the Duration of the Event?
\*Dose of ZULRESSO at Time of Event (mcg/kh/h)
\*Was the Event Witnessed?
\*Was Infusion Stopped Due to Event?
\*Infusion Stop Date (MM/DD/YYYY)
\*Infusion Stop Time (24-Hour Clock HH:MM)
\*Was Infusion Restarted After the Event Resolved?
\*Infusion Restart Date (MM/DD/YYYY)
\*Infusion Restart Time (24-Hour Clock HH:MM)
\*Dose of Zulresso Restarted (mcg/kg/h)
\*Did the Patient Complete the Infusion?
\*Was There a Desaturation Event Noted on Pulse Oximetry?
Vital Signs Prior to Infusion (if Available)
Date (MM/DD/YYYY)
Time (24-Hour Clock HH:MM)
Heart Rate (BPM)
BP (mmHg)
Respiratory Rate (Breaths/Minute)
O2 Saturation (%)
Vital Signs at Time (or Closest to Time) of the Event
Date (MM/DD/YYYY)
Time (24-Hour Clock HH:MM)
Heart Rate (BPM)
BP (mmHg)
Respiratory Rate (Breaths/Minute)
O2 Saturation (%)
\*Did the Event Result in a Fall?
\*Did the Event Result in an Injury?
\*What Was the Patient's Position at the Time of the Event?
\*What was the Patient's Activity at the Time of the Event?
\*Patient Activity Other
\*During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient
\*Within 2 Hours Prior to the Event Did the Patient Report Symptoms of
\*Symptoms Other
\*Did the Event Need Treatment?
If Yes, Please Provide Treatment Information in the Section Below.
Please Include Additional Information Regarding the Event That Is Not Captured Above (Including Other Symptoms Preceding the Event, Location/Activities During the Onset of Event, Treatment for the Event [If Applicable], and Any Other Details Thought to Be Relevant or Resulting From the Event [eg, Falls, Injury]).
\*Did the Patient Have More Than One Event of Excessive Sedation or LOC Event During the Infusion?

EXCESSIVE SEDATION OR LOSS OF CONSCIOUSNESS EVENT INFORMATION
\*Event Type
\*Event Onset Date (MM/DD/YYYY)
\*Event Onset Time (24-Hour Clock HH:MM)
\*Did the Event Resolve?
\*If Excessive Sedation or Loss of Consciousness Occurred What Was the Duration of the Event?
\*Dose of ZULRESSO at Time of Event (mcg/kh/h)
\*Was the Event Witnessed?
\*Was Infusion Stopped Due to Event?
\*Was Infusion Restarted After the Event Resolved?
\*Was There a Desaturation Event Noted on Pulse Oximetry?
Vital Signs Prior to Infusion (if Available)
Date (MM/DD/YYYY)
Time (24-Hour Clock HH:MM)
Heart Rate (BPM)
BP (mmHg)
Respiratory Rate (Breaths/Minute)
O2 Saturation (%)
Vital Signs at Time (or Closest to Time) of the Event
Date (MM/DD/YYYY)
Time (24-Hour Clock HH:MM)
Heart Rate (BPM)
BP (mmHg)
Respiratory Rate (Breaths/Minute)
O2 Saturation (%)
\*Did the Event Result in a Fall?
\*Did the Event Result in an Injury?
\*What Was the Patient's Position at the Time of the Event?
\*What was the Patient's Activity at the Time of the Event?
\*During the Event Indicate the Minimum Stimulus to Elicit a Response From the Patient
\*Within 2 Hours Prior to the Event Did the Patient Report Symptoms of
\*Did the Event Need Treatment?

REMOVE ADVERSE EVENT

PLEASE CLICK "ADDITIONAL ADVERSE EVENT" TO REPORT EACH ADDITIONAL EVENT.
+ ADDITIONAL ADVERSE EVENT

THE SAGE THERAPEUTICS, INC. DRUG SAFETY DEPARTMENT MAY FOLLOW-UP TO OBTAIN MORE INFORMATION ABOUT THESE EVENTS.
\*Administering HCP Signature:
HCP Email (Optional)
HCP Phone Number

CANCEL SUBMIT

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*\*Indicates required field*

### PATIENT AND HEALTHCARE SETTING INFORMATION

<b>Patient First Name:</b> Peggy	<b>Healthcare Setting Where ZULRESSO Was Administered or Was Scheduled to be Administered :</b> Professional Associates		
<b>Middle Initial:</b>	Address 1: 123 Main Street		
<b>Patient Last Name:</b> Sue	Address 2:		
<b>Patient Date of Birth (MM/DD/YYYY):</b> 1/1/2000	<b>City:</b> Malvern	<b>State:</b> PA	<b>ZIP:</b> 19542
<b>REMS ID:</b> 1234567890	<b>Phone Number:</b> 555 555-1212		
	<b>Email:</b> abc@abc.com		

### HEALTHCARE PROFESSIONAL (HCP) INFORMATION

The HCP identified below may be contacted for further information.

\*First Name  \*Last Name

\*Credentials  MD/DO  NP/PA  Pharmacist  Nurse  Other

\*Specialty  Psychiatry  OB/GYN  Family Practice  Other

\*Did the Patient Receive ZULRESSO?  
 Yes  No

\*Please check all reasons that apply  
 Logistical challenges  Change in treatment plan  Other

\*Administering HCP Signature:

HCP Email (Optional)  \*HCP Phone Number

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## My Profile

Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSO REMS portal.

### Healthcare Settings

 ADD HEALTHCARE SETTING

#### Healthcare Setting 1

123 Main Street  
City, State Zip

Healthcare Setting DEA Number: 11111

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: Yes

#### Delegates

 ADD/MODIFY DELEGATE

 Loretta Maybly

 (555) 555-1212

 (555) 555-9999

 lmably@hcs1.com

 REMOVE ASSOCIATION

 Steve Mason

 (555) 555-3434

 (555) 555-8888

 smason@hcs1.com

 REMOVE ASSOCIATION

#### Associated NPI #'S

 ADD NPI #

 2345678901

 REMOVE ASSOCIATION

 3456789012

 REMOVE ASSOCIATION

 4567890123

 REMOVE ASSOCIATION

#### Healthcare Setting 2

100 Broadway  
City State ZIP

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: No

#### Delegates

 ADD/MODIFY DELEGATE

 Corey Pearson

Phone #: 555 555-1212

Fax #: 555 555-8888

Email: spearson@hcs1.com

 REMOVE ASSOCIATION

#### Associated NPI #'S

 ADD NPI #

There are no NPI#s associated with this Healthcare Setting

# My Profile

Below is a list of your associated

REMS portal.

## Healthcare Settings

### Healthcare Setting 1

123 Main Street  
City, State Zip

Healthcare Setting DEA Number:

Site Type: Hospital

Enrolled as Both Healthcare Setting

### ZULRESSO Add Healthcare Setting

**\* National Provider Identifier (NPI#)**

**\* Site Type**  
 Hospital  Infusion Center  Other

**Associated National Provider Identifier (NPI #)**

**\* Healthcare Setting Name**

**\* Healthcare Setting DEA Number**

**\* Address 1**

**Address 2**

**\* City**

**\* State**

**\* ZIP**

**\* Healthcare Setting Enrolling as Both Healthcare Setting and Pharmacy**  
 Yes  No

**CANCEL** **SUBMIT**

 2345678901

 REMOVE ASSOCIATION

 3456789012

 REMOVE ASSOCIATION

 4567890123

 REMOVE ASSOCIATION

Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSO REMS portal.

## Healthcare Settings

### Healthcare Setting 1

123 Main Street  
City, State Zip

Healthcare Setting DEA Number:

Site Type: Hospital

Enrolled as Both Healthcare Setti

### ZULRESSO Add/Modify Delegate

#### SELECT EXISTING DELEGATE OR ADD A NEW DELEGATE

Please click on the Delegate's first or last name in the grid to select the delegate, then hit "Continue". If this is a new delegate, click "New Delegate".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com



Page 1 of 11 | Total Records: 55

NEW DELEGATE

CONTINUE

 4567890123

 REMOVE ASSOCIATION

ATION

## Healthcare Settings

### Healthcare Setting 1

123 Main Street  
City, State Zip

Healthcare Setting DEA Number:

Site Type: Hospital

Enrolled as Both Healthcare Setti

### ZULRESSO Add/Modify Delegate

#### SELECT EXISTING DELEGATE OR ADD A NEW DELEGATE

Please click on the Delegate's first or last name in the grid to select the delegate, then hit "Continue". If this is a new delegate, click "New Delegate".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com

Page 1 of 11 | Total Records: 55

[NEW DELEGATE](#) [CONTINUE](#)



4567890123

REMOVE ASSOCIATION

ATION

# My Profile

Below is a list of your associated Health...

## Healthcare Settings

### Healthcare Setting 1

123 Main Street  
City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Ph...

#### SELECT EXISTING DELEGATE OR ADD A NEW DELEGATE

Please click on the Delegate's first or last name in the grid to select the delegate, then hit "Continue". If this is a new delegate, click "New Delegate".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com



Page 1 of 11 | Total Records: 55

NEW DELEGATE

CONTINUE

#### Modify Delegate Information

\*First Name

Loretta

\*Last Name

Maybly

\*Phone

555 555-3434

\*Fax

555 555-9999

CANCEL

UPDATE

**SELECT EXISTING DELEGATE OR ADD A NEW DELEGATE**

Please click on the Delegate's first or last name in the grid to select the delegate, then hit "Continue". If this is a new delegate, click "New Delegate".

First Name	Last Name	Phone	Email
LORETTA	MAYBLY	555 555-3434	lmaybly@hcs1.com
STEVE	MASON	555 555-3434	smason@abc.com

**NEW DELEGATE** **CONTINUE**

**Enter Delegate Information**

\*First Name  \*Last Name

Healthcare Facility

\*Phone  \*Fax  \*Email

**CANCEL** **ADD**

## Healthcare Settings

 ADD HEALTHCARE SETTING

### Healthcare Setting 1

123 Main Street  
City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: Yes

### Delegates

 ADD/MODIFY DELEGATE

Delegate has been added successfully  
Emails containing a username and temporary password will be sent shortly to the delegate.

 Loretta Maybly

 (555) 555-1212

 (555) 555-9999

 lmably@hcs1.com

 REMOVE ASSOCIATION

 Steve Mason

 (555) 555-3434

 (555) 555-8888

 smason@hcs1.com

 REMOVE ASSOCIATION

 Molly Malone

 (555) 555-5656

 (555) 555-7777

 mmalone@hcs1.com

 REMOVE ASSOCIATION

### Associated NPI #'S

 ADD NPI #

 2345678901

 REMOVE ASSOCIATION

 3456789012

 REMOVE ASSOCIATION

 4567890123

 REMOVE ASSOCIATION

City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pha

### ZULRESSO Add NPI

## ZULRESSO Add National Provider Identifier (NPI #)

National Provider Identifier (NPI#)

CANCEL

SUBMIT

Molly Malone

(555) 555-5656

(555) 555-7777

mmal0ne@hcs1.com

REMOVE ASSOCIATION

2345678901

REMOVE ASSOCIATION

3456789012

REMOVE ASSOCIATION

4567890123

REMOVE ASSOCIATION

City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: Yes

 Loretta Maybly

 (555) 555-1212

 (555) 555-9999

 lmably@hcs1.com

 REMOVE ASSOCIATION

 Steve Mason

 (555) 555-3434

 (555) 555-8888

 smason@hcs1.com

 REMOVE ASSOCIATION

 Molly Malone

 (555) 555-5656

 (555) 555-7777

 mmalone@hcs1.com

 REMOVE ASSOCIATION

Associated NPI #'S

 ADD NPI #

 2345678901

 REMOVE ASSOCIATION

 3456789012

 REMOVE ASSOCIATION

 4567890123

 REMOVE ASSOCIATION

 55678901234

 REMOVE ASSOCIATION

## My Profile

Below is a list of your associated Healthcare Settings and associated Delegates who require access to the online ZULRESSO REMS portal.

### Healthcare Settings

ADD HEALTHCARE SETTING

#### Healthcare Setting 1

123 Main Street  
City, State Zip

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: Yes

#### Delegates

ADD/MODIFY DELEGATE

Loretta Maybly

(555) 555-1212

(555) 555-9999

lmaybly@hcs1.com

REMOVE ASSOCIATION

Steve Mason

(555) 555-3434

(555) 555-8888

smason@hcs1.com

REMOVE ASSOCIATION

Are you sure you want to remove this Delegate from this Healthcare Setting?

YES  NO

ADD NPI #

2345678901

REMOVE ASSOCIATION

3456789012

REMOVE ASSOCIATION

4567890123

REMOVE ASSOCIATION

#### Healthcare Setting 2

100 Broadway  
City State ZIP

Healthcare Setting DEA Number: 22222

Site Type: Hospital

Enrolled as Both Healthcare Setting and Pharmacy: No

#### Delegates

ADD/MODIFY DELEGATE

Corey Pearson

Healthcare Setting 2

Phone #: 555 555-1212

Fax #: 555 555-8888

Email: spearson@hcs1.com

REMOVE ASSOCIATION

#### Associated NPI #'S

ADD NPI #

There are no NPI#s associated with this Healthcare Setting

-----  
**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/  
-----

TIFFANY R FARCHIONE  
12/13/2019 12:49:54 PM