SPRAVATO® REMS (Risk Evaluation and Mitigation Strategy)

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

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product.

The goal of the REMS is to mitigate the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO® administration, and abuse and misuse of SPRAVATO® by:

- Ensuring that SPRAVATO® is only dispensed and administered to patients in a medically supervised healthcare setting that monitors these patients
- Ensuring pharmacies and healthcare settings that dispense SPRAVATO® are certified
- Ensuring that each patient is informed about the serious adverse outcomes resulting from sedation and dissociation and need for monitoring
- Enrollment of all patients in a registry to further characterize the risks and support safe use

SPRAVATO® is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO® must never be dispensed directly to a patient for home use.

Program Requirements

- **Healthcare Setting**: Healthcare Settings must be certified in the SPRAVATO® REMS in order to treat patients with SPRAVATO®
  - Healthcare Setting Certification

- **Pharmacy**: Pharmacies must be certified in the SPRAVATO® REMS in order to dispense SPRAVATO®
  - Pharmacy Certification

- **Patient**: Patients must be enrolled in the SPRAVATO® REMS in order to receive SPRAVATO® treatment
  - Patient Enrollment

SPRAVATO® Indication

SPRAVATO® is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment for treatment-resistant depression (TRD) in adults.

SPRAVATO® is only available through select distribution channels.

If you have any questions about the SPRAVATO® REMS or need help with certification or enrollment, call 1-855-382-6022 Monday – Friday 8AM – 8PM ET
SPRAVATO™ REMS Healthcare Setting Enrollment

Healthcare settings must be certified in the SPRAVATO™ REMS in order to prescribe product. SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO™ must never be dispensed directly to a patient for home use.

How does my Healthcare Setting become certified in the SPRAVATO™ REMS?

1. Step 1: Designate an Authorized Representative to oversee implementation and compliance with the REMS requirements

2. Step 2: Review the following materials:
   - SPRAVATO™ REMS Fact Sheet
   - SPRAVATO™ Prescribing Information
   - SPRAVATO™ Medication Guide
   - SPRAVATO™ Instructions for Use

3. Step 3: Complete and submit the SPRAVATO™ REMS Healthcare Setting Enrollment Form to the REMS
   - Online
   - By Fax

PDFs for Download: Resources for Healthcare Settings

- SPRAVATO™ REMS Healthcare Setting Enrollment Form
- SPRAVATO™ REMS Fact Sheet
- SPRAVATO™ REMS Patient Enrollment Form
- SPRAVATO™ Prescribing Information
- SPRAVATO™ REMS Patient Monitoring Form
- SPRAVATO™ Medication Guide
- SPRAVATO™ REMS Letter for Healthcare Providers
- SPRAVATO™ Instructions for Use
SPRAVATO™ REMS Pharmacy Enrollment

Pharmacies must be certified in the SPRAVATO™ REMS to be able to receive and dispense/fulfill medication orders for SPRAVATO™.

How does my Pharmacy become certified in the SPRAVATO™ REMS?

1. Step 1: Designate an Authorized Representative to oversee implementation and compliance of the SPRAVATO™ REMS requirements

2. Step 2: Review the following materials:
   - SPRAVATO™ REMS Fact Sheet
   - SPRAVATO™ Prescribing Information
   - SPRAVATO™ Medication Guide
   - SPRAVATO™ Instructions for Use

3. Step 3: Complete and submit the SPRAVATO™ REMS Pharmacy Enrollment Form to the REMS
   - Online  |  By Fax

PDFs for Download: Resources for Pharmacies

- SPRAVATO™ REMS Pharmacy Enrollment Form
- SPRAVATO™ Prescribing Information
- SPRAVATO™ REMS Letter for Healthcare Providers
- SPRAVATO™ Medication Guide
- SPRAVATO™ REMS Fact Sheet
- SPRAVATO™ Instructions for Use
What is the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy)?

Because of the risks associated with SPRAVATO™, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS). As part of the REMS, your doctor will discuss the risks of misuse, abuse, sedation (feeling sleepy), dissociation (feeling disconnected from yourself, including thoughts, feelings, and things around you) while on SPRAVATO™ with you. Both you and your doctor must sign the Patient Enrollment Form for you to receive SPRAVATO™. Your doctor will provide a copy of the signed form to the SPRAVATO™ REMS.

How do I enroll in the SPRAVATO™ REMS?

If your healthcare provider and you have both agreed that SPRAVATO™ is the appropriate treatment for you, you will need to enroll in the SPRAVATO™ REMS in order to receive treatment with SPRAVATO™.

These are the steps to take in partnership with your healthcare provider:

1. **Step 1: Read the SPRAVATO™ Medication Guide and Instructions for Use.** Your healthcare provider will review specific risk and safety information for SPRAVATO™ with you and describe how to use the product.

2. **Step 2: Ask your healthcare provider any questions you have about taking SPRAVATO™ and about the SPRAVATO™ REMS.**

3. **Step 3: Make sure you understand:**
   - **A. How to enroll and take part in the SPRAVATO™ REMS:**
   - **B. The benefits and risks of SPRAVATO™:**
   - **C. That each time you receive SPRAVATO™:**
     - You will need to use SPRAVATO™ nasal spray yourself under direct observation of a healthcare provider in a healthcare setting, such as a doctor’s office, clinic, or hospital.
     - You will be monitored by a healthcare provider for at least 2 hours; the healthcare provider will then decide when you are ready to leave the healthcare setting.
     - After treatment with SPRAVATO™, do not drive, operate heavy machinery, or do anything you need to be fully alert until the next day following a peaceful sleep.

4. **Step 4: Together with your healthcare provider complete and sign the SPRAVATO™ REMS Patient Enrollment Form.** Your healthcare provider will fill out most of the enrollment form for you and will send the form to SPRAVATO™ REMS.

PDFs for Download: Resources for Patients

- SPRAVATO™ Medication Guide
- SPRAVATO™ Instructions for Use
Contact Us

Phone: 1-855-382-6022
Fax: 1-877-778-0091

Hours of Operation: Monday — Friday 8:00 AM — 8:00 PM ET
Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™
to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy)

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

A REMS (Risk Evaluation and Mitigation Strategy) is a program managed by the manufacturer to manage known or potential serious risks associated with a drug. The goal of the REMS is to mitigate the risks of the drug, including prevention, detection, and management of adverse events caused by SPRAVATO™.

- Ensuring that SPRAVATO™ is used only when clinically indicated and under adequate supervision in a healthcare setting that monitors these patients.
- Ensuring pharmacies and healthcare professionals understand the risks and how to properly dispense or prescribe the drug.
- Ensuring that each patient is informed about the serious adverse outcomes resulting from cessation and dosage adjustment and need for monitoring their condition.
- Enrollment of all patients in a registry to further characterize the risks and improve patient safety.

SPRAVATO™ is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO™ must never be dispensed directly to a patient for home use.

Program Requirements

Healthcare Setting

Healthcare Settings must be certified in the SPRAVATO™ REMS in order to treat patients with SPRAVATO™

Pharmacy

Pharmacies must be certified in the SPRAVATO™ REMS in order to dispense SPRAVATO™

Patient

Patients must be enrolled in the SPRAVATO™ REMS in order to receive SPRAVATO™ treatment

SPRAVATO™ Indication

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepresant, for the treatment for treatment-resistant depression (TRD) in adults.

If you have any questions about the SPRAVATO™ REMS or need help with certification or enrollment, call 1-855-382-6022 Monday – Friday 8AM – 8PM ET
Login

Your username is the email address you registered with when you created your account online or is the username supplied to you via email if your account was created for you.

Forgot Username

Login

Don’t have an online account?

Register

To create your web account for the SPRAVATO™ REMS, please complete the fields below. The email address you specify must be unique with the SPRAVATO™ REMS website, and will be used as your username to log in to the site.

* I am a
  - Healthcare Setting
  - Prescribing Physician
  - Pharmacy

Healthcare Setting Authorized Representative Information

* First Name

* Last Name

* Phone Number

* Fax Number

* Email Address

* Credentials
  - Physician
  - Physician Assistant
  - Nurse Practitioner
  - Nurse
  - Other

* Credentials Other

Submit

If you have questions about the SPRAVATO™ REMS or need help enrolling, call 1-855-382-6022
Monday – Friday, 8:00 AM – 6:00 PM ET

Phone: 1-855-382-6022
Fax: 1-877-778-0091
www.SPRAVATOrems.com

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
Login
Your username is the email address you registered with when you created your account online or is the username supplied to you via email if your account was created for you.

User Name

Forgot Username

LOGIN

Don’t have an online account?

Register
To create your web account for the SPRAVATO™ REMS, please complete the fields below. The email address you specify must be unique with the SPRAVATO™ REMS website, and will be used as your username to log in to the site.

* I am a
  □ Healthcare Setting  □ Prescribing Physician  □ Pharmacy

Prescribing Physician
Healthcare Setting Information

* Certified Healthcare Setting DEA #

CONTINUE

If you have questions about the SPRAVATO™ REMS or need help enrolling, call 1-855-382-6022
Monday – Friday, 8:00 AM – 8:00 PM ET
Register

To create your web account for the SPRAVATO™ REMS, please complete the fields below. The email address you specify must be unique with the SPRAVATO™ REMS website, and will be used as your username to log in to the site.

*I am a
- Healthcare Setting
- Prescribing Physician
- Pharmacy

Prescribing Physician

Healthcare Setting Information

* Certified Healthcare Setting DEA #

Prescribing Physician Information

* First Name

* Last Name

* Phone Number

* Fax Number

* Email Address

* Prescriber DEA #

* Credentials
  - MD
  - DO
  - NP
  - PA
  - Other

* Specialty
  - Psychiatry
  - Internal Medicine
  - Family Practice
  - Other

SUBMIT

If you have questions about the SPRAVATO™ REMS or need help enrolling, call 1-855-382-6022
Monday – Friday, 8:00 AM – 8:00 PM ET
Login

Your username is the email address you registered with when you created your account online or is the username supplied to you via email if your account was created for you.

Forgot Username

OR

Don't have an online account?

Register

To create your web account for the SPRAVATO™ REMS, please complete the fields below. The email address you specify must be unique with the SPRAVATO™ REMS website, and will be used as your username to log in to the site.

* I am a
  - [ ] Healthcare Setting
  - [ ] Prescribing Physician
  - [ ] Pharmacy

Prescribing Physician

Healthcare Setting Information

* Certified Healthcare Setting DEA #

Prescribing Physician Information

* First Name

* Last Name

* Phone Number

* Fax Number

* Email Address

* Prescriber DEA #

* Credentials
  - [ ] MD
  - [ ] DO
  - [ ] NP
  - [ ] PA
  - [ ] Other

* Specialty
  - [ ] Psychiatry
  - [ ] Internal Medicine
  - [ ] Family Practice
  - [ ] Other

* Specialty Other
  - [ ] Other

If you have questions about the SPRAVATO™ REMS or need help enrolling, call 1-855-382-6022
Monday – Friday, 8:00 AM – 8:00 PM ET
Account Submitted Successfully

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

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 SPRAVATO™ REMS at 1-855-382-6022.

Phone: 1-855-382-6022
Fax: 1-877-778-0091
www.SPRAVATOrems.com

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
Login

Please enter your password

*Password:

CANCEL  NEXT

Forgot Username

LOGIN

Phone: 1-855-382-6022
Fax: 1-877-778-0091
www.SPRAVATOREMS.com

If you have questions about the SPRAVATO™ REMS or need help enrolling, call 1-855-382-6022
Monday – Friday, 8:00 AM – 8:00 PM ET

Healthcare providers should report all adverse events and product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736).
Change Password

Your password has expired and must be changed.

* New Password:

* Re-type new Password:

[Cancel] [Next]
Review Materials

If you have not previously reviewed the material below, please review now by clicking on the link. The document will open up in a new window for you to review.

SPRAVATO™ REMS Materials

- Prescribing Information
SPRAVATO™ REMS
Healthcare Setting Enrollment Form

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Healthcare Setting, enroll by following these 3 steps:

**STEP 1: REVIEW**
- Designate an Authorized Representative
- The Authorized Representative must review the following:
  - Prescribing Information

**STEP 2: COMPLETE AND SIGN**
- The Authorized Representative must complete the Healthcare Setting Enrollment Form
- If the designated Authorized Representative changes, the new Authorized Representative must enroll and complete these 3 steps

**STEP 3: SUBMIT**
- Submit the Healthcare Setting Enrollment Form either:
  - Online at: www.SPRAVATOREms.com
  - OR
  - Print and fax completed form to 1-877-778-0091

*Indicates Required Field

Healthcare Setting Information

*Facility DEA License Number (on file with distributor account)

CONTINUE

Phone: 1-855-382-6022
Fax: 1-877-778-0091
www.SPRAVATOREms.com

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
# SPRAVATO™ REMS Healthcare Setting Enrollment Form

**SPRAVATO™** is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Healthcare Setting, enroll by following these 3 steps:

1. **STEP 1: REGISTER**
   - Designate an Authorized Representative
   - The Authorized Representative must review the following:
     - Prescribing Information

2. **STEP 2: SIGN**
   - The Authorized Representative must complete the Healthcare Setting Enrollment Form:
     - If the designated Authorized Representative changes, the new Authorized Representative must enroll and complete steps 1 & 2.

3. **STEP 3: SUBMIT**
   - Submit the Healthcare Setting Enrollment Form online:
     - Click on [www.SPRAVATOREMS.com](http://www.SPRAVATOREMS.com)
     - Print and sign the form and fax it to 1-877-779-0991.

## Healthcare Setting Information

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<th>Facility DEA License Number (if file with distributor account)</th>
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- **DEA License Expiration Date** (MM/DD/YYYY)
- **Healthcare Setting Name**
  - [EMAIL] 1000 W Main St.
- **Healthcare Setting Address 1**
  - Southwest Medical Care
- **City**
  - Miami
- **Healthcare Setting Telephone Number**
  - 305-600-5722

### Healthcare Setting Type
- [ ] Hospital
- [ ] Nursing Facility
- [ ] Long Term Care
- [ ] Outpatient Clinic
- [ ] Independent Practice
- [ ] Group Practice
- [ ] Other

For each additional healthcare setting where SPRAVATO™ will be delivered, dispersed, and administered within your healthcare system for which the same Authorized Representative will be responsible, click below:

- ADD ANOTHER HEALTHCARE SETTING

Your healthcare setting information will be shared with patients, providers, and distribution systems, to allow your healthcare setting to purchase product.

Your healthcare setting information (name, location, and phone number) will be listed on a location finder, so certified healthcare setting, available to healthcare professionals and patients seeking treatment with SPRAVATO™. If you do not want your information listed, please call SPRAVATO REMS at 1-855-308-6022.

## Authorized Representative Information

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<td>Nurse</td>
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- **Telephone Number**
  - EXT: 000
  - Fax: 1-877-779-0991

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## Healthcare Setting Authorized Representative

I am the Authorized Representative designated by my Healthcare Setting to receive implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I agree, on behalf of myself and my Healthcare Setting, to comply with the following requirements:

- [ ] Review the SPRAVATO™ REMS Prescribing Information
- [ ] Enroll in the SPRAVATO™ REMS by completing this Healthcare Setting Enrollment Form and submitting this form to the SPRAVATO™ REMS.
- [ ] Have a prescription-ready treatment plan during SPRAVATO™ administration and monitoring.
- [ ] Have a healthcare provider available to monitor each patient for at least 2 hours following administration of SPRAVATO™, for resolution of side effects and dose adjustment.
- [ ] Enroll all relevant staff involved in prescribing, dispensing, and administering SPRAVATO™ and establish processes and procedures to ensure that the following take place in my healthcare Setting:
  - A healthcare provider must consult the patient on the healthcare enhancements, side effects, and doses adjustment, and changes in side effects prior to receiving SPRAVATO™.
  - All patients are enrolled in the SPRAVATO™ REMS by completing and submitting the Patient Enrollment Form.
  - The patient's healthcare provider is enrolled in the REMS by dispensing SPRAVATO™ for patient self-administration.
  - The patient self-administers SPRAVATO™ under the direct supervision of a healthcare provider.
  - A healthcare provider monitors every patient for at least 2 hours for resolution of side effects and dose adjustment before the patient leaves the healthcare setting.
  - A Patient Information Form is submitted to the SPRAVATO™ REMS for every patient within 7 calendar days following administration of every dose.
  - SPRAVATO™ is not dispensed via the usual healthcare Setting.

- [ ] Have any new Authorized Representative enroll in the REMS by completing the Healthcare Setting Enrollment Form.
- [ ] Do not distribute, transfer, issue, or sell SPRAVATO™.
- [ ] Maintain accurate records documenting staff competency.
- [ ] Maintain accurate records documenting all approved and authorized personnel in place and current or being reviewed.
- [ ] Maintain records on this implement the SPRAVATO™ REMS and dispensing information including the patient name, dose, number of doses and date administered.

Signature:

**Signature:**

- [ ] CONTINUE
- [ ] CANCEL
SPRATOV™ REMS
Healthcare Setting Enrollment Form

SPRATOV™ REMS is only available through the SPRATOV™ REMS Risk Evaluation and Mitigation Strategy. Only Personnel or healthcare settings that are certified in the SPRATOV™ REMS can receive SPRATOV™.

To become a SPRATOV™ REMS certified healthcare setting, follow these 3 steps:

1. **Authorized Person**: 
   - The Authorized Person must review the following form.
   - The Healthcare Setting must be reviewed and approved by the Manufacturer. 
   - Submit the completed form to SPRATOV™ REMS.

2. **Healthcare Setting Information**: 
   - Facility DEA License Number (or RIN with picR eBHR agent account).
   - SPRATOV™ REMS License Number (or RIN with DEA eBHR agent account).

3. **Authorized Representative Information**: 
   - First Name
   - Last Name
   - Contact Information

The Authorized Person must review the Healthcare Setting Enrollment Form before the Healthcare Setting is certified. 

If you would like to return to the previous page, please use your browser's back button or click here: [Return to previous page].

[Submit Form]

**Please read the Instructions before filling out the form.**

**Facility DEA License Number (or RIN with picR eBHR agent account):**

**SPRATOV™ REMS License Number (or RIN with DEA eBHR agent account):**

**Authorized Representative Information**: 

- **First Name**
- **Last Name**
- **Contact Information**

**Healthcare Setting Information**: 

- **Facility DEA License Number**: 
  - Address Line 1
  - City
  - State
  - Zip
  - Phone
  - Email

- **SPRATOV™ REMS License Number**: 
  - Address Line 1
  - City
  - State
  - Zip
  - Phone
  - Email

- **For each certified healthcare setting where SPRATOV™ will be delivered, dispensed, and administered within your healthcare system for which the name Authorized Representative will be responsible, check here:**

  [Check Box]

**Your healthcare setting information will be shared with prescriber/patient support and other stakeholders, to allow you to track your setting's progress.**

**You can fill out this form electronically and submit it to SPRATOV™ REMS.**
SPRAVATO™ REMS Pharmacy Enrollment Form

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Pharmacy, enroll by following these 3 steps:

STEP 1: REVIEW
- Designate an Authorized Representative
- Authorized Representative must review the following:
  - Prescribing Information
  - Patient Sheet
  - Medication Guide
  - Instructions for Use

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

STEP 3: SUBMIT
- Submit the Pharmacy Enrollment Form either:
  - Online at www.SPRAVATOREMS.com
  - OR
  - Print and fax completed form to 1-877-778-0091

* Indicates Required Field

Pharmacy Information

DEA License Number (On file with distributor account)

DEA Expiration Date:

Name of Pharmacy

ABC Healthcare Setting

Pharmacy Address 1

Address Line 2

City

State

ZIP

Pharmacy Telephone Number

Pharmacy Type (select all that apply)

- Specialty
- Hospital
- Outpatient
- Mental Health
- Other

Your pharmacy information will be shared with Janssen’s patient support and distribution partners, to allow your pharmacy to purchase product.

Pharmacy Shipping Address, if different than above

Shipping Address - Same as above

Pharmacy Address (address must match the DEA address associated with your Pharmacy’s DEA number)

Address Line 2

City

State

ZIP

Pharmacy Authorized Representative Information

First Name

Lost Name

Title

Telephone Number

Ext

Fax

Email Address

Pharmacy Authorized Representative Agreement

I am the Authorized Representative designated by my pharmacy to oversee implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I agree, on behalf of myself and pharmacy, to comply with the following requirements:

- I will
  - Enroll in the SPRAVATO™ REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO™ REMS.
  - Train all relevant staff involved in dispensing SPRAVATO™ on the following:
    - SPRAVATO™ cannot be dispensed by a certified healthcare setting.
    - SPRAVATO™ must never be dispensed directly to a patient for home use.
    - Establish processes and procedures to verify that a healthcare setting is certified before dispensing SPRAVATO™.
    - Before dispensing SPRAVATO™, verify the healthcare setting is certified using the established processes and procedures.
    - Hot distribute, transfer, issue or sell SPRAVATO™ except to certified dispensers.
    - Maintain records documenting staff's completion of training.
    - Maintain records that all REMS processes and procedures are in place and are being followed.
    - Maintain records of all shipments of SPRAVATO™ received and dispensing information including patient name, dosage, number of doses and date dispensed.
    - Comply with audits carried out by Janssen Pharmaceuticals, Inc. or third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure all processes and procedures are in place and are being followed.

Signature:

[CANCEL] [CONTINUE]
SPRAVATO™ REMS Pharmacy Enrollment Form

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Pharmacy, enroll by following these three steps:

**STEP 1: REVIEW**
- Designate an Authorized Representative
- Authorized Representative must review the following:
  - Prescribing Information
  - Fact Sheet
  - Medication Guide
  - Instructions for Use

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

**STEP 3: SUBMIT**
- Submit the Pharmacy Enrollment Form either:
  - Online at www.SPRAVATO.com
  - OR
  - Print and fax completed form to 1-877-778-0091

* Indicates Required Field.

### Pharmacy Information

<table>
<thead>
<tr>
<th>DEA License Number (On file with distributor accountant)</th>
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<th>DEA Expiration Date:</th>
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<th>Name of Pharmacy</th>
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<thead>
<tr>
<th>City</th>
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<tr>
<th>State</th>
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<tr>
<th>ZIP</th>
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<table>
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<tr>
<th>Pharmacy Telephone Number</th>
</tr>
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</table>

Your pharmacy information will be shared with Janssen’s patient support and distribution partners, to allow your pharmacy to purchase product.

### Pharmacy Shipping Address, if different than above

- Shipping Address - Same as above

### Pharmacy Authorized Representative Information

<table>
<thead>
<tr>
<th>First Name</th>
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<th>Last Name</th>
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<table>
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<th>Title</th>
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<table>
<thead>
<tr>
<th>Email Address</th>
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</table>

### Alternate Contact

<table>
<thead>
<tr>
<th>First Name</th>
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<table>
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<tr>
<th>Last Name</th>
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<table>
<thead>
<tr>
<th>Telephone Number</th>
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<th>Fax</th>
</tr>
</thead>
</table>

### Pharmacy Authorized Representative Agreement

I am the Authorized Representative designated by my pharmacy to oversee implementation and coordinate the activities of the SPRAVATO™ REMS. By signing this form, I agree, on behalf of myself and pharmacy, to comply with the following requirements:

1. I will:
   - Enroll in the SPRAVATO™ REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO™ REMS.
   - Train all relevant staff involved in dispensing SPRAVATO™ on the following:
     - SPRAVATO™ can only be dispensed to a certified healthcare setting.
     - SPRAVATO™ must be dispensed directly to a patient for home use.
   - Establish procedures and processes to verify that a healthcare setting is certified before dispensing SPRAVATO™.
   - Before dispensing SPRAVATO™, verify the healthcare setting is certified using the established procedures and processes.
   - Has distribution, transfer, and use of SPRAVATO™ except to certified dispensers.
   - Maintain records documenting staff compliance of training.
   - Maintain records of all shipments of SPRAVATO™ received and dispensing information including patient name, dose, number of doses, and date dispensed.
   - Comply with audits carried out by Janssen Pharmaceuticals, Inc. or their third party acting on behalf of Janssen Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

   *Signature*
SPRAVATO™ REMS Healthcare Setting Certification

**Action Needed**

- **Healthcare Setting**
  The Healthcare Setting is now certified in the SPRAVATO™ REMS.
  [Healthcare Setting #4 Name]
  Please check your email for next steps.
  You selected to acquire SPRAVATO™ as bulk supply directly from a Janssen qualified specialty distributor. Please click below to continue.

- **Complete**
  - **Healthcare Setting**
    The Healthcare Setting is now certified in the SPRAVATO™ REMS.
    [Healthcare Setting #1 Name]
    (associated with [Pharmacy #1 Name])
    Please check your email for next steps.
  - **Pharmacy**
    Healthcare Setting / Pharmacy Association
    The Pharmacy is now certified in the SPRAVATO™ REMS.
    [Pharmacy #1 Name]
    (associated with [Healthcare Setting #1 Name])

- **Pending**
  - **Healthcare Setting Enrollment**
    The certification of the following Healthcare Setting(s) in the SPRAVATO™ REMS is pending.
    [Healthcare Setting #3 Name]
    If you have any questions, please contact the SPRAVATO™ REMS Coordinating Center at 1-855-382-6022.

**ADD ANOTHER HEALTHCARE SETTING**

Phone: 1-855-382-6022
Fax: 1-877-778-0091
www.SPRAVATOREMS.com

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
Review Materials

If you have not previously reviewed the material below, please review now by clicking on the link. The document will open up in a new window for you to review.

SPRAVATO™ REMS Materials

- Prescribing Information
- REMS Fact Sheet
- Medication Guide
- Instructions for Use

NEXT

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
SPRAVATO™ REMS Pharmacy Enrollment Form

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Pharmacy, enroll by following these 3 steps:

**STEP 1: REVIEW**
- Designate an Authorized Representative
- Authorized Representative must review the following:
  - Prescribing Information
  - Fact Sheet
  - Medication Guide
  - Instructions for Use

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

**STEP 3: SUBMIT**
- Submit the Pharmacy Enrollment Form either:
  - Online at: www.SPRAVATOREms.com
  - OR
  - Print and fax completed form to 1-877-778-0091

* Indicates Required Field.

Pharmacy Information

* DEA License Number (On file with distributor account)

Phone: 1-855-382-6022
Fax: 1-877-778-0091
www.SPRAVATOREms.com

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
SPRAVATO™ REMS Pharmacy Enrollment Form

SPRAVATO™ is only available through the SPRAVATO™ REMS (Risk Evaluation and Mitigation Strategy). Only Pharmacies and Healthcare Settings that are certified in the SPRAVATO™ REMS can receive SPRAVATO™.

To become a SPRAVATO™ REMS certified Pharmacy, enroll by following the below 3 steps:

**STEP 1: REVIEW**
- Designate an Authorized Representative
- Authorized Representative must read the following:
  - Prescribing Information
  - Fact Sheet
  - Indication Guide
  - Instructions for Use

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

**STEP 3: SUBMIT**
- Submit the Pharmacy Enrollment Form:
  - Online at: www.SPRAVATO.com
  - OR
  - Print and fax completed form to 1-877-779-0091

*Indicates Required Field.

### Pharmacy Information

<table>
<thead>
<tr>
<th>*DEA License Number (On file with distributor exclusively)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CONTINUE</strong></td>
</tr>
<tr>
<td>*DEA Expiration Date:</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>*Name of Pharmacy</td>
</tr>
<tr>
<td><strong>ABC Pharmacy</strong></td>
</tr>
<tr>
<td>*Pharmacy Address 1</td>
</tr>
<tr>
<td>Extensive Street</td>
</tr>
<tr>
<td>*City</td>
</tr>
<tr>
<td>State</td>
</tr>
<tr>
<td>*ZIP</td>
</tr>
<tr>
<td>94569</td>
</tr>
<tr>
<td>*Pharmacy Telephone Number</td>
</tr>
<tr>
<td>123-456-9876</td>
</tr>
</tbody>
</table>

Your pharmacy information will be shared with Janssen’s patient support and distribution partners, to allow your pharmacy to purchase product.

### Pharmacy Shipping Address, if different than above

- **Shipping Address - Same as above**
- Pharmacy Address (address must match the DEA address associated with your Pharmacy’s DEA number)
- Address Line 2

### Pharmacy Authorized Representative Information

- **First Name**
- **Last Name**
- **Title**
- **Telephone Number**
- **Email Address**

### Alternate Contact

- **First Name**
- **Last Name**
- **Telephone Number**

### Pharmacy Authorized Representative Agreement

I, the Authorized Representative designated by my pharmacy to oversee implementation and coordination of the activities of the SPRAVATO™ REMS, by signing this form, I agree, on behalf of myself and pharmacy, to comply with the following requirements:

- Self:
  - Email the SPRAVATO™ REMS by completing this Pharmacy Enrollment Form and submitting this form to the SPRAVATO™ REMS.
  - Train all relevant staff involved in dispensing SPRAVATO™ on the following:
    - SPRAVATO™ can only be dispensed to a certified healthcare setting.
    - SPRAVATO™ must never be dispensed directly to a patient for home use.
  - Establish processes and procedures to verify that a healthcare setting is certified before dispensing SPRAVATO™.
  - Before dispensing SPRAVATO™, verify the healthcare setting is certified using the established processes and procedures.
  - Do not transfer, loan, or sell SPRAVATO™ except to certified dispensers.
  - Maintain records documenting staff completion of training.
  - Maintain records of all REMS processes and procedures in place and are being followed.
  - Maintain records of all dispensers of SPRAVATO™ involved and dispensing information including patient name, dose, number of devices and state dispensed.
  - Comply with third party audits on behalf of Janssen Pharmaco, Inc. or any third party audits on behalf of Janssen Pharmaco, Inc. to ensure that all processes and procedures are in place and are being followed.

**Signature**: 

**CONTINUE**

---

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
SPRAVATO™ REMS Pharmacy Certification

Complete

Pharmacy

The Pharmacy is now certified in the SPRAVATO™ REMS.

[Pharmacy Name]

Please check your email for next steps.

CONTINUE
### Patient Listing

- **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.**

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>Zip</th>
<th>Date of Birth</th>
<th>REMS Status</th>
<th>Most Recent Ship Date</th>
<th>PMF Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Robert</td>
<td>Smith</td>
<td>123 Main Street</td>
<td>Philadelphia</td>
<td>PA</td>
<td>19042</td>
<td>1/1/2000</td>
<td>Certified</td>
<td>5/23/2018</td>
<td></td>
<td>Submit a Patient Monitoring Form</td>
</tr>
<tr>
<td>Mary</td>
<td>Connors</td>
<td>3 Broadway</td>
<td>Blue Bell</td>
<td>PA</td>
<td>19042</td>
<td>1/1/2000</td>
<td>Pending</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Patient Monitoring Form

Patient Information
First Name: Peggy
Middle Initial: F
Last Name: Sun
Birthdate (mm/dd/yyyy): 1/1/2000
Sex: F

Concomitant Medication
Is the patient currently taking any of the following concomitant medication(s) that may cause sedation or blood pressure changes?
- Benzodiazepines
  - Yes
  - No
- Non-benzodiazepine sedative hypnotics
  - Yes
  - No
- * Psychoactive
  - Yes
  - No
- * Monoamine oxidase inhibitors (MAOIs)
  - Yes
  - No

Healthcare Setting and Healthcare Provider Information
First Name: John
Last Name: Jones
Phone: 555-555-5555
Email: jones@john.com
Healthcare Setting Name: ABC Healthcare
Healthcare Setting Address 1: 123 Main Street
City: New York
State: NY
ZIP: 10003

Treatment Session Information
Date (MM/DD/YYYY): 
Actual Dose Administered: 28 mg
Time at Start of Administration (from 1st device use): AM
Patient must be monitored for at least 2 hours
Time When Patient Completed Treatment Session: PM

- * Confirm vital signs (BP, HR, RR) were in an acceptable range prior to SPRAVATO™ administration.
  - Yes
  - No
- Confirm vital signs were in an acceptable range prior to patient ready to leave.
  - Yes
  - No
- BP Prior to Administration (mmHg):
  - Yes
  - No
- 80 Minutes Post Administration (mmHg):
  - Yes
  - No
- BP Prior to Patient Ready to Leave (mmHg):
  - Yes
  - No
- Was the patient clinically ready to leave prior to the required 2 hours?
  - Yes
  - No

Sedation and Dissociation
Did the patient experience sedation or dissociation?
- Sedation
  - Yes
  - No
- Dissociation
  - Yes
  - No

Serious Adverse Events
Did the patient experience a serious adverse event during this treatment session or since the last treatment session? A serious adverse event is defined as any undesirable experience associated with the use of SPRAVATO™ that resulted in patient hospitalization, a disability or permanent damage, death, required medical intervention, or was life-threatening.
If Yes, please provide detailed information:
- Serious Adverse Event:
- Occurrence:
- Date of Event (MM/DD/YYYY):
- The event resulted in (check all that apply): [ ] death, [ ] hospitalization
- Did the event resolve?

* ADD SERIOUS ADVERSE EVENT

Janssen Pharmaceuticals, Inc., Safety Department may follow-up to obtain more information about these events.

Reporting of other events
For any other adverse event not captured above, healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

CANCEL | SUBMIT

Phone: 1-800-365-8227
Fax: 1-877-778-5281
www.Janssen101.com

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.
## Patient Monitoring Form

### Patient Information
- **First Name**: [Name]
- **Last Name**: [Name]
- **Middle Initial**: [Initial]
- **Birthdate**: [Date]

### Concomitant Medication
- **Diuretics**
  - Yes
  - No
- **Non-steroidal anti-inflammatory drugs**
  - Yes
  - No
- **Psychostimulants**
  - Yes
  - No
- **Antidepressants**
  - Yes
  - No
- **Antihypertensive medications**
  - Yes
  - No

### Healthcare Setting and Healthcare Provider Information
- **Provider Name**: [Name]
- **Provider Email**: [Email]
- **Healthcare Setting Name**: [Name]
- **Healthcare Setting Address**: [Address]

### Treatment Session Information
- **Date (MM/DD/YYYY)**: [Date]
- **Actual Time Administered**
  - 28 mg
  - 56 mg
  - 84 mg
- **Time at least of administration from last device use**: [Time]

### Patient must be monitored for at least 2 hours
- **Time When Patient Completed Treatment Session**: [Time]

### Sedation and Disorientation
- **Did the patient experience sedation or disorientation?**
  - Yes
  - No
- **Indicate onset of symptoms from start of administration**
  - 0-15 minutes
  - 16-60 minutes
  - 61-120 minutes
  - greater than 120 minutes
- **Did symptoms resolve within 2 hours of administration?**
  - Yes
  - No

### Serious Adverse Events
- Did the patient experience a serious adverse event during this treatment session or since the last treatment session? A serious adverse event is defined as any undesirable experience associated with the use of SPRAVATO™ that resulted in patient hospitalization, a disability or permanent damage, death, required medical intervention, or was life-threatening.

### Reporting of other events
For any other adverse event not captured above, healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO™ to Janssen Pharmaceuticals, Inc., Safety Department by following: [Link].
### Change Healthcare Setting

Please click on the Healthcare Setting name to select, then click "Continue".

<table>
<thead>
<tr>
<th>DEA#</th>
<th>HCS Name</th>
<th>City</th>
<th>State</th>
</tr>
</thead>
<tbody>
<tr>
<td>11111</td>
<td>Healthcare Facility Name1</td>
<td>Philadelphia</td>
<td>PA</td>
</tr>
<tr>
<td>22222</td>
<td>Healthcare Facility Name2</td>
<td>NY</td>
<td>NY</td>
</tr>
</tbody>
</table>
SPRATOM™ REMS
Patient Enrollment Form

SPRATOM is available only through the SPRATOM REMS, or restricted distribution program. Only healthcare settings, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive SPRATOM. Your healthcare provider will help you complete this form and provide you with a copy.

Healthcare Setting Information

Healthcare Setting Name:
Address:
City:
Phone Number:

Change Healthcare Setting

Prescribing Physician

First Name:
Last Name:
* prescribed by:
MedEpi:
Specialty:
Specialty Other:

Referring Physician - If different than Prescribing Physician

Referring Physician: Same as Prescribing Physician

Relevant Clinical Information

Has the patient previously been treated with ketamine for treatment-resistant depression, pain syndromes or any other conditions? Yes No
List all pre-existing conditions treated with ketamine:
List all pre-existing medical and psychiatric conditions:
List concomitant medications

Patient Information

First Name:
Last Name:
Street:
City:
* Phone:

Patient Agreement

By signing this form, I understand and acknowledge that:
Before my treatment begins, I will:
• Be advised by the SPRATOM REMS provider by completing this. Patient Enrollment Form with my healthcare provider. Additional information will be provided by the REMS.
• Agree to receive counseling on the risks and the need for monitoring for resolution of addiction and dissociation, and for any changes in my vital signs.
During treatment, I will:
• Use the SPRATOM REMS to report any signs or symptoms I may experience under the direct observation of a healthcare provider.
• Be aware that the healthcare setting where I get SPRATOM for at least 3 hours each treatment until the healthcare provider determines I can safely leave the healthcare setting.
Understand:
• Sedation and dissociation can result from treatment with SPRATOM and must occur after each treatment. Until these effects resolve, I may feel depressed, withdrawal, I should avoid making any important decisions or driving until these effects resolve. I may feel

Patient Acknowledgement

If patient currently available to complete patient signature during online enrollment? Yes No

Prescriber Confirmation

In order to sign this form electronically, please re-enter your username and password.

Reference ID: 4454144
A new document from SPRAVATO REMS is available for you to sign.

You will be given the opportunity to:
- Preview the document.
- Send feedback or questions to SPRAVATO REMS.
- Decline signing and send feedback to SPRAVATO REMS.
- Sign the document electronically using AssureSign.
Review the terms and conditions below and check the checkbox indicating your agreement to receive and sign this document electronically. Click Start Signing when you are ready to sign.

By checking the box below, I agree that the electronic digitized signatures I apply on the following document are representations of my signature and are legally valid and binding as if I had signed the document with ink on paper in accordance with the Uniform Electronic Transactions Act (UETA) and the Electronic Signatures in Global and National Commerce Act (E-SIGN) of 2000.

AssureSign complies with requirements and standards of the Electronic Signatures In Global and National Commerce Act (E-SIGN Act) effective October 1, 2000, the Uniform Electronic Transaction Act (UETA), and the Government Paperwork Elimination Act (GPEA).

I have read and agree to the terms and conditions

Start Signing

Powered by AssureSign

Reference ID: 4454144
Adopt a Signature

Provide your name by drawing with touch, mouse, or stylus.

Signature

By clicking "Adopt Signature", I agree that the signature and initials above will be the electronic representation of my signature and initials for all purposes when I use them to sign documents. Applying them to a document is legally equivalent to signing with a pen on paper.

Adopt Signature
All Information Entered

You have entered all requested information and signatures.

When ready, click Finish to complete this step of the document signing process.

Finish
A new document from SPRAVATO REMS is available for you to sign.

You will be given the opportunity to:

- Preview the document
- Send feedback or questions to SPRAVATO REMS.
- Decline signing and send feedback to SPRAVATO REMS.
- Sign the document electronically using AssureSign.

**UserName:** abc@abc.com

**Note - Please check your email for the password**

Password*

[Continue]
Review the terms and conditions below and check the checkbox indicating your agreement to receive and sign this document electronically. Click **Start Signing** when you are ready to sign.

By checking the box below, I agree that the electronic digitized signatures I apply on the following document are representations of my signature and are legally valid and binding as if I had signed the document with ink on paper in accordance with the Uniform Electronic Transactions Act (UETA) and the Electronic Signatures in Global and National Commerce Act (E-SIGN) of 2000.

AssureSign complies with requirements and standards of the Electronic Signatures In Global and National Commerce Act (E-SIGN Act) effective October 1, 2000, the Uniform Electronic Transaction Act (UETA), and the Government Paperwork Elimination Act (GPEA).

☐ I have read and agree to the terms and conditions
Adopt a Signature

Provide your name by drawing with touch, mouse, or stylus.

Signature

By clicking "Adopt Signature", I agree that the signature and initials above will be the electronic representation of my signature and initials for all purposes when I use them to sign documents. Applying them to a document is legally equivalent to signing with a pen on paper.

Adopt Signature
All Information Entered

You have entered all requested information and signatures.

When ready, click Finish to complete this step of the document signing process.

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name</td>
<td>Mary</td>
</tr>
<tr>
<td>Last Name</td>
<td>Smith</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>1/1/2000</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:abc@abc.com">abc@abc.com</a></td>
</tr>
<tr>
<td>Phone Number</td>
<td>555-555-1212</td>
</tr>
<tr>
<td>Address 1</td>
<td>100 Main St</td>
</tr>
<tr>
<td>City</td>
<td>Philadelphia</td>
</tr>
<tr>
<td>State</td>
<td>PA</td>
</tr>
<tr>
<td>Zip Code</td>
<td>90099</td>
</tr>
</tbody>
</table>

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:
- Enroll in the SPRAVATO REMS by completing this Patient Enrollment Form with my healthcare provider.
- Agree to receive counseling on the risks and the need for monitoring for resolved or new onset sedation and dissociation, and for any changes in my vital signs.

During treatment I will:
- Use the SPRAVATO nasal spray myself under the direct observation of a healthcare provider.
- Be observed at the healthcare setting where I get SPRAVATO at least once every 2 weeks until the healthcare provider determines I am ready to leave the healthcare setting.

I understand:
- Sedation and dissociation can result from spraying SPRAVATO and I must stay after each treatment. Until these effects resolve, I may feel: sleepy and disconnected from myself, my surroundings, and things around me.
- I should make arrangements to have someone stay with me at the healthcare setting and get home.
- I should not drive or perform any activity requiring the use of my hands for the rest of the day on which I receive SPRAVATO.
- I should contact my doctor or inform him/her at my next visit if I believe I have a side effect or reaction from SPRAVATO.
- In order to receive SPRAVATO, I am required to be enrolled in the REMS, and my information will be stored in a database of all patients who receive SPRAVATO in the United States.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me via phone, mail, fax, or email to support administration of the REMS.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may use, disclose, and share my personal health information for the purpose of the operations of the REMS, including enrolling me into the REMS and administering the REMS, coordinating the dispensing of SPRAVATO, and releasing and disclosing my personal health information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law.

Patient Name: Mary Smith

Patient Signature: [Signature]

Date:
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
06/25/2019 08:31:23 PM