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	STEP 2: COMPLETE AND SIGN	STEP 3: SUBMIT
➤ Designate an Authorized Representative ➤ The Authorized Representative must review the following: • Prescribing Information	➤ 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	➤ 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

Healthcare Setting Name*:		
Healthcare Setting Address 1*:	Address Line 2:	
City*:	State*:	ZIP*:
Healthcare Setting Telephone Number*:	Healthcare Setting Website URL:	
Facility DEA License Number* (on file with distributor account):		DEA License Expiration Date (MM/DD/YYYY)*:

Healthcare Setting Type* (select all that apply): ☐ Hospital ☐ Mental Health Facility ☐ Long Term Care ☐ Outpatient Clinic

☐ Independent Practice ☐ Group Practice ☐ Other: _____

If your healthcare setting is an **independent (private) practice, or group practice, or outpatient clinic,** how does your practice intend to acquire SPRAVATO™ for patients? (Select only one option)

☐ By sending a patient-specific prescription for SPRAVATO™ CIII (controlled substance) to a REMS certified pharmacy, have that pharmacy deliver patient-name product to your practice, and follow all required State and Federal DEA laws and regulations.

OR

☐ By acquiring SPRAVATO™ CIII (controlled substance) as bulk supply directly from a Janssen qualified specialty distributor, and follow all required State and Federal DEA laws and regulations.

For each additional healthcare setting where SPRAVATO™ will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, you will **need to** complete page 3.

Your healthcare setting information will be shared with Janssen'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 professionals and patients seeking treatment with SPRAVATO™. If you do not want your information listed, please call SPRAVATO™ REMS at 1-855-382-6022.

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.

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**Indicates required field*

Authorized Representative Information			
First Name*:	MI:	Last Name*:	
Credentials*: ☐ Physician ☐ Physician Assistant ☐ Nurse Practitioner ☐ Pharmacist ☐ Nurse ☐ Other: _____			
Telephone Number*:	EXT:	Fax*:	Email Address*:

Alternate Contact			
First Name:		Last Name:	
Telephone Number:	EXT:	Fax:	Email Address:

Healthcare Setting Authorized Representative Agreement

I am the Authorized Representative designated by my Healthcare Setting to oversee 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:

I will:

- Review the SPRAVATO™ Prescribing Information.
- Enroll in the SPRAVATO™ REMS by completing this *Healthcare Setting Enrollment Form* and submitting this form to the SPRAVATO™ REMS.
- Have a prescriber onsite during SPRAVATO™ administration and monitoring.
- Have a healthcare provider(s) onsite to monitor each patient for at least 2 hours following administration of SPRAVATO™ for resolution of sedation and dissociation, and changes in vital signs.
- **Train** 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 counsels the patient on the need for enrollment, monitoring, and risks of sedation and dissociation, and changes in vital signs prior to receiving SPRAVATO™.
  - All patients are enrolled in the SPRAVATO™ REMS by completing and submitting the *Patient Enrollment Form*.
  - Verify the patient is enrolled in the REMS before 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 sedation and dissociation and changes in vital signs after every dose.
  - A *Patient Monitoring Form* is submitted to the SPRAVATO™ REMS for every patient within 7 calendar days following administration of every dose.
  - SPRAVATO™ is not dispensed for use outside the Healthcare Setting.
- Have any new Authorized Representative enroll in the REMS by completing the *Healthcare Setting Enrollment Form*.
- Do not distribute, transfer, loan, or sell SPRAVATO™.
- Maintain records documenting staff's completion of training.
- Maintain records that all processes and procedures are in place and are being followed.
- Maintain records on all shipments of SPRAVATO™ received and dispensing information including the patient name, dose, number of devices, and date administered.
- Comply with audits carried out by Janssen Pharmaceuticals, Inc., or a third party acting on behalf of Janssen Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.

Name (please print):	
Authorized Representative Signature*:	**Date*:**

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Use this form to add each additional healthcare setting location for which the same Authorized Representative will be responsible.

**Indicates required field*

Additional Healthcare Setting			
Authorized Representative First Name*:	MI:	Last Name*:	
Authorized Representative Email:			
Healthcare Setting Name*:			
Healthcare Setting Address 1*:	Address Line 2:		
City*:	State*:	ZIP*:	
Healthcare Setting Telephone Number*:	Healthcare Setting Website URL:		
Facility DEA License Number* (on file with distributor account):		DEA License Expiration Date (MM/DD/YYYY)*:	

Healthcare Setting Type* (select all that apply): ☐ Hospital ☐ Mental Health Facility ☐ Long Term Care ☐ Outpatient Clinic

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OR

☐ By acquiring SPRAVATO™ CIII (controlled substance) as bulk supply directly from a Janssen qualified specialty distributor, and follow all required State and Federal DEA laws and regulations.

Alternate Contact Information			
First Name:		Last Name:	
Telephone Number:	EXT:	Fax:	Email Address:

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