SPRAVATO® REMS

Outpatient Healthcare Setting Enrollment Form

INSTRUCTIONS:

1. Review the **SPRAVATO® Prescribing Information** and the **SPRAVATO® REMS Program Overview**
2. Complete this form online at www.SPRAVATOrems.com.

This form is intended only for Outpatient Medical Offices and Clinics. Emergency departments within hospitals are certified through the Inpatient Healthcare Setting enrollment.

**** 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:	
DEA License Number* (associated with the Healthcare Setting address):	Name of DEA License Holder (if different from Healthcare Setting Name):	DEA License Expiration Date (MM/DD/YYYY)*:

Healthcare Setting Type*: (select all that apply)
☐ Mental Health Facility ☐ Outpatient Clinic ☐ Independent Practice ☐ Group Practice
☐ Hospital Outpatient Department (HOPD) ☐ Other:_____

If your healthcare setting is an **independent (private) practice, group practice, outpatient clinic, or HOPD**, how does your practice intend to acquire SPRAVATO® for patients? (Select all that apply)

☐ 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.

☐ By acquiring SPRAVATO® CIII (controlled substance) as bulk supply directly from a SPRAVATO® REMS-qualified 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 Pharmaceuticals, Inc., a Johnson & Johnson Company'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.**

Your healthcare setting's information will be shared with Janssen Pharmaceuticals, Inc., wholesaler-distributor partners, to allow your healthcare setting to purchase product.

Healthcare Setting Authorized Representative Information

First Name*:	MI:	Last Name*:

Credentials*: ☐ Physician ☐ Physician Assistant ☐ Nurse ☐ Pharmacist ☐ Nurse Practitioner ☐ Other: _____

Telephone Number*:	EXT:	Fax*:	Email Address*:

Healthcare Setting Alternate Contact

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

Healthcare providers should report suspected adverse events or product quality complaints associated with SPRAVATO® to Janssen Pharmaceuticals, Inc., at 1-800-526-7736 or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

Spravato® (esketamine) nasal spray

Johnson&Johnson

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Healthcare Setting Authorized Representative Agreement

I am the Authorized Representative designated by my healthcare setting to carry out the certification process and oversee implementation and coordinate the activities of the SPRAVATO® REMS. By signing this form, I agree, on behalf of the healthcare setting, to comply with all REMS requirements:

To become certified to dispense, I will:

- Have a prescriber onsite during SPRAVATO® administration and monitoring.
- Have healthcare provider(s) and a pulse oximeter to monitor patients onsite.
- Review the SPRAVATO® **Prescribing Information and REMS Program Overview**.
- Enroll in the SPRAVATO® REMS by completing and submitting the **Outpatient Healthcare Setting Enrollment Form**.
- Establish processes and procedures to:
  - Enroll the patient in the SPRAVATO® REMS.
  - Counsel the patient on the requirement for enrollment, monitoring, and the risks of sedation, dissociation, respiratory depression and other changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
  - Verify the patient is enrolled in the REMS before each administration.
  - Verify SPRAVATO® is not dispensed for use outside the certified healthcare setting.
  - Complete and submit the **Patient Monitoring Form** after each administration within 7 calendar days.
  - Identify all staff involved in prescribing, dispensing, and administering SPRAVATO® and ensure they are trained on:
    - Counseling the patient on the requirement for monitoring and risks of sedation, dissociation, respiratory depression, and other changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in hazardous activities.
    - Patient administration under the supervision of a healthcare provider.
    - Monitoring for resolution of sedation, dissociation, respiratory depression using pulse oximetry and other changes in vital signs for a minimum of 2 hours.

Before treatment initiation, I will:

- Counsel the patient on the requirement for monitoring for resolution of sedation, dissociation, respiratory depression, and other changes in vital signs, and on the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
- Enroll the patient by completing and submitting the **Patient Enrollment Form** to the REMS.

Before administering, I will:

- Counsel the patient on the requirement for monitoring for resolution of sedation, dissociation, respiratory depression, and other changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
- Verify the patient is enrolled in the REMS through the processes and procedures established as a requirement of the REMS.

During and after administering, for at least 2 hours, I will:

- Assess the patient for administration of SPRAVATO® and resolution of sedation, dissociation, respiratory depression using pulse oximetry, and other changes in vital signs.

After administering, within 7 calendar days, I will:

- Document and submit to the REMS using the **Patient Monitoring Form**.

To maintain certification to dispense, I will:

- Have any new authorized representative enroll in the REMS by completing the **Outpatient Healthcare Setting Enrollment Form**.

At all times, I will:

- Not dispense SPRAVATO® for use outside a certified healthcare setting.
- 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 of all shipments of SPRAVATO® received and dispensing information including 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*:**

Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may use, disclose, and share the site's information (name, location, contact information) for purpose of the operations of the REMS, including releasing and disclosing the site's information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law.

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Spravato® (esketamine) CIII nasal spray

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Johnson&Johnson

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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:
DEA License Number* (associated with the Healthcare Setting address):	Name of DEA License Holder (if different from Healthcare Setting Name):	DEA License Expiration Date (MM/DD/YYYY)*:

Healthcare Setting Type*: (select all that apply)
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Additional Alternate Contact Information

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

Your healthcare setting information will be shared with Janssen Pharmaceuticals, Inc.'s patient support and distribution partners, to allow your outpatient healthcare setting to purchase product.

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