SPRAVATO® REMS

Inpatient Healthcare Setting Enrollment Form

Johnson&Johnson

INSTRUCTIONS:

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

As an Inpatient Healthcare Setting (with inpatient units, emergency department, etc.), your Inpatient Pharmacy, operating under the same Drug Enforcement Administration (DEA) license and physical location, will be considered certified once this form is completed/submitted. A separate pharmacy enrollment is not required.

**** 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)
☐ Hospital-Emergency Department ☐ Hospital-Inpatient ☐ Mental Health Facility
☐ Other:_____

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 and Pharmacy 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 and Pharmacy 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

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** Indicates Required Field*

Healthcare Setting and Pharmacy 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 **Inpatient Healthcare Setting Enrollment Form**.
- Establish processes and procedures to counsel 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 potentially hazardous activities.
- Establish processes and procedures to verify SPRAVATO® is not dispensed for use outside the certified healthcare setting.
- Train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® on:
  - Counseling the patient on the requirement for monitoring. 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.
  - 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 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.

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.

To maintain certification to dispense, I will:

- Have any new authorized representative enroll in the REMS by completing the **Inpatient 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® except to certified dispensers.
- 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 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.

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.