SPRAVATO® REMS

Inpatient 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, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091

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'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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Reference ID: 4649523

Spravato® (esketamine) CIII nasal spray

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

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** Indicates Required Field*

Healthcare Setting and Pharmacy Authorized Representative Information

First Name*:	MI:	Last Name*:

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

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

Healthcare Setting and Pharmacy Alternate Contact

First Name:	Last Name:

Telephone Number:	EXT:	Fax:	Email Address:

Healthcare Setting and Pharmacy 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 all REMS requirements:

I will:

- Review the SPRAVATO® Prescribing Information and REMS Program Overview.
- Enroll in the SPRAVATO® REMS by completing this 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.
- **Establish processes and procedures** and **train** all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® to ensure that the following takes place in my Healthcare Setting:
  - A healthcare provider counsels the patient prior to receiving SPRAVATO® on the need for monitoring due to risks of sedation and dissociation, changes in vital signs, and the need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
  - The patient 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.
  - SPRAVATO® is not dispensed for use outside the Healthcare Setting.
  - If the authorized representative changes, have the new authorized representative re-certify the Inpatient Healthcare Setting into the REMS by completing the *Inpatient Healthcare Setting Enrollment Form*.
  - 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 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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