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

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
☐ 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 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'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.

© Janssen Pharmaceuticals, Inc. 2020 08/20

Reference ID: 4649523

SPRAVATO® REMS

Outpatient Healthcare Setting Enrollment Form

** Indicates Required Field*

Healthcare Setting Authorized Representative Information

First Name*:	MI:	Last Name*:

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

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

Healthcare Setting 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 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:
  - Prior to the patient receiving SPRAVATO®, a healthcare provider counsels the patient on the need for enrollment, monitoring, risks of sedation and dissociation, and changes in vital signs.
  - All patients are enrolled in the SPRAVATO® REMS by completing and submitting the *Patient Enrollment Form* with their prescriber.
  - Verify the patient is enrolled in the REMS before dispensing SPRAVATO® for patient administration.
  - 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.
  - A *Patient Monitoring Form* is submitted to the SPRAVATO® REMS for every patient within 7 days following administration of every dose.
  - Notify the SPRAVATO® REMS in advance if patient treatment will be transferred from one REMS-certified Healthcare Setting to another REMS-certified Healthcare Setting.
  - SPRAVATO® is not dispensed for use outside the Healthcare Setting.
  - If the authorized representative changes, have the new authorized representative re-certify the Outpatient Healthcare Setting into the REMS by completing the *Outpatient 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*:**

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.

© Janssen Pharmaceuticals, Inc. 2020 08/20

Reference ID: 4649523

SPRAVATO® REMS

Outpatient Healthcare Setting Enrollment Form

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) ☐ Mental Health Facility ☐ 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 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.

Additional Alternate Contact Information

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

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

Your healthcare setting information (name, location, and phone number) will be listed on a location finder, as a certified outpatient 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.

© Janssen Pharmaceuticals, Inc. 2020 08/20

Reference ID: 4649523