SPRAVATO® REMS

Patient Enrollment Form - Outpatient Use Only

INSTRUCTIONS:

This form is intended only for use by outpatient medical offices or clinics, excluding emergency departments

1. Complete this form online at www.SPRAVATOrems.com.

This section is to be completed by the Prescriber

**** Indicates required field***

Healthcare Setting Information

Healthcare Setting Name*:		
Healthcare Setting DEA License Number* (associated with the Healthcare Setting address):		
Address 1*:	Address 2:	
City*:	State*:	ZIP*:
Phone*:	Fax*:	

Prescriber Information

First Name*:	Last Name*:	
Credentials*: ☐ Physician ☐ Physician Assistant ☐ Nurse ☐ Pharmacist ☐ Other _____ **Specialty*:** ☐ Psychiatry ☐ Internal Medicine ☐ Family Practice ☐ Other_____		Prescriber DEA License Number*:
Phone*:	Fax:	Email*:
Prescriber Signature*:		**Date*:**

Referring Healthcare Provider – if different from Prescriber

First Name:	Last Name:

Relevant Clinical Information

List all pre-existing medical and psychiatric conditions*:

_____

_____

List concomitant medications (e.g.,CNS depressants, adjunctive depression medications, sedative hypnotics, psychostimulants, monoamine oxidase inhibitors [MAOIs])*:

_____

_____

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

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This section is to be completed by the Patient

Your healthcare provider will help you complete this form and provide you with a copy.

**** Indicates required field***

Patient Information

First Name*:	MI:	Last Name*:	Birthdate*: (MM/DD/YYYY):	Sex*: ☐ Male ☐ Female ☐ Other

Email*: (Email is required for online enrollment only)	Phone Number*:

Address 1*:	Address 2:

City*:	State*:	ZIP*:

Patient Agreement

By signing this form, I understand and acknowledge that:

Before my treatment begins, I will:

- Receive counseling from a healthcare provider on:
  - The risk of sedation, dissociation, and respiratory depression.
  - The need for monitoring for resolution of sedation, dissociation, respiratory depression, and other changes in vital signs.
  - The need to have arrangements to safely leave the healthcare setting and not engage in potentially hazardous activities.
- For outpatients: Enroll in the REMS by completing the **Patient Enrollment Form** with a healthcare provider. Enrollment information will be provided to the REMS.

During treatment, before each dose I will:

- Receive counseling from a healthcare provider 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 treatment, during and after administration for at least two hours I will:

- Be monitored for taking SPRAVATO®, resolution of sedation, dissociation, respiratory depression, and other changes in vital signs at the healthcare setting.

I understand:

- I understand that my protected health information will be stored in a secure and confidential database and shared for the management of the REMS.
- I understand that Janssen Pharmaceuticals, Inc. and its agents, may contact me or my prescriber via phone, mail, fax, or email to support administration of the REMS.
- I give permission to Janssen Pharmaceuticals, Inc and its agents to use and share my personal health information for the purposes of enrolling me into the REMS and administering the REMS, coordinating the dispensing of SPRAVATO, and releasing my personal health information to the Food and Drug Administration (FDA) as necessary.

Patient Name (please print):	
Patient Signature*:	**Date*:**