

# SPRAVATO<sup>®</sup> REMS

# **Pharmacy Enrollment Form**

## **INSTRUCTIONS:**

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

If you are an Inpatient Pharmacy (support inpatient units, emergency department, etc.) and operate under the same DEA license and physical location with your Inpatient Healthcare Setting, your pharmacy will be considered certified once the Inpatient Healthcare Setting Enrollment form is completed/submitted, and you <u>do not require a separate</u> pharmacy enrollment form. This form is intended only for pharmacies that dispense to outpatient facilities.

#### \* Indicates Required Field

Pharmacy Information					
Name of Pharmacy*:					
Pharmacy Address 1*:			Address Line 2:		
City*:			State*:		ZIP*:
Pharmacy Telephone Number*:		DEA License Number	* (On file with distributor account)		DEA Expiration Date* (MM/DD/YYYY):
Pharmacy Type*(select all that apply) Community/Retail Specialty Other:					
Your pharmacy information will be shared with Janssen Pharmaceuticals, Inc., a Johnson & Johnson Company's patient support and distribution partners, to allow your pharmacy to purchase product.					
Pharmacy Shipping Address, if different from above					
Pharmacy Address (address must match the DEA address associated with your Pharmacy's Address Line 2: DEA License Number):					
City:		State:		ZIP:	
Pharmacy Authorized Representative Information					
First Name*:		Last Name*:			Title*:
Telephone Number*:	Ext:	Fax*:		Email Add	ress*:
Pharmacy Alternate Contact					
First Name:			Last Name:		
Telephone Number:	Ext:	Fax:		Email Add	ress:
Pharmacy Authorized Representative Agreement					
I am the Authorized Representative designated by my pharmacy to carry out the certification process and oversee implementation and coordinate the activities of the SPRAVATO <sup>®</sup> REMS. By signing this form, I agree, on behalf of the pharmacy, to comply with all					

## REMS requirements:

- To become certified to dispense, I will:
- Enroll in the SPRAVATO® REMS by completing this Pharmacy Enrollment Form and submitting it to the REMS.
- Establish processes and procedures to verify that a healthcare setting is certified in the REMS before dispensing SPRAVATO®.

• Train all relevant staff involved in dispensing that SPRAVATO<sup>®</sup> must only be dispensed to a certified healthcare setting. **Before dispensing, I will:** 

- Verify that the healthcare setting is certified through the processes and procedures established as a requirement of the REMS. At all times, I will:
- Not distribute, transfer, loan or sell SPRAVATO® except to certified dispensers.
- Not dispense SPRAVATO® for use outside a certified healthcare setting.
- 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<sup>®</sup> received and dispensing information including patient name, dose, number of devices, and date dispensed.
- 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.

#### To maintain certification to dispense, I will:

• Have the new authorized representative re-certify the Pharmacy into the REMS by completing the Pharmacy Enrollment Form if the authorized representative changes.

Authorized Representative Signature\*:

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<sup>®</sup> to Janssen Pharmaceuticals, Inc., at 1-800-7736 or the FDA at 1-800-FDA-1088 or online at www.fda.gov/medwatch.

Date: