ST. CLAIR COUNTY COMMUNITY MENTAL HEALTH AUTHORITY

ADMINISTRATIVE PROCEDURES

Date Issued 7/23

CHAPTER Health/Medical		**CHAPTER** 04	**SECTION** 001	**SUBJECT** 0090
SECTION Drugs and Medications	**SUBJECT** Spravato Clinic			
WRITTEN BY Tracey Pingitore	**REVISED BY** **Brandon Moore, Sarah Ingles and Cassidy Haley**		**AUTHORIZED BY** Tracey Pingitore	

I. APPLICATION:

- ☐ SCCCMHA Board
- ☒ SCCCMHA Providers & Subcontractors
- ☒ Direct-Operated Programs
- ☒ Community Agency Contractors
- ☐ Residential Programs
- ☐ Specialized Foster Care
- ☐ SUD Providers

II. PURPOSE STATEMENT:

St. Clair County Community Mental Health Authority (SCCCMHA) to ensure a coordinated management system regarding the prescribing and monitoring of the medication Spravato. For Spravato prescribing management and monitoring guidelines refer to Spravato REMS program at https://www.spravatorems.com/. It shall always be the policy and directive that when prescribing Spravato, prescriber is to follow the requirements and guidelines set forth in Spravato REMS Program.

III. DEFINITIONS:

A. Prescriber: CMH Psychiatrist/Nurse Practitioner who is licensed to prescribe and has completed Spravato REMS training.

B. Spravato (esketamine): FDA approved nasal spray antidepressant indicated for use in conjunction with an oral antidepressant for adults with treatment-resistant depression as well as depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions.

C. Spravato Nurse: A Registered Nurse assigned as the onsite healthcare provider to monitor and execute a smooth, efficient and safe clinic for individuals receiving Spravato. All nurses, pharmacists and prescribers must be certifiedin the REMS program.

D. Spravato REMS: A restricted distribution program that requires the drug be administered in a health care setting that is certified in the Risk Evaluation and Mitigation Strategies (REMS) where the health care provider can monitor the patient. The Spravato REMS program also requires that theprescriber and the patient both sign a Patient Enrollment Form (Exhibit D) and follow specific procedures.

E. Treatment-Resistant Depression (TRD): A failed adequate response to two (2) separate antidepressant medications that were given in adequate doses for at least six (6) week trials.

IV. STANDARDS:

A. As a certified and enrolled Spravato treatment center, SCCCMHA is required to follow Spravato REMS requirements (EXHIBIT E).

B. Eligibility for Spravato Clinic at SCCCMHA includes the following criteria (subject to change):

1. Individual with treatment resistant depression, who has failed adequate trial of two (2) different antidepressant medications; and/or depressive symptoms in adults with major depressive disorder with suicidal thoughts or actions.
2. Individual who is not experiencing psychosis.
3. Individual without a diagnosis or history of dissociation/multiple personality disorder.
4. Individual who is not an active substance user; those with history of substance use disorder must be clean and sober for a minimum of three (3) months.
5. Individual who has at least one (1) support person who can bring the individual for treatment, remain present until the individual is considered stable to go home and agree to take the individual back home. Minimum time required will be three (3) hours. However, it may be longer if individual is not stable to return home at three (3) hours.
6. Individual must agree not to drive for 24 hours after taking the treatment.
7. Individual must agree to submit to urine drug screen, breathalyzer test, and vital sign monitoring prior to each treatment.
8. Individual must also be screened by the nurse assigned to the Spravato Clinic and approved for treatment by the prescriber.
9. Individual must review, sign and abide by the Consent for Spravato Treatment (form #0362) which includes the conditions for participation in the Spravato Clinic.

C. Spravato treatment will be offered to eligible persons served on-site at SCCCMHA. This will require a commitment by the individual to come to the Main Site, accompanied by a support person who is able and willing to drive or provide transportation to the individual back to his home upon discharge on each treatment day, twice weekly.

D. Eligible individuals include those currently receiving services by SCCCMHA as well as those currently served by community providers. Individuals referred by a community provider must also, minimally, receive Case Management Services through SCCCMHA (this is not a medication only program). ***During the time individual is receiving Spravato therapy, he/she shall not also receive psychiatric prescribing services from a community provider.***

E. Spravato is not distributed, transferred, loaned, sold or dispensed outside of SCCCMHA.

F. Spravato prescribers and nurses (staff) must complete Spravato training and follow all established processes and procedures to comply with all Spravato REMS requirements. Training logs must be maintained.

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V. PROCEDURES:

A. Spravato Referral (new cases)

Access Program

1. Receives request for Spravato therapy from an individual or a community provider.

2. Sends referral to Central Intake Unit (CIU) as a potential candidate for Spravato.

Central Intake Unit (CIU)

3. Completes Biopsychosocial Assessment (BPS) as normal and contacts the Spravato Nurse.

B. Spravato Referral (existing cases)

Prescriber

4. Sends referral to Spravato Nurse requesting a Spravato screening.

C. Spravato Screening

Spravato Nurse

5. Makes contact with the individual served and conducts the Spravato screening.

6. Completes Questionnaire Regarding History of Dissociation (form #0360) and the Spravato Screening Questions (form #0361).

D. Process for Individuals Meeting Criteria

Spravato Nurse

7. Submits information for benefits investigation, collects pertinent medical records, and presents case to prescriber.

Prescriber

8. Conducts Psychiatric Evaluation and/or medication review (whichever is clinically appropriate) to further determine the suitability of Spravato treatment.

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9. Informs individual if he/she is a suitable candidate for Spravato therapy following all assessments and evaluations.

10. Prior to the individual receiving Spravato, the individual/guardian is counselled on the need for enrollment, monitoring, risk of sedation and dissociation and changes in vitals signs.

11. Ensures all individuals are enrolled in the Spravato REMS by completing and submitting the Patient Enrollment Form with the Prescriber.

12. Writes prescription for Spravato.

E. Individuals Determined to be Suitable for Spravato Therapy

Spravato Nurse

13. Requests individual sign the SCCCMHA Consent for Spravato Treatment (form #0362), Spravato REMS Patient Enrollment Form (Exhibit A), and Spravato With Me Spravato Patient Enrollment (Exhibit B). These are all required as conditions of participation in the Spravato Clinic.

14. Provides individual with a copy of the Spravato Medication Guide.

15. Conducts a baseline Hamilton Depressing Rating Scale (HAM-D) (form #0359).

16. Reviews with individual their Spravato Clinic appointment, including the following:

    a. Individual and their support person are to arrive at the designated appointment time.
    b. Support person will be required to stay with the individual during the entire appointment time, which will be a minimum of three (3) hours.
    c. Support person will be required to drive or accompany the individual on a bus, cab or Uber to their home.
    d. Individual must sign a written commitment that he/she will not drive for 24 hours after Spravato treatment.
    e. Individual is required to bring all of their prescription and over the counter medications with them to each appointment.

F. Spravato Appointment Day

Spravato Nurse

17. Verifies that the individual is enrolled in REMS before dispensing Spravato for patient administration.

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18. Ensures that there is a prescriber onsite during Spravato administration and monitoring.

19. Welcomes the individual and their support person.

20. Reviews all prescribed and over the counter medications.

21. Conducts urine drug screen, breathalyzer, and vitals with the individual.

22. Reviews with individual the results of the urine drug screen, breathalyzer and vitals. Consults with the individual's prescriber if there are any concerns.

23. Obtains Spravato from the Spravato-certified pharmacy and brings it to the treatment room.

24. Provides a "trainer" Spravato cartridge to practice until comfortable with administration.

Individual Prescribed Spravato

25. Administers Spravato under direct supervision of the Spravato Nurse.

Spravato Nurse

26. Observes the individual for the next two (2) hours and completes the observation sheet/Patient Monitoring Form (Exhibit D). Submit via fax or online at www.spravatorems.com

27. Ensures the Patient Monitoring Form (Exhibit D) is submitted to the Spravato Rems for every individual/patient within 7 calendar day following the administration of every does.

28. Completes vitals assessment before administration, 40 minutes post-administration, and prior to release.

29. Reports any adverse reactions and consults with the individual's prescriber as often as necessary. All contacts are to be documented in OASIS.

30. Discharges individual to the care of the support person with clear instructions that the individual should not drive for the next 24 hours.

31. Completes the HAM-D (form #0359) with the individual during every Spravato treatment session throughout the course of the Spravato treatment.

32. Notifies the Spravato REMS in advance if the individual treatment will be transferred from SCCCMHA to another REMS-certified Healthcare setting.

33. Does this 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 (Exhibit C).

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VI. REFERENCES:

A. Program Operations Directive on "Referral to Spravato Clinic"

VII. EXHIBITS:

A. Spravato REMS Patient Enrollment Form
B. Spravato With Me Spravato Patient Enrollment Form (update 11.22) and Jannsen Patient Support Program Patient Authorization Form
C. Spravato REMS Outpatient Healthcare Setting Enrollment Form
D. Spravato REMS Patient Monitoring Form
E. Spravato REMS Program Overview (Risk Evaluation and Mitigation Strategy)

VIII. REVISION HISTORY:

Dates issued 5/21, 09/22.

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

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

Has the patient previously been treated with ketamine or esketamine for major depressive disorder, treatment-resistant depression, pain syndromes, or any other condition?*	☐ Yes ☐ No

If YES, list all pre-existing conditions treated with ketamine or esketamine:

_____

_____

List all pre-existing medical and psychiatric conditions*:

_____

_____

List concomitant medications (e.g., 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.

Spravato® (esketamine) nasal spray

SPRAVATO® REMS
Patient Enrollment Form - Outpatient Use Only

janssen

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:

- Enroll in the SPRAVATO® REMS by completing this *Patient Enrollment Form* with my healthcare provider. Enrollment information will be submitted to the SPRAVATO® REMS.
- Receive counseling on safety risks and the need for monitoring to observe for resolution of sedation and dissociation, and for any changes in vital signs.

During treatment, and after administration I will:

- Use the SPRAVATO® nasal spray myself under the direct observation of a healthcare provider.
- Be observed at the healthcare setting where I get SPRAVATO® for at least 2 hours after each treatment until the healthcare provider determines I am ready to leave the healthcare setting.

I understand:

- Sedation and dissociation can result from treatment with SPRAVATO® and I must stay after each treatment. Until these effects resolve, I may feel:
  - sleepy and/or
  - disconnected from myself, my thoughts, feelings and things around me.
- I should make arrangements to safely get home.
- I should not drive or use heavy machinery for the rest of the day on which I receive SPRAVATO®.
- I should contact my doctor or inform him/her at my next visit if I believe I have a side effect or reaction from SPRAVATO®.
- In order to receive SPRAVATO® as an outpatient, I am required to be enrolled in the REMS, and my information will be stored in a database of all outpatients who receive SPRAVATO® in the United States.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may contact me or my prescriber via phone, mail, fax, or email to support administration of the REMS.
- Janssen Pharmaceuticals, Inc. and its agents, including trusted vendors, may use, disclose, and share my personal health information for the purpose of the operations of the REMS, including enrolling me into the REMS and administering the REMS, coordinating the dispensing of SPRAVATO®, and releasing and disclosing my personal health information to the Food and Drug Administration (FDA), as necessary, and as otherwise required by law.

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

UPDATE 11.22

Spravato withMe | Spravato® (esketamine) 28 mg nasal spray

Patient Enrollment Form

Complete and fax this form to SPRAVATO withMe at 844-577-7282.

SPRAVATO withMe is unable to process any information without the signed Patient Authorization Form, included on the last 2 pages of this form. The Patient Authorization Form is also available upon request by calling 844-4S-WITHME (844-479-4846). The information you provide will be used by Johnson & Johnson Health Care Systems Inc., our affiliates, and our service providers for your patient's enrollment and participation in SPRAVATO withMe. Our Privacy Policy governs the use of the information you provide. By submitting this form, you indicate that you read, understand, and agree to these terms.

All fields are REQUIRED except where noted

1. Patient Information

Patient First Name _____ Patient Last Name _____ Sex: ☐ M ☐ F

Date of Birth (mm/dd/yyyy) _____ Preferred Language: ☐ English ☐ Spanish ☐ Other _____

Address _____ City _____ State _____ ZIP _____

Phone _____ (☐ Cell ☐ Home) Best Time to Contact: ☐ AM ☐ PM Email _____

Caregiver/Contact _____ Relationship to Patient _____
(A caregiver/contact is someone who can be contacted in place of the patient.)

Phone _____ (☐ Cell ☐ Home) Best Time to Contact: ☐ AM ☐ PM Email _____

☐ I authorize SPRAVATO withMe/Partner withMe to leave a message if I am unavailable when they call.

☐ If I cannot be reached, I authorize SPRAVATO withMe/Partner withMe to contact my caregiver.

☐ I prefer and authorize SPRAVATO withMe/Partner withMe to contact my caregiver in place of me.

2. Insurance Information (Please attach copy of the front and back of insurance cards OR complete below.)

Prescription Drug Insurance _____ Phone _____ Employer _____

Cardholder Name (First, MI, Last) _____ BIN # _____ Policy # _____ Group # _____

Primary Medical Insurance _____ Phone _____ Employer _____

Cardholder Name (First, MI, Last) _____ Policy # _____ Group # _____

Secondary Medical Insurance/Behavioral Health Insurance _____ Phone _____

Cardholder Name (First, MI, Last) _____ Policy # _____ Group # _____

3. Prescriber Information

Where do you plan for the patient to be treated?

☐ Physician's Office (CMS-1500) ☐ Outpatient Facility (UB-04) ☐ Undecided

Treating Physician Name (First, Last) _____ Specialty (optional) _____

Treatment Site Name _____ Treatment Site Contact _____

Address _____ City _____ State _____ ZIP _____

Phone _____ Fax _____ After Hours Phone _____ Email _____

Provider NPI # _____ DEA # _____ State License # _____ Tax ID # _____

I agree that my contact information may be shared with another healthcare professional, when requested, to assist with patient care.

If referring physician is known: Name (First, Last) _____ Phone _____ Fax _____

Please see the full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®. Provide the Medication Guide to your patients and encourage discussion.

Spravato withMe | Spravato® (esketamine) CIII 28 mg nasal spray

Patient Enrollment Form

Complete and fax this form to SPRAVATO withMe at 844-577-7282.

Patient First Name _____ Patient Last Name _____ DOB _____

4. Product Acquisition Plan (Optional)

Healthcare Setting or Pharmacy must be Risk Evaluation and Mitigation Strategy (REMS)-certified prior to ordering and/or dispensing SPRAVATO®. Information will be provided based on the patient's health plan requirements (major medical and/or prescription).

Please select one of the following checkboxes for your preferred product acquisition:

☐ REMS-certified Pharmacy: We will provide information associated with REMS-certified pharmacies that are covered under this patient's plan.

☐ Medical Buy & Bill

5. Clinical Information (The information requested here is needed to investigate benefits. This form does NOT serve as a valid prescription.)

Common ICD-10 Codes*: ☐ F32.1 ☐ F32.2 ☐ F32.3 ☐ F33.2 ☐ R45.851 ☐ Other ICD-10 Code _____

**These codes do not represent all available codes.*

Treatment History:

Concomitant Oral Antidepressant _____

Other therapies prescribed within the current depressive episode _____

Dose Strength(s) to Investigate: ☐ 84 mg ☐ 56 mg ☐ Both

Indication

☐ **Treatment-resistant depression in adults**

☐ The patient with MDD and in the current depressive episode has not responded adequately to at least two different antidepressants of adequate dose and duration.

☐ **Depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior**

Treatment Location Ship to:

Site Name _____ Site Contact _____ Phone _____

Address _____ City _____ State _____ ZIP _____

Information about your patient's insurance coverage, cost support options, and treatment support is given by service providers for SPRAVATO withMe. The information you get does not require you or your patient to use any Janssen product. Because the information we give you comes from outside sources, SPRAVATO withMe cannot promise the information will be complete. SPRAVATO withMe cost support is not for patients in the Johnson & Johnson Patient Assistance Foundation.

SPRAVATO withMe is limited to education for patients about SPRAVATO®, its administration, and/or their disease, and is not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, or provide case management services.

Please see the full Prescribing Information, including Boxed WARNINGS, and Medication Guide for SPRAVATO®. Provide the Medication Guide to your patients and encourage discussion.

Janssen Patient Support Program
Patient Authorization Form

Patients should read the Patient Authorization, check the desired permission boxes, sign, and return both pages of the Form to the Janssen Patient Support Program.

- Completed Form may be faxed to 844-577-7282 or mailed to Partner withMe, 680 Century Point, Lake Mary, FL 32746.
- Patients may also read, eSign, and submit a digital version of this form at **SpravatowithMePatientAuth.com**

Patient Name _____ **Email Address** _____

I give permission for each of my "Healthcare Providers" (eg, my physicians, pharmacists, specialty pharmacies, other healthcare providers, and their staff) and "Insurers" (eg, my health insurance plans) to share my Protected Health Information as described on this Form.

My "Protected Health Information" includes any and all information related to my medical condition, treatment, prescriptions, and health insurance coverage.

The following person(s) or class of person(s) are given permission to receive and use my Protected Health Information (collectively "Janssen"):

- Johnson & Johnson Health Care Systems Inc., its affiliated companies, agents, and representatives
- Providers of other sources of funding, including foundations and co-pay assistance providers
- Service providers for the patient support programs, including subcontractors or Healthcare Providers helping Janssen run the programs
- Service providers maintaining, transmitting, de-identifying, aggregating, or analyzing data from Janssen patient support programs

Also, I give permission to Janssen to receive, use, and share my Protected Health Information in order to:

- see if I qualify for, sign me up for, contact me about, and provide services relating to Janssen patient support programs, including in-home services
- manage the Janssen patient support programs
- give me educational and adherence materials, information, and resources related to my Janssen medication in connection with Janssen patient support programs
- communicate with my Healthcare Providers regarding access to, reimbursement for and fulfillment of my Janssen medication, and to tell my Healthcare Provider that I am participating in Janssen patient support programs
- verify, assist with, and coordinate my coverage for my Janssen medication with my Insurers and Healthcare Providers
- coordinate prescription or treatment location and associated scheduling
- conduct analysis to help Janssen evaluate, create, and improve its products, services, and customer support for patients prescribed Janssen medications
- share and give access to information created by the Janssen patient support programs that may be useful for my care

I understand that my Protected Health Information may be shared by Janssen for the uses written in this Form to:

- My Insurers
- My Healthcare Providers
- Any of the persons given permission to receive and use my Protected Health Information as mentioned above
- Any individual I give permission as an additional contact

Janssen and the other data recipients listed on this Form may share information about me as permitted on this Form or if any information that specifically identifies me is removed. I understand that Janssen will use reasonable efforts to keep my information private but once my Protected Health Information is disclosed as allowed on this Form, it may no longer be protected by federal privacy laws.

Janssen Patient Support Program
Patient Authorization Form

I understand that I am not required to sign this Form. My choice about whether to sign will not change how my Healthcare Providers or Insurers treat me. If I do not sign this Form, or cancel or remove my permission later, I understand I will not be able to participate or receive assistance from Janssen's patient support programs.

I understand that pharmacies that dispense and ship my medication and service providers for the patient support programs may be paid by Janssen for their services and data. This may include payment for sharing Protected Health Information and other data in connection with these programs, as allowed on this Form.

This Form will remain in effect 10 years from the date of signature, except where state law requires a shorter time, or until I am no longer participating in any Janssen patient support programs. Information collected before that date may continue to be used for the purposes set forth in this Form.

I understand that I may cancel the permissions given by this Form at any time by letting Janssen know in writing at: Partner withMe, 680 Century Point, Lake Mary, FL 32746.

I can also cancel my permission by letting my Healthcare Providers and Insurers know in writing that I do not want them to share any information with Janssen.

I further understand that if I cancel my permission it will not affect how Janssen uses and shares my Protected Health Information received by Janssen prior to my cancellation.

I understand I may request a copy of this Form.

Permission for communications outside of Janssen patient support programs:

☐ Yes, I would like to receive communications relating to my Janssen medication.

☐ Yes, I would like to receive communications relating to other Janssen products and services.

For privacy rights and choices specific to California residents, please see Janssen's California privacy notice available at **https://www.janssen.com/us/privacy-policy#california**

Permission for text communications:

☐ Yes, I would like to receive text messages. By selecting this option, I agree to receive text messages as allowed by this Form to the cell phone number provided below. Message and data rates may apply. Message frequency varies. I understand I am not required to provide my permission to receive text messages to participate in the Janssen patient support programs or to receive any other communications I have selected.

Cell phone number: _____

Patient name (print): _____

Patient sign here: _____ **Date:** _____

If the patient cannot sign, patient's legally authorized representative must sign below:

By: _____ **Print Name:** _____ **Date:** _____

(Signature of person legally authorized to sign for patient)

Describe relationship to patient and authority to make medical decisions for patient:

_____

janssen

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.

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.

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.

For Healthcare Setting Use Place Patient Label or Barcode Here

Spravato® (esketamine) nasal spray

SPRAVATO® REMS

Patient Monitoring Form - Outpatient Use Only

INSTRUCTIONS:

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

1. Complete all required fields on this form after every treatment session for all outpatients enrolled in the SPRAVATO® REMS.
2. Submit completed patient monitoring forms within 7 days, online at www.SPRAVATOrems.com or by fax (1-877-778-0091).

** Indicates Required Field*

Patient Information (PRINT)

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

Concomitant Medication

Is the patient currently taking any of the following medication(s) that may cause sedation or blood pressure changes?

- Benzodiazepines* ☐ Yes ☐ No
- Non-benzodiazepine sedative hypnotics* ☐ Yes ☐ No
- Psychostimulants* ☐ Yes ☐ No
- Monoamine oxidase inhibitors (MAOIs)* ☐ Yes ☐ No

Healthcare Provider Conducting Patient Monitoring (PRINT)

First Name*:	Last Name*:
Telephone*:	Email*:

Healthcare Setting Information (PRINT)

Healthcare Setting Name*:		
Healthcare Setting Address 1*:	Healthcare Setting Address 2:	
City*:	State*:	ZIP*:

Patient Treatment Session Information (Administration and Monitoring)

Treatment Date*	Date (MM/DD/YYYY): _____		
Dose Administered*	☐ 56 mg ☐ 84 mg ☐ Other: _____		
Treatment Duration*	Total time _____ minutes (from 1st device administration to completion of monitoring) **Patient must be monitored for at least 2 hours**		
REMS Evaluation Question*	*If there was not a 2-hour minimum monitoring requirement, when would this patient have been ready to leave/no longer require monitoring? _____ minutes from start of administration*		
Monitoring of Vital Signs*	Vital signs were in acceptable range **prior** to: • administration? ☐ Yes ☐ No • treatment session completion? ☐ Yes ☐ No		
Monitoring of Blood Pressure*	**Prior to administration** _____ mmHg	**40 mins post-administration** _____ mmHg	**Prior to treatment session completion** _____ mmHg

Did the patient experience Sedation and/or Dissociation

Sedation*: ☐ Yes ☐ No	**Dissociation*:** ☐ Yes ☐ No
Onset of symptoms from start of administration* ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins ☐ >120 mins	**Onset of symptoms** from start of administration* ☐ 1-29 mins ☐ 30-59 mins ☐ 60-89 mins ☐ 90-120 mins ☐ >120 mins
Resolution of symptoms within 2 hours?* ☐ Yes ☐ No Specify total time to resolution*: _____ min	**Resolution of symptoms** within 2 hours?* ☐ Yes ☐ No Specify total time to resolution*: _____ min
Medication(s) given for sedation?* ☐ Yes ☐ No •If YES, name and dose of medication(s): _____	**Medication(s) given for dissociation?*** ☐ Yes ☐ No •If YES, name and dose of medication(s): _____

For Healthcare Setting Use Place Patient Label or Barcode Here

Spravato® (esketamine) CIII nasal spray

SPRAVATO® REMS

Patient Monitoring Form - Outpatient Use Only

** Indicates Required Field*

Patient Information (PRINT)

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

Healthcare Provider Conducting Patient Monitoring (PRINT)

First Name*:	Last Name*:
Phone*:	Email:

Serious Adverse Events (PRINT)

A serious adverse event (SAE) for this SPRAVATO® REMS is defined as any event that results in/is:

- **Hospitalization**
- **Disability or permanent damage**
- **Death**
- **Life-threatening**
- **Important medical event**
  – defined as any event that may jeopardize the patient or may require intervention to prevent one of the above outcomes

All non-serious adverse events or product quality complaints that are not defined above, should be reported to: Janssen at 1-800-JANSSEN (1-800-526-7736) or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Did the patient experience a serious adverse event?* ☐ **Yes** ☐ **No** **If YES, describe below.**

Event resulted in the following: (check all that apply)	Event Timing	Event Description (Please list one event per row)	Event Resolution
☐ Hospitalization ☐ Disability or permanent damage ☐ Death ☐ Life-threatening ☐ Important Medical Event	☐ During treatment sessions ☐ Between treatment sessions Date of Event ____ (MM/DD/YYYY)		☐ Yes ☐ No ☐ Unknown
☐ Hospitalization ☐ Disability or permanent damage ☐ Death ☐ Life-threatening ☐ Important Medical Event	☐ During treatment sessions ☐ Between treatment sessions Date of Event ____ (MM/DD/YYYY)		☐ Yes ☐ No ☐ Unknown
☐ Hospitalization ☐ Disability or permanent damage ☐ Death ☐ Life-threatening ☐ Important Medical Event	☐ During treatment sessions ☐ Between treatment sessions Date of Event ____ (MM/DD/YYYY)		☐ Yes ☐ No ☐ Unknown

Janssen Pharmaceuticals, Inc., Safety Department may follow up to obtain more information about these events.

SPRAVATO® REMS Program Overview
(Risk Evaluation and Mitigation Strategy)

This overview describes the SPRAVATO® REMS requirements and responsibilities of inpatient healthcare settings, outpatient healthcare settings, pharmacies, and patients.

If you have any questions regarding the SPRAVATO® REMS, please visit www.SPRAVATOrems.com or call 1-855-382-6022

Spravato® (esketamine) C III nasal spray

Reference ID:

Table of contents

What is the SPRAVATO® REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

SPRAVATO® is available only through a restricted distribution program called the SPRAVATO® REMS because of the risks of serious adverse outcomes resulting from sedation and dissociation caused by SPRAVATO® administration, and abuse and misuse of SPRAVATO®. SPRAVATO® is intended for use only in a certified Healthcare Setting.

SPRAVATO® is intended for patient administration under the direct observation of a healthcare provider, and patients are required to be monitored by a healthcare provider for at least 2 hours. SPRAVATO® must never be dispensed directly to a patient for home use.

Spravato® (esketamine) CII nasal spray

janssen

How does the SPRAVATO® REMS work?

	Before Prescribing/ Dispensing SPRAVATO®	Before Starting SPRAVATO® for each Patient	During SPRAVATO® Treatment
INPATIENT HEALTHCARE SETTING	Inpatient Healthcare Setting Certification *[covers hospital inpatient, inpatient pharmacy, and emergency departments]*	**Counsel** the patient on the risks and need for monitoring for resolution of sedation and dissociation, and changes in vital signs.	**Supervise** patient administration of SPRAVATO®. **Monitor** each patient for at least 2 hours following administration of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs. **Report** all suspected adverse events to the SPRAVATO® REMS.
OUTPATIENT HEALTHCARE SETTING	Outpatient Healthcare Setting Certification *[covers outpatient medical offices and clinics]*	**Counsel** the patient on the risks and need for monitoring for resolution of sedation and dissociation, and changes in vital signs. **Enroll** the patient using the ***Patient Enrollment Form***.	**Supervise** patient administration of SPRAVATO®. **Monitor** each patient for at least 2 hours following administration of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs. **Submit** the ***Patient Monitoring Form***
PHARMACY	Pharmacy Certification *[covers community, retail, and specialty pharmacies]*	**Verify** that the healthcare setting is certified through the processes and procedures established as a requirement of the SPRAVATO® REMS.	
PATIENT		**Receive counseling** from a healthcare provider on the need for monitoring for resolution of sedation and dissociation, and changes in vital signs. Outpatient Enrollment	**Administer SPRAVATO®** under the direct supervision of a healthcare provider. **Be observed** for at least 2 hours after each treatment of SPRAVATO® for resolution of sedation and dissociation, and changes in vital signs at the healthcare setting.

What are the Requirements of the SPRAVATO® REMS?

- In order for patients to receive SPRAVATO®, healthcare settings, pharmacies, and patients must comply with all requirements of the SPRAVATO® REMS

INPATIENT HEALTHCARE SETTING REQUIREMENTS

Become Certified*:

1. **Designate** an Authorized Representative to oversee implementation and coordinate the activities of the SPRAVATO® REMS
2. **Review** the following materials:
   - SPRAVATO® Prescribing Information
   - SPRAVATO® REMS Program Overview (this document)
3. Have the Authorized Representative **complete** and **submit** the ***Inpatient Healthcare Setting Enrollment Form*** at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091
4. Once submitted, you will be notified of certification in the SPRAVATO® REMS and you will receive information on additional requirements necessary to order and receive SPRAVATO®

Before treating a patient:

1. **Establish** processes and procedures and train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO®
2. Have a healthcare provider **counsel** 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.

*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 the ***Inpatient Healthcare Setting Enrollment Form*** is completed/submitted. **A separate pharmacy enrollment is not required**.

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with SPRAVATO® REMS requirements†
2. **Have a prescriber onsite** during SPRAVATO® administration and monitoring
3. **Have a healthcare provider monitor** every patient for at least 2 hours for resolution of sedation and dissociation and changes in vital signs after every dose
4. **Ensure** SPRAVATO® is not dispensed for use outside the Healthcare Setting
5. **Maintain** records documenting staff completion of training
6. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered
7. **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 review all SPRAVATO® REMS Inpatient Healthcare Setting requirements see the ***Inpatient Healthcare Setting Enrollment Form***

OUTPATIENT HEALTHCARE SETTING REQUIREMENTS

Become Certified:

1. **Designate** an Authorized Representative to oversee implementation and coordinate the activities of the SPRAVATO® REMS
2. **Review** the following materials:
   - SPRAVATO® Prescribing Information
   - SPRAVATO® REMS Program Overview (this document)
3. Have the Authorized Representative **complete** and **submit** the ***Outpatient Healthcare Setting Enrollment Form*** at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091.
4. Once submitted, you will be notified of certification in the SPRAVATO® REMS and you will receive information on additional requirements necessary to order and receive SPRAVATO®

Before treating a patient:

1. **Establish** processes and procedures and train all relevant staff involved in prescribing, dispensing, and administering SPRAVATO® to comply with all SPRAVATO® REMS requirements
2. Have a healthcare provider **counsel** the patient prior to receiving SPRAVATO® on the need for enrollment, monitoring, risks of sedation and dissociation, and changes in vital signs
3. Have a prescriber **enroll** the patient by completing and submitting the ***Patient Enrollment Form*** to the SPRAVATO® REMS
4. **Verify** the patient is enrolled in the SPRAVATO® REMS before dispensing SPRAVATO® for patient administration

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with all SPRAVATO® REMS requirements*
2. Have a **prescriber onsite** during SPRAVATO® administration and monitoring
3. Have the patient **administer** SPRAVATO® under the direct supervision of a healthcare provider
4. 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 after every dose
5. **Document** and **submit** a ***Patient Monitoring Form*** for every patient within 7 days following administration of every dose of SPRAVATO®
6. **Notify** the SPRAVATO® REMS in advance if patient treatment will be transferred from one REMS-certified Healthcare Setting to another REMS-certified Healthcare Setting
7. **Ensure** SPRAVATO® is not dispensed for use outside the Healthcare Setting
8. **Maintain** records documenting staff completion of training
9. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date administered
10. **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 review all SPRAVATO® REMS Outpatient Healthcare Setting requirements see the ***Outpatient Healthcare Setting Enrollment Form***

PHARMACY REQUIREMENTS - FOR OUTPATIENT DISPENSING ONLY

Become Certified:

1. **Designate** an Authorized Representative to oversee implementation and coordinate the activities of the SPRAVATO® REMS
2. **Review** the following materials:
   - SPRAVATO® Prescribing Information
   - SPRAVATO® REMS Program Overview (this document)
3. Have the Authorized Representative **complete** and **submit** the ***Pharmacy Enrollment Form*** at www.SPRAVATOrems.com, or complete the paper form and fax to the SPRAVATO® REMS at 1-877-778-0091
4. Once submitted, you will be notified of certification in the SPRAVATO® REMS and you will receive information on additional requirements necessary to order and receive SPRAVATO®

Before Dispensing:

1. **Establish** processes and procedures and train all relevant staff involved in dispensing SPRAVATO® to comply with all SPRAVATO® REMS requirements
2. **Verify** the healthcare setting is certified before dispensing SPRAVATO®

At All Times:

1. **Ensure** relevant staff are trained and follow all established processes and procedures to comply with all SPRAVATO® REMS requirements*
2. **Ensure** SPRAVATO® is never dispensed directly to a patient for home use
3. **Ensure** SPRAVATO® is only dispensed to a certified healthcare setting
4. **Maintain** records documenting staff's completion of training
5. **Maintain** records of all shipments of SPRAVATO® received and dispensing information including the patient name, dose, number of devices, and date dispensed
6. **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 review all SPRAVATO® REMS Pharmacy requirements see the ***Pharmacy Enrollment Form***

PATIENT REQUIREMENTS

Before Treatment:

1. **Receive** counseling from a healthcare provider on risks and the need for monitoring for resolution of sedation and dissociation, and changes in vital signs
2. **Outpatient Only:**
   Enroll in the SPRAVATO® REMS Program by completing the ***Patient Enrollment Form*** with a healthcare provider. Enrollment information will be provided to the SPRAVATO® REMS Program

During Treatment:

1. **Administer** SPRAVATO® nasal spray under the direct observation of a healthcare provider
2. **Be observed** at the healthcare setting where SPRAVATO® is received for at least 2 hours after each treatment until the healthcare provider determines the patient is ready to leave the healthcare setting

At All Times*:

1. **Make arrangements** to safely get home after receiving SPRAVATO®, if leaving the healthcare setting
2. **Do not** drive or use heavy machinery for the rest of the day after receiving SPRAVATO®
3. **Contact the healthcare provider** or inform the healthcare provider at the next visit if a side effect or reaction from SPRAVATO® occurs

*To review all SPRAVATO® REMS requirements for patients receiving SPRAVATO® in an Outpatient Healthcare Setting, see the ***Patient Enrollment Form***

SPRAVATO® REMS Resources

INPATIENT HEALTHCARE SETTING	OUTPATIENT HEALTHCARE SETTING	PHARMACY
• *Inpatient Healthcare Setting Enrollment Form* • *REMS Program Overview* • *Prescribing Information*	• *Outpatient Healthcare Setting Enrollment Form* • *Patient Enrollment Form* • *Patient Monitoring Form* • *REMS Program Overview* • *Prescribing Information*	• *Pharmacy Enrollment Form* • *REMS Program Overview* • *Prescribing Information*

Contact the SPRAVATO® REMS

Phone: 1-855-382-6022
Fax: 1-877-778-0091
Hours of Operation: Monday- Friday 8:00 AM - 8:00 PM ET
Visit www.SPRAVATOrems.com

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.

Please see the Prescribing Information for more information.

Spravato® (esketamine) CII nasal spray

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