

In Reply Refer To: **FOIA Request: 19-11256-F**

June 1, 2021

Melanie Sloan
American Oversight
1030 15th Street, NW
Washington, DC, 20005
foia@americanoversight.org

Dear Ms. Sloan:

This letter is the first partial initial agency decision to your September 4, 2019, request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, submitted to the Department of Veterans Affairs (VA), Veterans Health Administration (VHA) Central Office FOIA Office requesting the following records:

1. All email communications (including email messages, email attachments, calendar invitations, and calendar invitation attachments) sent by any of the VA officials and employees listed below regarding Spravato (esketamine) nasal spray:
 - a. Richard A Stone, Executive in Charge, Veterans Health Administration.
 - b. Steven L. Lieberman, Acting Principal Deputy Under Secretary for Health.
 - c. Lawrence Connell, Chief of Staff, Veterans Health Administration
 - d. Jon M. Jensen, Acting Deputy Chief of Staff
 - e. Valerie Mattison Brown, Assistant Deputy Under Secretary for Health, Policy and Planning
 - f. Maria Llorente, Acting Assistant Deputy Under Secretary for Health for Patient Care Services (PCS).
 - g. Michael A. Valentino, Chief Consultant – Pharmacy Benefit Management Services (PBM), and anyone serving as his assistant or scheduler.
 - h. Yasuharu Okuda, Acting Deputy Chief PCS Officer.
 - i. Thomas Emmendorfer, Deputy Chief Consultant – PBM.
 - j. Joseph Canzolino, Deputy Chief Consultant – Formulary Management.
 - k. Timothy Stroup, Deputy Chief Consultant – PBM Strategic Planning.
 - l. Virginia Torrise, Deputy Chief Consultant – PBM Professional Practice and Clinical Informatics.
 - m. Louis Cobuzzi, Associate Chief Consultant – Planning Analysis and Policy Development.
 - n. John Lowe, Associate Chief Consultant – Planning Analysis and Policy Development.
 - o. Lynn Sanders, Associate Chief Consultant – Clinical Informatics and Pharmacy Re-engineering.
 - p. Vaiyapuri Subramaniam, Associate Chief Consultant – Adverse Drug Events/United States Pharmacopeia 797/Policy.

- q. Matthew A. Fuller, National Clinical Pharmacy Program Manager, PBM.
- r. Chester B. Good, Chair, Medical Advisory Panel, PBM.
- s. David Carroll, Executive Director, Office of Mental Health and Suicide Prevention.
- t. Lynda O'Neill, Contracting Officer, National Acquisition Center.
- u. Craig Robinson, Associate Executive Director, National Acquisition Center

American Oversight believes that records containing the terms below are likely to be responsive records, and American Oversight requests that VA, at a minimum, employ these search terms to identify responsive records.

§ Spravato
§ esketamine
§ nasal spray
§ "treatment-resistant" AND depress*
§ stimulant AND suicide
- 4 - VA-19-1109
§ stimulant AND depress*
§ "J&J" AND drug
§ "J&J" AND suicide
§ "J&J" AND depress*
§ "J&J" AND buy
§ "Johnson & Johnson" AND drug
§ "Johnson & Johnson" AND suicide
§ "Johnson & Johnson" AND depress*
§ "Johnson & Johnson" AND buy
§ Janssen AND drug
§ Janssen AND suicide
§ Janssen AND depress*
§ Janssen AND buy

Please note that American Oversight is using the asterisk (*) to designate the standard use of "wildcards" in the search for responsive records. For example, a search for "depress*" would return both depression and depressant. If VA is unable to search for wildcards, please advise so that we may specifically include the variations that we would like searched. Please provide all responsive records from within the following date ranges:

§ March 5–26, 2019
§ June 10–28, 2019
§ August 14–28, 2019.

Your FOIA request was received in my office on September 4, 2019. As stated within the September 5, 2019 letter, line items t. Lynda O'Neill and u. Craig Robinson were referred to the Office of Acquisitions and Logistics, under FOIA tracking number 19-11257-F.

On April 23, 2021, we requested further clarification regarding your request in which you provided a response to eliminate marketing emails; VA Media Summary and News Clips; Long excel spreadsheets/reports from pharmacy staff or other offices of all medications, that do not directly discuss the key search terms "Spravato, Esketamine" regarding price and News Alerts from external sources.

At this time VHA is rendering its first partial initial agency decision. These documents resulted in an online search conducted by the VA Office of Information and Technology, responsive for Richard Stone, Executive in Charge; Steven L. Lieberman, Acting Principal Deputy Under Secretary for Health; Lawrence Connell, Chief of Staff; Jon M. Jenson, Acting Deputy Chief of Staff; Valerie Mattison Brown, Assistant Deputy Under Secretary for Health, Policy and Planning; Maria Llorente, Acting Assistant Deputy Under Secretary for Health for Patient Care Services (PCS); Michael A. Valentino, Chief Consultant; Thomas Emmendorfer, Deputy Chief Consultant; Virginia Torrise, Deputy Chief Consultant; Lynn Sanders, Associate Chief Consultant; Matthew A. Fuller, National Clinical Pharmacy Program Manager; Chester B. Good Chair, Medical Advisory Panel, PBM; and David Carroll, Executive Director, Office of Mental Health and Suicide Prevention, for the date range of March 5-26, 2019, June 10-28, 2019 and August 14-28, 2019. The search terms used were: Spravato, esketamine, nasal spray, treatment-resistant" AND depress, stimulant AND suicide, 4 - VA-19-1109, stimulant AND depress, J&J" AND drug, "J&J" AND suicide, "J&J" AND depress, "J&J" AND buy, "Johnson & Johnson" AND drug, "Johnson & Johnson" AND suicide, "Johnson & Johnson" AND depress*, "Johnson & Johnson" AND buy, Janssen AND drug, Janssen AND suicide, Janssen AND depress*, Janssen AND buy. Provided within this release is 953 pages of responsive records.

Upon my review I have found information protected under the FOIA, specifically, FOIA exemption 5, 5 U.S.C. § 552(b)(5), FOIA exemption 6, 5 U.S.C. § 552(b)(6).

FOIA Exemption 5 [5 U.S.C. § 552 (b)(5)] permits VA to withhold a document or information contained within a document as "pre-decisional" if two requirements are met. First, there must be an identifiable deliberative process. That is, the document must be a direct part of the deliberative process. Second, the agency generated the information or document as part of the agency decision process. Stated another way, VA may withhold information under Exemption 5 where the document or its content makes recommendations or expresses opinions about legal or policy matters during a decision-making process and the document is not the decision document or incorporated into the decision document. Additionally, in accordance with the FOIA Improvement Act of 2016, an agency shall withhold information under the FOIA only if the agency reasonably foresees that disclosure would harm an interest protected by an exemption or disclosure is prohibited by law. Stated another way, if the disclosure is not prohibited by law, the agency must state an articulable, foreseeable harm to the agency or its activities that could occur as a result of release of the document or information.

My review reveals pages that contain information that falls within the protection of Exemption 5. Specifically, information is being withheld under Exemption 5 as the

documents contain open and frank pre-decisional communications between staff at various levels of the organization. Staff are providing feedback by voicing their opinions. There are several categories of documents that routinely are protected by the deliberative process privilege of Exemption 5. Among the protected documents are advisory opinions, recommendations, and deliberations comprising parts of a process by which governmental decisions and policies are formulated. They are protected because, by their very nature, their release would likely "stifle honest and frank communication within the agency." Materials of this nature go to the very heart of the privilege, for, as the Supreme Court has stated, "the deliberative process privilege rests on the obvious realization that officials will not communicate candidly among themselves if each remark is a potential item of discovery and front page news. Schell, 843 F.2d at 941 "A subordinate who wishes to provide information candidly should not fear that the public will be privy to his views merely because his superiors have not yet acted on his recommendations." In determining whether a document is pre-decisional, an agency does not necessarily have to point specifically to an agency final decision, but merely establish "what deliberative process is involved, and the role played by the documents in issue in the course of that process. Thus, so long as a document is generated as part of such a continuing process of agency decision making, courts have found Exemption 5 can be applicable. In a particularly instructive decision, Access Reports v. DOJ, the Court of Appeals for the District of Columbia Circuit emphasized the importance of identifying the larger process to which a document sometimes contributes. Further, "pre-decisional" documents are not only those circulated within the agency but can also be those from an agency lacking decisional authority that advises another agency possessing such authority. They even can be "documents which the agency decision maker herself prepared as part of her deliberation and decision-making process, or documents that do not end up being considered by the agency decision maker at all. Release of this information would inhibit employees from freely exchanging opinions resulting in harm to deliberative process itself. If employees believed that their open and frank feedback were to become public, staff would be less likely to freely communicate their opinions. See, e.g., Russell v. Dep't of the Air Force, 682 F.2d 1045, 1048 (D.C. Cir. 1982); Coastal States Gas Corp. v. DOE, 617 F.2d 854, 866 (D.C. Cir. 1980); Jordan v. DOJ, 591 F.2d 753, 772-73 (D.C. Cir. 1978) (en banc); Brown v. EEOC, No. 09-111, 2010 U.S. Dist. LEXIS 46466, at *9 (W.D. Ky. May 12, 2010) (holding that Exemption 5 was properly applied to prevent potential chilling effect on agency's discussions and undermining of agency's ability to perform its duties); Morley v. CIA, 699 F. Supp. 2d 244, 255-56 (D.D.C. 2010) (stating that privilege is "intended to prevent chilling future government employees from engaging in frank discussions during the deliberative process" (citing Coastal States, 617 F.2d at 866)), *aff'd* in pertinent part, vacated and remanded on other grounds, 466 Fed. App'x. 1 (D.C. Cir. 2012).

In addition, releasing the discussions within the emails requested would cause confusion to the public because the information conveyed was not part of final decisions made and therefore would do very little to add to the public's understanding of the operations and activities of the agency. See, AFGE v. HHS, 63 F. Supp. 2d 104, 108

(D. Mass. 1999) (holding that release of pre-decisional documents "could cause harm by providing the public with erroneous information"), *aff'd*, No. 99-2208, 2000 U.S. App. LEXIS 10993 (1st Cir. May 18, 2000); Thus exemption 5 is applied to protect against public confusion that might result from disclosure of reasons or rationales that were not in fact ultimately the grounds for the agency's decision.

As emails containing pre-decisional content, the release of this information would cause injury to the deliberative process described in the above paragraphs. The deliberative process privilege of FOIA exemption 5 is invoked as I have determined that the release of this information to the public would negatively impact frank discussions within VHA and would protect against public confusion that might result from disclosure of reasons and rationales that were not consistent with VHA actions. Pages within this document have been withheld both in part and in full and pages have been marked (B5) to annotate the redaction applied.

FOIA Exemption 6 [5 U.S.C. § 552 (b)(6)] covers "personnel and medical files and similar files of which the disclosure would constitute a clearly unwarranted invasion of personal privacy." Stated another way, VA may withhold information under FOIA Exemption 6 where disclosure of the information, either by itself or in conjunction with other information available to either the public or the FOIA requester, would result in an unwarranted invasion of an individual's personal privacy without contributing significantly to the public's understanding of the activities of the federal government.

In United States Department of Justice v. Reporters committee for Freedom of the Press, 489 U.S. 749 (1989), we must determine if a privacy interest is involved, and determine if disclosure of the requested information would serve the public interest, and balance the personal privacy interest against the public interest. In evaluating the public interest in a given case, we must focus on the nature of the requested document and its relationship to the public interest generally. We must consider whether disclosure of the requested document, or portions thereof that have been withheld, would "open agency action to the light of public scrutiny" rather than focus on the particular purpose for which the document is being requested. See Reporters Committee, 489, U.S. at 772.

The coverage of FOIA Exemption 6 is absolute unless the FOIA requester can demonstrate a countervailing public interest in the requested information by demonstrating that the individual is in a position to provide the requested information to members of the general public and that the information requested contributes significantly to the public's understanding of the activities of the Federal government. Additionally, the requester must demonstrate how the public's need to understand the information significantly outweighs the privacy interest of the person to whom the information pertains. Upon consideration of the materials provided, it is recognized that you are in a position to provide the requested information to members of the general public however; I have not been able to identify a countervailing public interest of sufficient magnitude to outweigh the privacy interest in this case. Consequently, the names of non-VA employees, employee email addresses and

phone numbers have been redacted under Exemption 6. Inserted is (b6) to identify the FOIA Exemption applied.

VHA will continue to make rolling releases in response to this request.

If you disagree with my determinations, please be advised you may appeal to:

Office of the General Counsel (024)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, D.C. 20420
Email: ogcfoiaappeals@va.gov

If you should choose to file an appeal, your appeal must be postmarked or electronically transmitted no later than ninety (90) calendar days from the date of this letter. Please include a copy of this letter with your written appeal and clearly state why you disagree with the determinations set forth in this response.

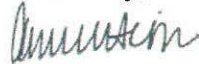
You may also seek assistance and/or dispute resolution services for any other aspect of your FOIA request, excluding the release determination, from VHA's FOIA Public Liaison and/or Office of Government Information Services (OGIS) as provided below:

VHA FOIA Public Liaison:
Email Address: vhafoia2@va.gov
Phone Number: (877) 461-5038

Office of Government Information Services (OGIS)
Email: ogis@nara.gov
Fax: (202) 741-5769
Mailing address: ✓
Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road
College Park, MD 20740-6001

Thank you for your interest in VA. If you have any further questions, please feel free to contact me at (319) 530-7694 or via email at Amber.Heim@va.gov.

Sincerely,



Amber Heim
VHA FOIA Officer

Enclosure: 953 pages

From:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI (b6) @va.gov>
To:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, (b6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <Jennifer.Zacher@va.gov>
Subject:	UPDATE STATUS: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 13:59:30
Priority:	Normal
Type:	Note

Hi All,

FAQ sheet on esketamine (Spravato®) disseminated. Please see attached for e-mail sent to pharmacy groups as requested.

Thanks,
Marie

Sender:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI (b6) @va.gov>
Recipient:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, (b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) @va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) @va.gov>
Sent Date:	2019/03/15 13:59:28
Delivered Date:	2019/03/15 13:59:30

From:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI (b6) @va.gov>
To:	VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a29ff0f0291a4a708de0731733c726c0-VHAPBH VISN <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bdd525bd2340749ff69f86d2e657f0-VHAPBH Phar <PharmacyChiefs@va.gov>; VHAPBM PMO /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03349ada043546d4b1c1543f977bfa89-VHAPBH PMO <PMO@va.gov>
Subject:	Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 13:55:28
Importance:	High
Priority:	Urgent
Type:	Note.NoReplyNoReplyAll

Attached is the **Frequently Asked Questions (FAQ)** sheet addressing the newly FDA-approved **esketamine (Spravato®)** nasal spray for treatment-resistant depression published by the VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention. This FAQ sheet accompanies VA's News Release and will also be available online at the following link <https://vawww.cmopnational.va.gov/cmop/pbm/default.aspx> (pending posting).

The purpose of this FAQ sheet is to:

AMERICAN
OVERSIGHT

001001

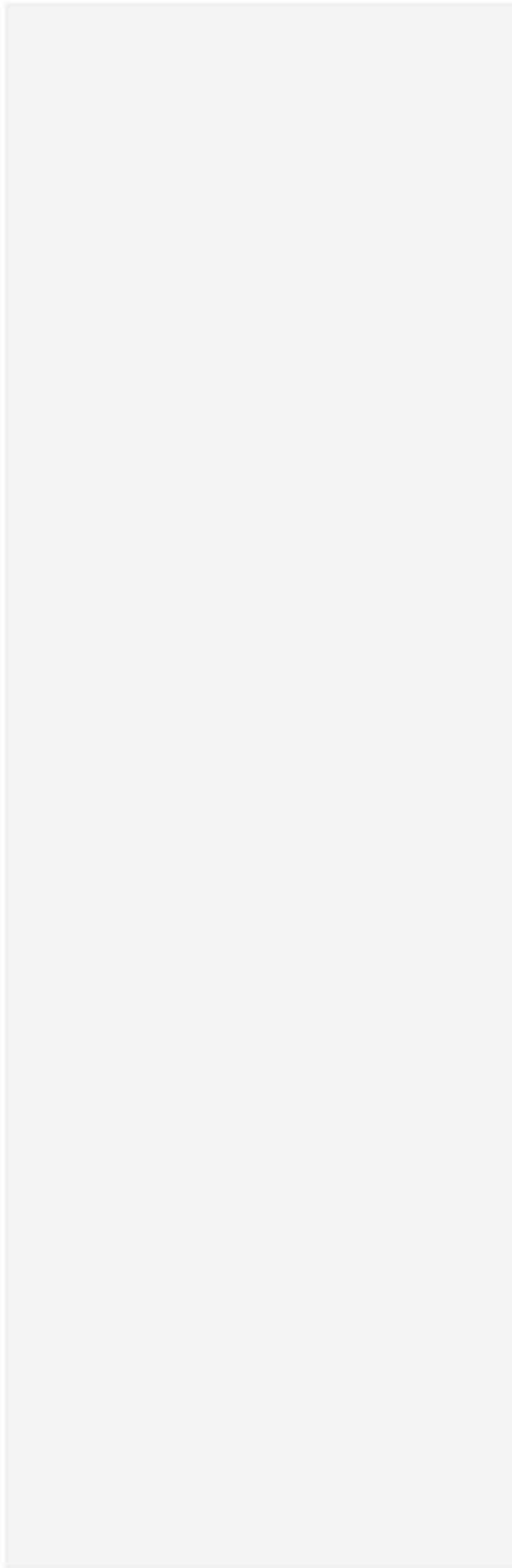
VA-19-1109-A-000001

- * Disseminate new drug information to the provider-level regarding esketamine (Spravato®)
- • * Provide answers on availability and accessibility of esketamine (Spravato®) within VA

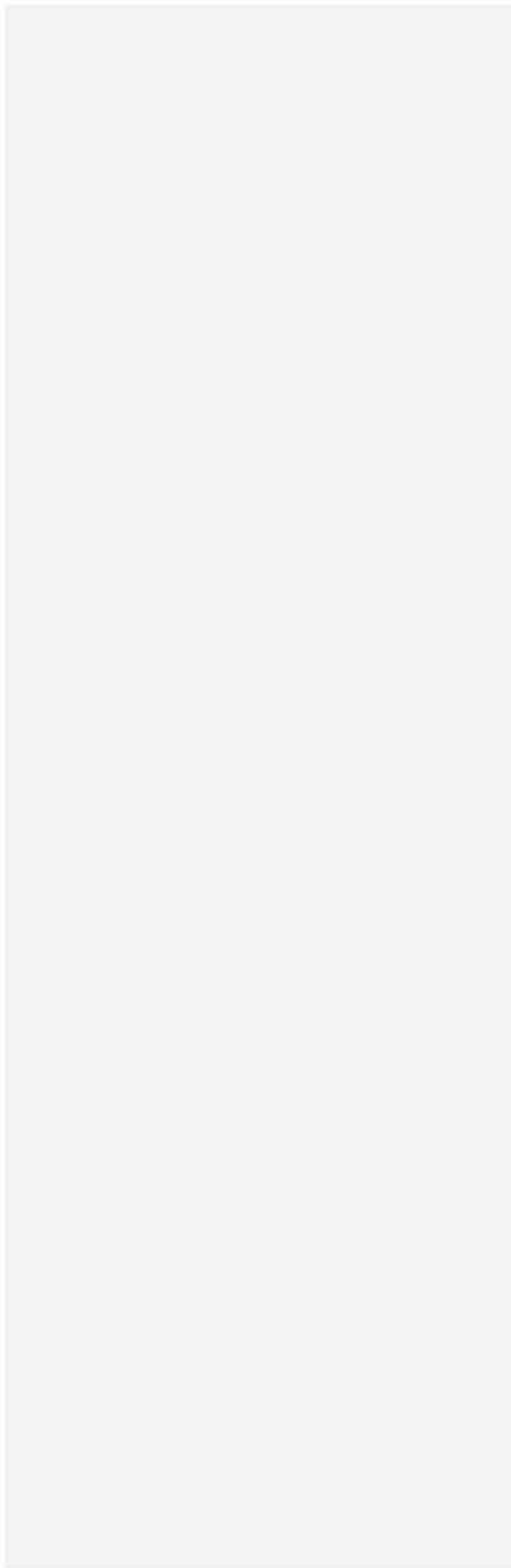
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Recipient:	VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a29ff0f0291a4a708de0731733c726c0-VHAPBH VISN <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bdd525bd2340749ff69f86d2e657f0-VHAPBH Phar <PharmacyChiefs@va.gov>; VHAPBM PMO /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03349ada043546d4b1c1543f977bfa89-VHAPBH PMO <PMO@va.gov>
Sent Date:	2019/03/15 13:55:23
Delivered Date:	2019/03/15 13:55:28

(b) (5)

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(b) (5)





Department of the Veterans Affairs' Drug Formulary Management Processes and Esketamine Review

Michael Valentino, R.Ph., MHSA, Chief
Consultant, Pharmacy Benefits Management
Services Office of Patient Care Services

Formulary Management Objectives



- Promote formulary decisions that are evidence-based, not preference-based and that enable an economically sustainable drug benefit
- Promote appropriate drug therapy/ discourage inappropriate drug therapy
- Reduce the geographic variability in utilization of drugs across the VA system
- Promote portability and uniformity of the drug benefit
- Conduct medication safety activities



Formulary Overview

- The VA National Formulary (VANF) is the sole drug formulary used in VAEvolved from 173 individual drug formularies in 1995 to a single formulary in 2009VA medical facilities and VISNs still have formulary committees to conduct traditional Pharmacy & Therapeutic committee work with the EXCEPTION of adding and/or removing drugs from the formulary Integrated non-formulary request processVA's "non-formulary" designation is similar to the "formulary, prior authorization" designation in other health care systemsStrict reliance on high-quality evidence to drive decision-making

Formulary Overview (cont.)



- Drug safety is the first priority
Drug effectiveness is the second priority
Cost is considered only after safety and effectiveness
VANF committee responsibilities
Updating and maintaining the VANF
Adding drugs, removing drugs, developing evidence-based guidance, standardization
contracting
Monitoring utilization
Data collection and review
Intervention when indicated (access issues, over/under utilization)
Adverse Drug Event monitoring
Contract adherence



Formulary Management Infrastructure

VA Medical Advisory Panel
Executives Committee
Experts
(PBM) Facilitation role
& Therapeutics Committees
Local committees
Committees

VISN Pharmacist
VA Clinical Subject Matter
VA Pharmacy Benefits Management
Regional (VISN) Pharmacy
Oversight role for
Local (VAMC) P&T
Implementation of VANF initiatives

Formulary
Management
Process
Decisions



VANF Committees

- Medical Advisory Panel (MAP) 13 practicing VA physicians 1 DoD physician (non-voting) 10 PBM clinical pharmacist specialists 1 VISN Pharmacist Executive member VISN Pharmacist Executives Committee (VPE) 18 pharmacists 1 DoD pharmacist and 1 IHS pharmacist (non-voting) 1 MAP member Meetings Monthly 2-hour conference calls with each group Quarterly 2-day face-to-face meetings (MAP and VPE) Strive for consensus decisions

New Molecular Entity (NME) Review Process



- NME approved by the FDA Literature search and draft review completed by PBM staff Presented to VPE/MAP committees and changes incorporated Disseminated widely to field-based clinical staff for comment Presented to VPE/MAP committees and changes incorporated VA National Formulary decision National criteria for use developed when indicated



Esketamine Review

Milestones



- March 5, 2019: Approved by the FDAMarch 11-12, 2019: Overview presented to internal clinical groups (Chief Medical Officers, Mental Health Leads, VISN Pharmacist ExecutivesMarch 15, 2019: FAQs distributed to the fieldMarch 18, 2019: Memo issues to the field with instructions to obtain Risk Evaluation and Mitigation Strategy (REMS) certification required by the FDAMarch 19, 2019: VA issues a press releaseMarch 19, 2019: Product is available in the supply chainMarch 25, 2019: Clinical Implementation Workgroup formed to develop guidance

Milestones (cont.)



- May 2019: Esketamine monograph, draft Criteria for Use and field-comments presented to the VPEs and MAP Issue tabled until June face-to-face meeting so documents could be revised based on feedback from the field and MAP/VPEs Materials developed in collaboration with the Office of Mental Health

Milestones (cont.)



- June 2019: Based on a careful review of the available evidence, the MAP and VPEs voted to:
Designate Esketamine as a non-formulary drug
Will be available with an approved prospective review
Issue evidence-based prescribing guidance
Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population
Make the drug "non-promotable" by the manufacturer
Enables VA to education providers with clear messaging
Date TBD: Request the manufacturer enter into a risk-share agreement with VA
Possibly reimburse VA for the cost of the drug for non-responders
Tiered discount Etc.



Department of Veterans Affairs Drug Formulary Management Processes: Esketamine Review

___ July 2019

Brief for:

House Committee on Veterans Affairs

Senate Committee on Veterans Affairs

Michael Valentino, RPh, MHSA, Chief Consultant, Pharmacy
Benefits Management Services Office of Patient Care
Services

Formulary Management Objectives



- Promote evidence-based formulary decisions, not preference-based
Enable economically sustainable drug benefits
Promote appropriate drug therapy; discourage inappropriate drug therapy
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Formulary Overview (cont.)

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Adverse Drug Event monitoring
Contract adherence



Formulary Management Infrastructure

- VA Medical Advisory Panel
Executives Committee
Experts
(PBM) Facilitation role
& Therapeutics (P&T) Committees
for Local committees
Committees
Implementation of VANF initiatives
- Formulary Management Process Decisions



VANF Committees

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New Molecular Entity (NME) Review Process



- NME approved by the FDAPBM staff complete literature search and draft review Presented to VPE/MAP committeesChanges incorporatedDisseminated widely to field-based clinical staff for commentPresented to VPE/MAP committeesChanges incorporatedVA National Formulary decisionNational criteria for use developed when indicated



Esketamine Review

Milestones 2019



- 5 March: Approved by the FDA
- 11-12 March: Overview presented to internal clinical groups (Chief Medical Officers, Mental Health Leads, VISN Pharmacist Executives)
- 15 March: FAQs distributed to the field
- 18 March: Memo issues to the field with instructions to obtain Risk Evaluation and Mitigation Strategy (REMS) certification required by the FDA
- 19 March: VA issues a press release
- Product is available in supply chain
- 25 March: Clinical Implementation Workgroup formed to develop guidance

Milestones 2019 (cont.)



- May: Esketamine monograph, draft Criteria for Use and field-comments presented to the VPEs and MAP Issue tabled for June face-to-face meeting Documents revision based on feedback from the field and MAP/VPEs Materials developed in collaboration with the Office of Mental Health June: Based on careful review of available evidence, the MAP and VPEs voted to: Designate Esketamine as a non-formulary drug Will be available with an approved prospective review Issue evidence-based prescribing guidance Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population Make the drug "non-promotable" by the manufacturer Provide education to VA providers with clear messaging

Milestones (cont.)



- Future Actions: Request the manufacturer enter into a risk-share agreement with VAPossibly reimburse VA for the cost of the drug for non-respondersTiered discount Etc.

From:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA <(b6)@va.gov>
To:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>
Subject:	VA Formulary Briefing
Date:	2019/06/27 09:39:06
Start Date:	2019/07/01 13:30:00
End Date:	2019/07/01 14:15:00
Priority:	Normal
Type:	Appointment
Location:	3400 O'Neill HOB
Attendees:	Valentino, Michael (VACO); Emmendorfer, Thomas (PBM); Llorente, Maria D.

Depart VACO 1pm

Meeting scheduled for 1:30PM

>-----Original Message-----

>From: (b6) (Veterans Affairs) <(b6)@vetaff.senate.gov>

>Sent: Friday, June 21, 2019 8:41 AM

>To: Brooks, Aja <(b6)@va.gov>

>Cc: (b6) (Veterans Affairs) <(b6)@vetaff.senate.gov>; (b6) (Veterans Affairs) <(b6)@vetaff.senate.gov>; (b6) (Veterans Affairs) <(b6)@vetaff.senate.gov>; (b6)@mail.house.gov;

(b6)@mail.house.gov

>Subject: [EXTERNAL] Briefing on formulary process

>

>Hi AJ -

>

>We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

>

>Thanks,

>(b6)

>

>Sent from my iPhone

Sender:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA (b6)@va.gov>
Recipient:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja (b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b6)@va.gov>
Sent Date:	2019/06/27 09:39:06
From:	Copeland, Brittany R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E0F1EBFFBC694BB09B048CE0F296763E-COPELAND, B (b6)@va.gov>
To:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja (b6)@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b6)@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Subject:	RE: 4- Corners Briefing on VA Formulary Process
Date:	2019/06/26 12:35:01
Priority:	Normal
Type:	Note

Afternoon AJ,

On behalf of Krystal Toles, both Dr. Llorente and the slides are cleared.

Thanks,

Brittany R. Copeland, MHA

Health System Specialist

Office of the VHA Chief of Staff (10B)

810 Vermont Ave NW | Washington, DC 20420

o: (b6) | c: (b6)

From: Brooks, Aja
Sent: Wednesday, June 26, 2019 11:43 AM
To: Law, Cassandra M. (b6) [REDACTED] <[REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; VHA 10B <vha10b@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

OCLA acknowledges receipt, adding VHA 10B for clearance.

OCLA also request Dr. Maria Llorente be cleared to attend this briefing.

v/r
AJ

From: Law, Cassandra M.
Sent: Wednesday, June 26, 2019 11:35 AM
To: Brooks, Aja (b6) [REDACTED] <[REDACTED]@va.gov>; VHA 10B3 Legislative Team <VHA10B3LegislativeTeam@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: 4- Corners Briefing on VA Formulary Process

Good morning Aja.

10P clears the attached PPT to support the 4 corners briefing.

Please Note: Dr. Maria Llorente's (ADUSH for PCS) name has been added to the title slide and she and Mr. Mike Valentino, Pharmacy Benefits Management will both participate in the briefing.

Thank you, Cassie

-----Original Message-----

From: Brooks, Aja
Sent: Monday, June 24, 2019 10:42 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: 4- Corners Briefing on VA Formulary Process

Good morning, VHA 10P

OCLA request Michael Valentino and Thomas Emmendorfer to brief the 4-Corners on VA's formulary process, including an overview of the drug Spravato. Please list availabilities of the above mentioned SME's for the week of:

June 25 -28
July 1 - 3
OR

July 9, - 1 -3pm

v/r
AJ

-----Original Message-----

From: (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 8:41 AM
To: Brooks, Aja ((b6) va.gov>
Cc: (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>; (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>; (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>; (b6) @mail.house.gov;
(b6) @mail.house.gov
Subject: [EXTERNAL] Briefing on formulary process

Hi AJ -

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Thanks,
(b6)

Sent from my iPhone

Sender:	Copeland, Brittany R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E0F1EBFFBC694BB09B048CE0F296763E-COPELAND, B (b6) @va.gov>
Recipient:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja ((b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10B /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e8da02703bf40af822fcc49b8463979-VHA 10B <vha10b@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan (b6) /a.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Sent Date:	2019/06/26 12:35:00
Delivered Date:	2019/06/26 12:35:01

From:	Cork, Travis J. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=11CAA312168F421BB41458BA3D4D92AD-CORK, TRAVI <(b6)@va.gov>
To:	VISN5 Pharmacy and Therapeutics Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc549b34da74364b3a1e578bc7d9537-VISN5 Pharm <VISN5TherapeuticsManagementCommittee@med.va.gov>; VISN5 Pharmacy Managers /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11c1a0951a524e8c9dbf86205c7ad520-VISN5 Pharm <VISN5PharmacyManagers@va.gov>; VISN5 COS /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=497c83296bc946cdbca57a649b3d6ddd-VISN5 COS <VISN5COS@med.va.gov>; VISN5 Mental Health Directors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42384154cf1a413f8291554eec80b0af-VISN5 Menta <VISN5MentalHealthDirectors@va.gov>; VISN5 Academic Detailing /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6605da81752450484555f1711f463f0-VISN5 Acade <VISN5AcademicDetailing@va.gov>
Subject:	UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 16:54:19
Importance:	High
Priority:	Urgent
Type:	Note

Good afternoon,

Please see the attached frequently asked questions regarding the recently FDA approved esketamine product. Please note that the product is not yet commercially available, once available will be restricted to distribution through an FDA approved Risk Evaluation and Mitigation Strategy (REMS) program, and that the product is not listed on the VA National Formulary with planned national review May 2019. Please also note that a special signed informed consent will be required and is expected to be released next week.

Thanks,

Travis

Travis J. Cork, PharmD, BCPS | VISN 5 – VA CAPITOL HEALTH CARE NETWORK

VISN Pharmacist Executive (VPE) | office (b6) cell (b6)

((b6)@va.gov|

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From: Sales, Marie

Sent: Friday, March 15, 2019 1:01 PM

To: VHAPBM MAP Committee <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs <PharmacyChiefs@va.gov>; VHAPBM PMO

Combating Treatment-Resistant Depression (TRD)

Major depression is a leading cause of disability and one of the most common mental health disorders in the United States and worldwide. (NIMH/WHO). For some individuals, major depression can result in severe impairments that interfere with or limit the ability to carry out major life activities.

It is estimated that 10 to 30% of adults diagnosed with major depression battle symptoms of depression that don't respond to treatment (Gaynes 2016).

- In general, depression is considered "treatment-resistant" when at least 2 adequately delivered treatments do not lead a person to become symptom-free, for at least 1 month. (Garay 2017, Ionescu 2015, mcintyre 2013)

Figure X. 64% of Adults had Severe Impairment with Major Depressive Episode

(NIMH)

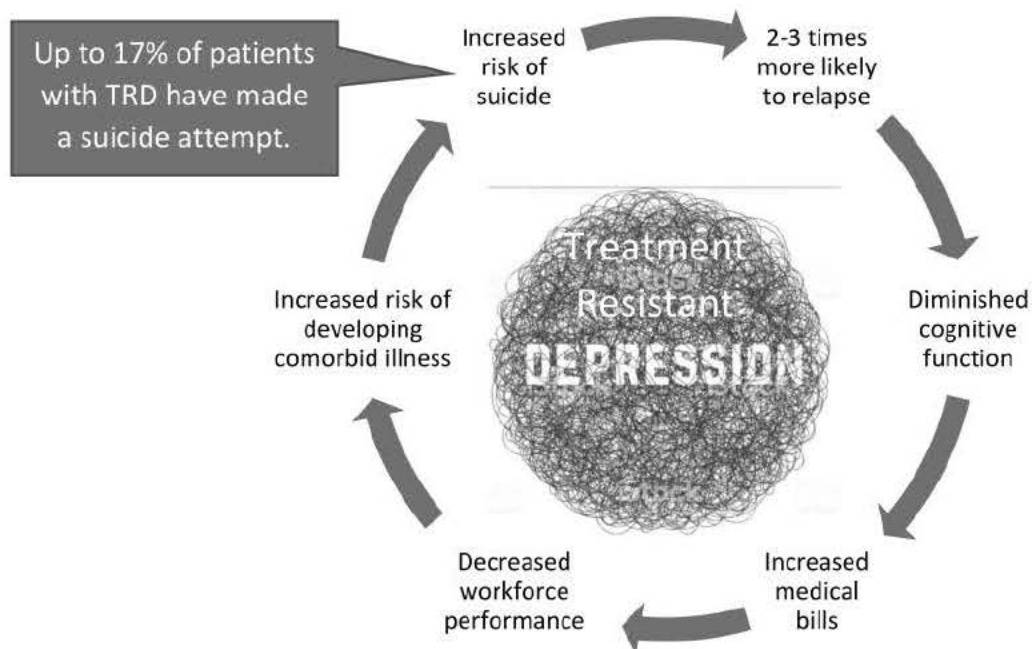
Without
Severe
Impairment
36%



With
Severe
Impairment
64%

Data from National Survey on Use and Health (U.S. adults in 2017). Severity was measured in four domains: home management, work, close relationships with others, and social life.

Figure X. Not Achieving Remission Can Lead to Severe Consequences (Gaynes 2016; Mrazek 2014; Judd 2000, Paykel 1995)



Measurement-based care

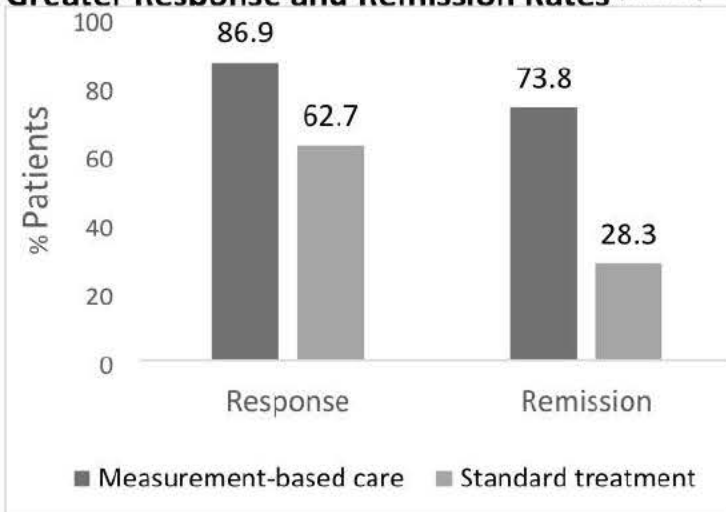
Use of measurement-based tools is feasible in busy clinical settings and can lead to improved

outcomes. (Trivedi Am J Psychiatry 2006; 163:28-40., Guo 2015)

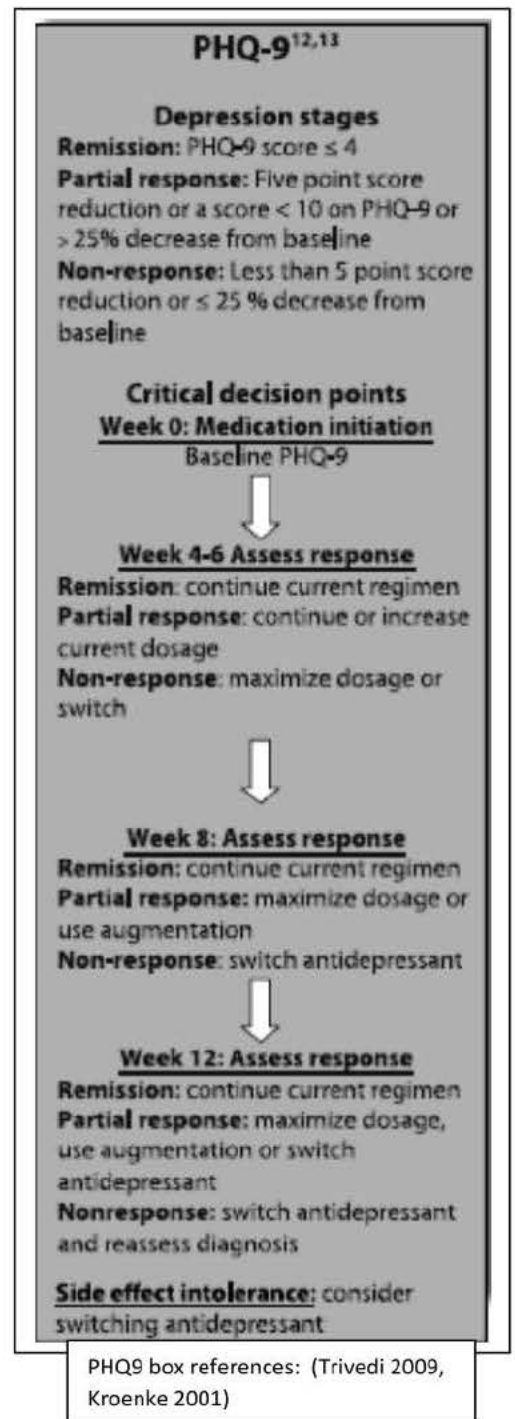
Measurement-based tools, like the PHQ-9, provide more consistent measure of a patient's clinical status than global judgments made by the clinician or patient, providing a more accurate foundation for clinical decision-making. (Trivedi 2009)

- Several tools can be used in the clinical setting to assess response
- The PHQ-9 is available through the Mental Health Assistant found under tools in CPRS.

Figure X. Measurement-Based Care Results in Greater Response and Remission Rates (Guo 2015)



Outpatients with moderate to severe major depression were randomized to 24 weeks of either measurement-based care (guideline- and rating scale-based decisions; N=61), or standard treatment (clinicians' choice decisions; N=59). Time to response and remission was shorter and more treatment adjustments occurred in the measurement-based care group.

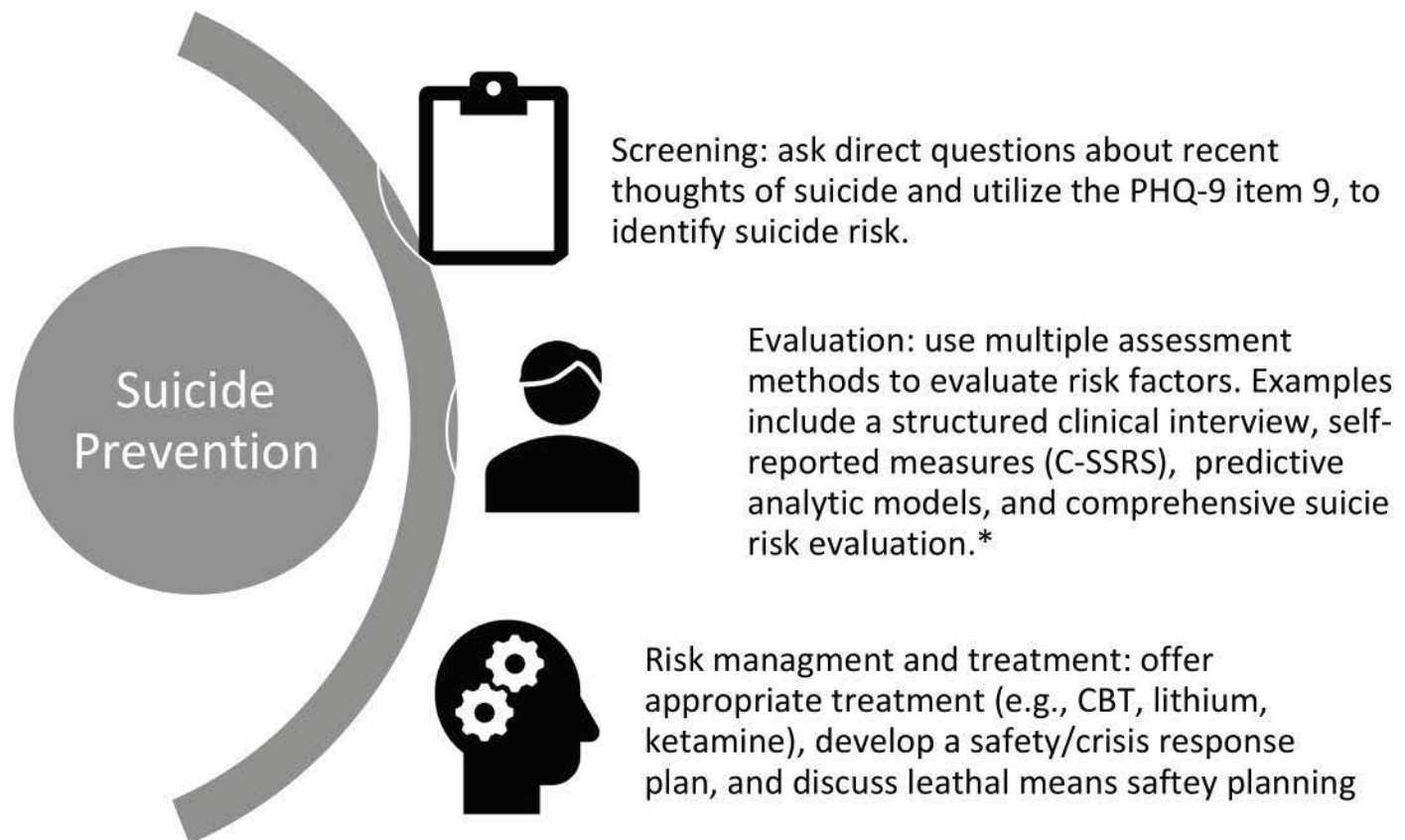


Use the PHQ-9 or similar assessment tool for sensitive and objective measurement of response and remission to the current treatment.

Suicide Prevention

It is important to assess for risk of suicide with MDD regardless of the presence or absence of other psychiatric problems. Other mental health disorders should be managed as indicated.

Figure X. Suicide Risk Assessment VA/dod SP CPG



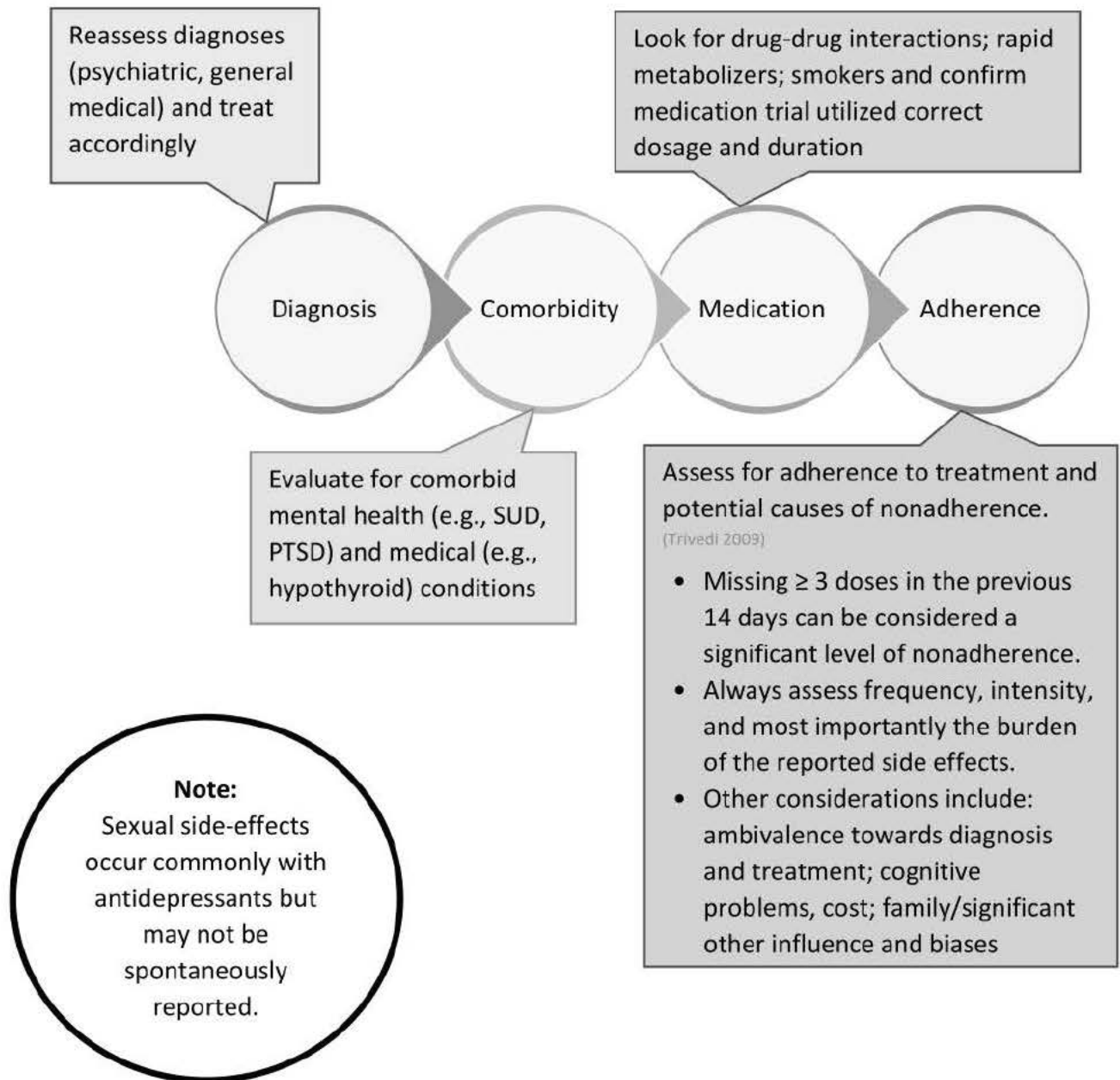
*additional information on VA suicide initiatives can be found: [add sp sharepoint url](#)

Screen, evaluate, and manage suicide risk in our Veterans with Depression

Evaluating TRD

When response to treatment is not as robust as hoped it is important to do a thorough evaluation before concluding that the patient is truly treatment resistant.

Figure X. Steps to Evaluating Treatment Resistant Depression (Ionescu 2015, Trivedi 2009)



Adequate antidepressant trial

Both dose and duration must be considered when determining whether an antidepressant trial was “adequate”.

- In the past, a duration of at least 6-8 weeks was recommended as the minimum duration, but newer literature recommends as many as 12-14 weeks on an adequate dose.

Trivedi Am J Psychiatry 2006; 163:28-40.

Titrate antidepressant to the therapeutic dose based on tolerability and response.

A ≥ 25% decrease in baseline PHQ-9 score by week 6 indicates a patient may benefit from an increase in dose if necessary and continuation for 10-12 weeks. (Trivedi Am J Psychiatry 2006; 163:28-40., Rush 2007)

Treatment strategies for TRD:

Switching or augmenting antidepressants

Response to initial agent	Treatment choice	Next step antidepressant examples	Key points
Non-response or intolerance to initial agent	Within-class switch	SSRI to SSRI	Antidepressants switched to do not differ on outcomes
	Out-of-class switch	SSRI to bupropion	
Partial response	Combination antidepressant therapy	SSRIs + bupropion SSRIs or SNRIs + mirtazapine SSRIs + TCAs	- May have synergistic antidepressant effect - Educate on the signs and symptoms of serotonin syndrome

SSRI = selective serotonin reuptake inhibitor; SNRI = serotonin and norepinephrine reuptake inhibitor; TCA = tricyclic antidepressant; Avoid combinations with monoamine oxidase inhibitors due to risk of hypertensive crisis or serotonin syndrome

Switch to, or augment with, another antidepressant if remission is not achieved after an adequate trial of antidepressant monotherapy. ^{Rush}

2007, Rush 2006, Trivedi N Engl J Med 2006;354:1243-52, McGrath 2006, Ruhe 2006, Lam 2002]

Treatment strategies for TRD: Psychotherapies

First-line treatment for patients with severe, chronic or recurrent MDD (complex)* includes a combination of pharmacotherapy and evidence-based psychotherapy during a new episode of care when the MDD is characterized as:

VA/DoD MDD 2016

- Severe (i.e., Patient Health Questionnaire (PHQ)-9 score >20)
- Chronic (duration greater than two years)
- Recurrent (with three or more episodes).



*Treatment selection should be based on patient preference, safety and side effect profile, personal or family history of response to a specific medication, concurrent medical illnesses, concurrently prescribed medications, cost of medication and provider training and competence.

Evidence-based Psychotherapy (EBP)

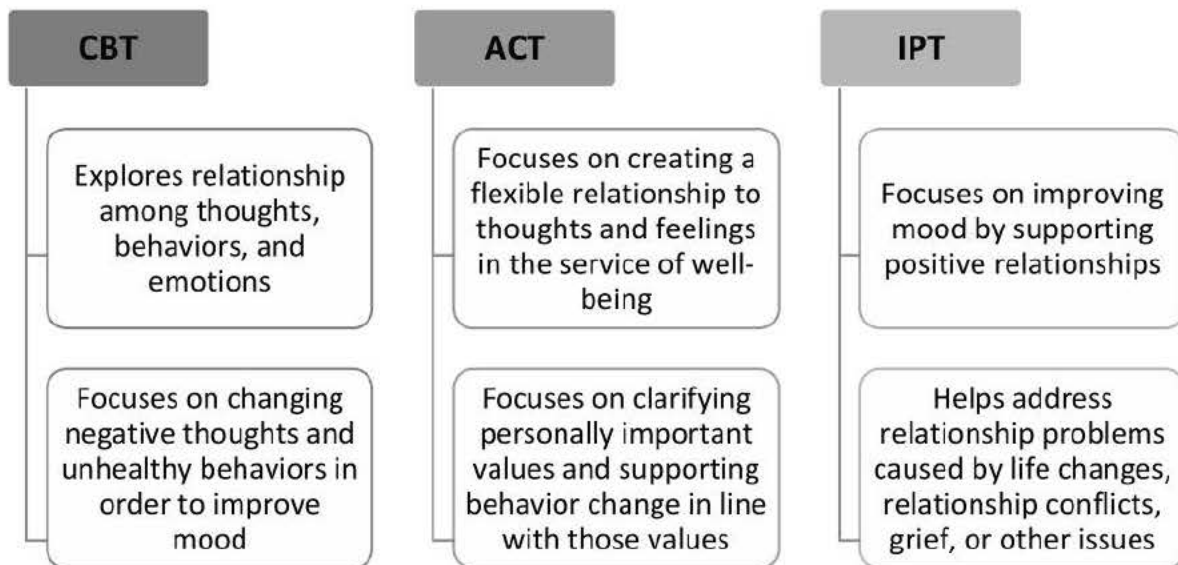
EBPs are recovery-oriented with Veterans and therapists working together to identify and reach personal goals. They are also time-limited in that symptom reductions can be achieved in as few as 12 sessions and have been shown to maintain their effectiveness after treatment ends.

- Studies show that evidence-based psychotherapies (EBP) are effective for:
 - Reducing symptoms
 - Improving quality of life
 - Promoting recovery



Figure X. Evidence-based psychotherapies for treatment of depression*

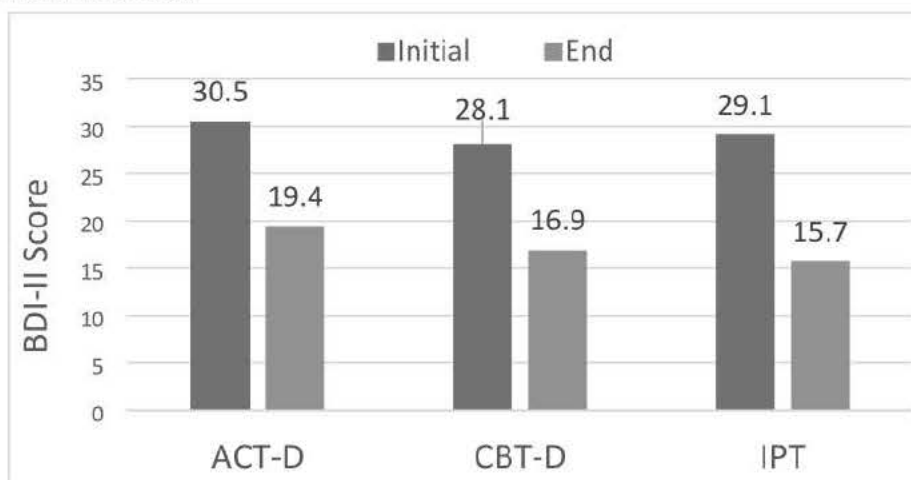
VA/DoD MDD 2016



*EBPs for depression currently disseminated by the VA National EBP Training Program: CBT = Cognitive Behavioral Therapy; ACT = Acceptance and Commitment Therapy; IPT = Interpersonal Psychotherapy

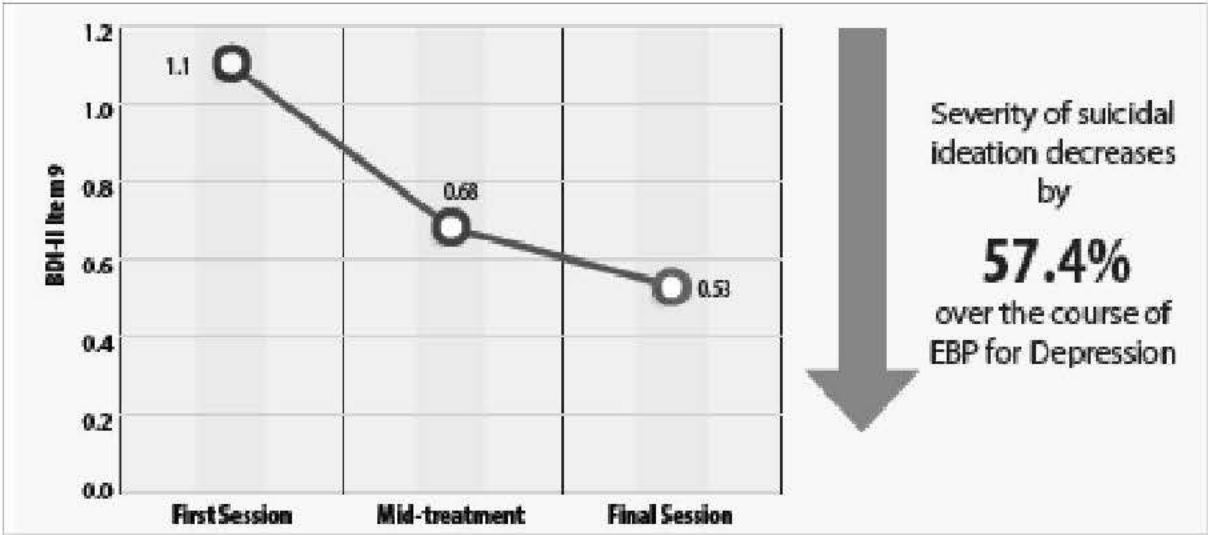
Figure XX. Veterans participating in EBP for depression experience a 41% average reduction in depression severity

(Karlén 2012 Journal of Consulting and Clinical Psychology, 80, 707-718, Stewart 2014, Walser 2013))



BDI-II Scores: 0-13 = Minimal depression, 14-19 = Mild depression, 20-28 = Moderate depression, 29-63 = Severe depression

Figure XX. Change in Suicidal Ideation Severity (Intent-to-treat Analysis) (Kimbrel 2018)



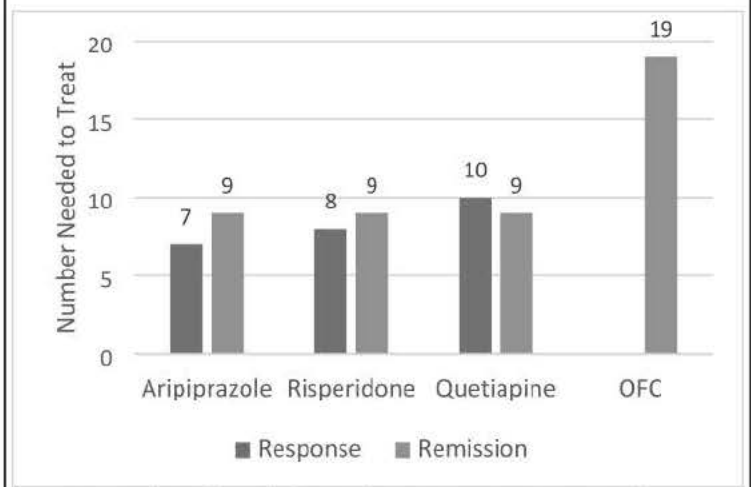
Refer to or augment with evidence-based psychotherapy in Veterans with treatment resistant depression.

Augmentation strategies for TRD: Atypical Antipsychotics

Atypical antipsychotics are effective in reducing depressive symptoms in patients with TRD. Papakostas 2007, Wang 2015, Mohamed 2017, Zhou 2015, Strawbridge 2019, Spielmans 2013

- Antipsychotic augmentation in TRD has been shown to lead to symptom reduction within 1-2 weeks
- Aripiprazole, risperidone, quetiapine, olanzapine + fluoxetine, brexpiprazole, cariprazine, and ziprasidone have evidence to support their use. bruijnzeel 2016, spielmans 2013, durgam 2016, Ionescu 2015

Atypical Antipsychotics are Effective as Adjunctive Treatment (spielmans 2013)



A meta-analysis found that adjunctive treatment with aripiprazole, risperidone, quetiapine and olanzapine/fluoxetine (OFC) was associated with a statistically significant benefit, with ORs ranging from 1.42 to 2.37. OFC was not statistically significant for response.

Risks of Long-term use of atypical antipsychotics

- Monitor for
 - Movement disorders (e.g., akathisia, tardive dyskinesia)
 - Sedation
 - Abnormal metabolic laboratory results
 - Weight gain
- Patients with affective disorders are at greater risk for developing tardive dyskinesia (TD). (Chen 2011) The number of cases of TD caused by atypical antipsychotics is increasing. Sharma 2003, Walsh 2011, Pena 2011, Hall 2009, Jankelowitz 2013 Patients should be informed of, and monitored for, these side effects.
- Long-term use should be evaluated frequently to assess whether discontinuation of the atypical antipsychotic can be considered.

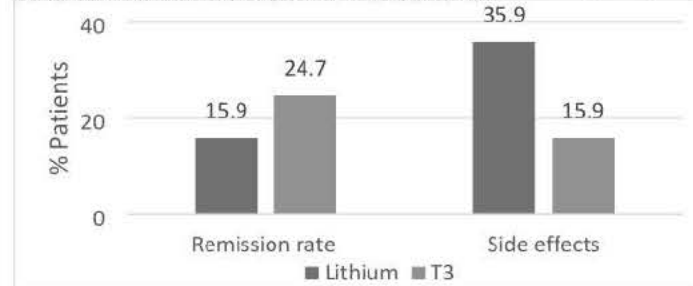
If no response is seen within 1 month of starting an antipsychotic, consider discontinuing use as risks of side effects may outweigh benefits.

Augmentation strategies for TRD: Lithium and Triiodothyronine (T3)

Both lithium and triiodothyronine improve remission rates in patients with MDD when added to SSRIs, TCAs and MAOIs. (Bauer 1999, Joffe 1993, Nierenberg 2006, Lojko 2007, Thase 1989, Abraham 2006, Smith 2017, Nelson 2014)

- Lithium
 - Well studied with response rates ranging from 12.5-50% in placebo-controlled trials. (Bauer 2003)
 - Anti-suicidal effects. (Smith 2017)
 - Effective treatment option for older adult patients. (Buspavanich 2019)
- Triiodothyronine (T3)
 - Not as well studied
 - Demonstrated response rates similar to lithium. (Lojko 2007, Shelton 2010)

Modest Remission Rates Seen with Both Lithium and T3 Augmentation but Less Side Effects with T3 (STAR*D Step 3) (Nierenberg 2006)



The STAR*D trial (Step 3) demonstrated modest remission rates with both lithium and T3 augmentation. The difference between treatment arms was not statically significant. Patients receiving lithium augmentation experienced more side effects (35.9 vs. 15.9%, $p=0.045$) and were more likely to discontinue treatment due to side effects (23.2 vs. 9.6%, $p=0.027$).

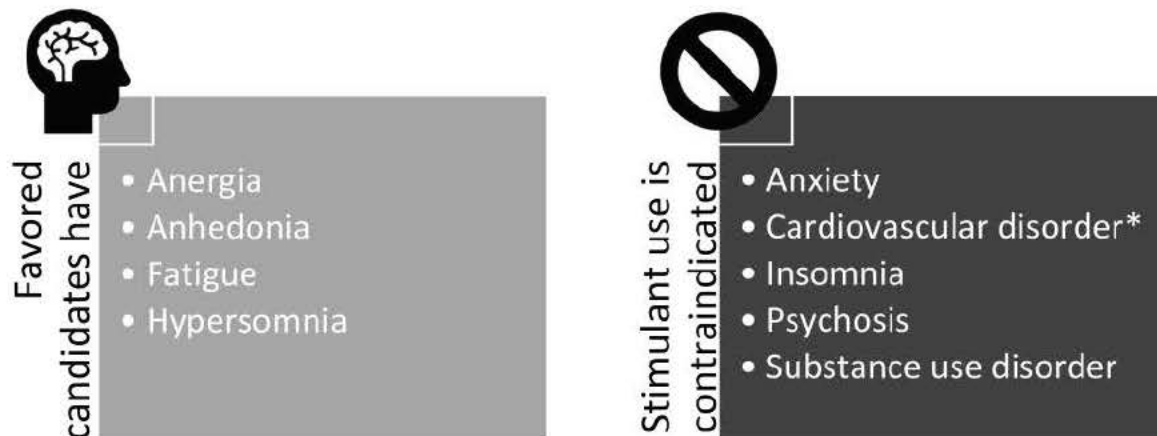
Consider augmenting antidepressants with lithium, triiodothyronine, or atypical antipsychotics in Veterans who have failed to achieve remission. Agent selection will need to take into consideration side effects, drug interactions and clinical characteristics of the patient.

Augmentation strategies for TRD: Stimulant agents (Gelenberg 2010, Corp 2014, Giacobbe 2018, Lavretsky 2015, Ionescu 2015)

For patients with depression, fatigue can be a residual symptom that inhibits functionality. There is evidence that some stimulants may improve depressive symptoms, remission rates, and fatigue in patients with MDD. (Ionescu 2015)

- Stimulant medications can be tapered over several days and stopped after the patient is in remission.
 - Patients with chronic depressive symptoms may relapse when the stimulant is decreased; restarting the stimulant at the lowest effective dose may be necessary.

Figure X. Stimulant Considerations in Patients with TRD^{Orr 2007}



*Seek cardiology consultation before prescribing stimulants with comorbid cardiovascular disease.

Medication	Clinical pearls	Amount of evidence	Effect on MDD
Modafinil Corp 2014, Goss 2013	May have a role in patients with depression and fatigue/sleepiness symptoms	++++	+
Methylphenidate Corp 2014, Lavretsky 2015	Monotherapy not shown to be effective; may be more effective in combo with an antidepressant	++	+/-
Dextroamphetamine	Has not been studied for use in MDD	N/A	N/A
Lisdexamfetamine Giacobbe 2016		+++	-
Atomoxetine	Has not been shown to be effective for depression	+	-

Dopamine Agonist: Pramipexole

Pramipexole, generally used for Parkinson disease and restless legs syndrome, has been shown to improve depression rating scores when used as adjunctive therapy for patients with MDD who failed to achieve remission with other treatment regimens.^{Cusin 2013, Gauthier 2017}

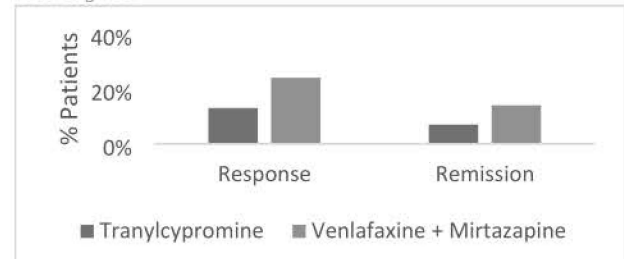
Treatment Strategy for TRD: Monoamine oxidase inhibitors (MAOI-I)

MAOI's may be effective in patients who do not respond to treatment with other antidepressants. In addition, patients with atypical depression may be more likely to respond to MAOIs. Perry 1997, Robinson 2008, Kim 2019

- Requirements for dietary restrictions, adverse effect profile and propensity for drug interactions limit use Gelenberg 2010
- Selegiline patch has a favorable side effect profile and no dietary restriction is required at the 6 mg/24-hour dose Robinson 2008
- When switching to or from a MAOI washout periods are required
 - MAOI to antidepressant 2 week
 - Antidepressant to MAOI 2 week
 - Fluoxetine to MAOI 5 weeks

Modest Remission Rates and Lower Side Effect Burden with Venlafaxine Mirtazapine Combination (STAR*D Step 4)

Gelenberg 2010



Patients who did not achieve remissions in four previous medication trials were randomized to Tranylcypromine (n = 58) or venlafaxine plus mirtazapine (n=51). Remission rates were modest for both treatment arms with a lower side effect burden seen with the venlafaxine plus mirtazapine combination.

Treatment Strategy for TRD: Glutamatergic agents_ Sanacora 2017, Short 2018, Fava 2018,

Popova 2019, Daly 2019

Ketamine is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor. Esketamine is the S-enantiomer of racemic ketamine.

- To date, there are no clinical trials comparing IV ketamine to IN esketamine.

Both are associated with sedation, dissociation, abuse and misuse, and suicidal thoughts and behaviors

Intravascular (IV) Ketamine

IV ketamine is approved as an anesthetic agent that has been used off-label for the management of major depression. There are currently no guidelines recommending the use of IV ketamine for TRD and long-term data with IV ketamine is lacking.

The use of a single IV infusion (0.5mg/kg), as monotherapy or as an augmenting agent to an antidepressant, has shown to produce a rapid antidepressant effect that may last up to seven days. Fond 2014, McGirr 2015

Figure X. IV Ketamine

Dose	• Single IV infusion (0.5mg/kg) • Monotherapy or as an augmenting agent to an antidepressant
Response	• Provides rapid antidepressant effect that may last up to 7 days Fond 2014, McGirr 2015 • Long-term data is missing
Role in Treatment	• Not a first-line treatment option for any severity level of depressive episode Sanacora 2017 • Adjunctive treatment for short-term reduction in suicidal ideation in patients with MDD^{va/dod} suicide
Considerations	• The risk of each ketamine infusion should be balanced with the risk of long-term exposure, including neurotoxicity, cystitis, and abuse potential Sanacora 2017

Intranasal (IN) Esketamine

IN esketamine was recently approved (2019) in conjunction with an oral antidepressant, for the treatment of TRD in adults.

- Long-term efficacy and safety data are lacking.
- Older Veterans (> 65 years of age) should not be considered candidates for esketamine given the non-significant efficacy data in this patient population.
- The patient population studied (median age of 47 years, 62% female, 93% Caucasian, and 5% Black) is not representative of the VA population.

Table X. Summary of Key Esketamine (ESK) Literature Popova 2019, Daly 2019 , FDA Briefing

Study	Duration	Important study population info	Dose	Outcome**
TRANSFORM-1	4 weeks	18 - 64 yo with TRD*; median age of 47; 62% female, 93% Caucasian	• Placebo + AD • ESK 56 mg + AD • ESK 84 mg + AD	Did not meet the pre-specified statistical tests for demonstrating effectiveness.
TRANSFORM-2	4 weeks	18 - 64 yo with TRD*; median age of 47; 62% female, 93% Caucasian	• Placebo + oral AD • ESK (56 mg or 84 mg) + oral AD	Esketamine demonstrated statistically significant effect compared to placebo on the severity of depression
TRANSFORM-3	4 weeks	≥ 65 years of age	• Placebo + AD • ESK (56 mg or 84 mg) + oral AD	Did not meet the pre-specified statistical tests for demonstrating effectiveness.
SUSTAIN-1 (longer-term maintenance-of-effect trial)	variable+	Achieved treatment response ESK in 1 of 2 short-term double-blind, active-controlled studies	• Placebo + AD • ESK (56 mg or 84 mg) + oral AD	Statistically significantly longer time to relapse of depressive symptoms than patients on placebo nasal spray plus an oral antidepressant. Patients may have experienced unblinding when switched to placebo nasal spray.

*In the current depressive episode, had not responded adequately to at least 2 different antidepressants of adequate dose and duration; **Primary efficacy measure was the change from baseline on the Montgomery-Asberg Depression Rating Scale (MADRS) total score at the end of the 4-week double-blind induction phase. +Study continued until requisite number of relapses occurred (up to 84 weeks for remission and 88 weeks for response).

Table X. IV Ketamine and IN Esketamine Comparison

	IV ketamine*	IN esketamine#
Indication	Induction and maintenance of general anesthesia	Treatment-resistant depression (in conjunction with an oral antidepressant)
DEA schedule	III	III
Onset of action	Rapid	Rapid
Comparator drug	Midazolam (active placebo)	Only compared to placebo
When to use	In patients who do not achieve remission from at least four adequate antidepressant trials	In patients who do not achieve remission from at least four adequate antidepressant trials
Administration	Twice weekly	Twice weekly x 4 wks (induction)
Duration	Individualized	Individualized
Restrictions	Requires Ketamine Safety Form to be completed after every treatment session and submitted to VAMedSAFE online	Requires Esketamine Safety Form to be completed after every treatment session and submitted to VAMedSAFE online
REMS	No	Yes
Cost/pt/yr (\$)	265	15,000-36,000

* See National Protocol Guidance for intravenous ketamine infusion for TRD for additional information;

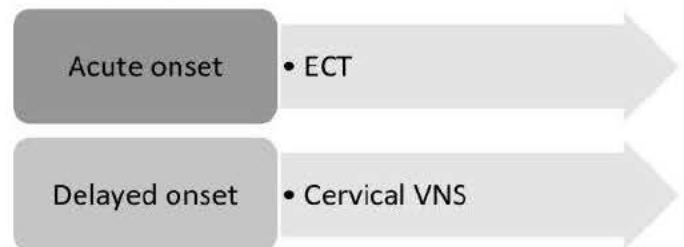
See National Protocol Guidance for intranasal esketamine for TRD for additional information

Consider using ketamine or esketamine in Veterans who have treatment resistant depression and have not responded to several past treatment options.

Treatment Strategy for TRD: Brain Stimulation

Brain stimulation treatments include electroconvulsive therapy (ECT), repetitive transcranial magnetic stimulation (rTMS), and vagus nerve stimulation (VNS). They differ in terms of invasiveness, and how well they work acutely, versus over the long-term.

Figure X. ECT is the most effective acute treatment available



Cervical VNS takes months or years to reach full effectiveness and is thus not useful acutely.

ECT

ECT is the father of the brain stimulation techniques, has the most evidence behind its use, and has been shown to quickly decrease or eliminate depressive symptoms.

- Most effective acute treatment for depression but benefits are hard to sustain.
 - o Has also been shown to be effective for bipolar depression, catatonia, psychotic depression, acute mania, Parkinson's Disease (PD) and status epilepticus. petrides 2001
 - o May be less effective for patients with a long duration of current symptoms, depression secondary to medical conditions or in patients with personality disorders.

ECT remission rates range between 30 to 75% and vary based on treatment setting, duration of current episode, and comorbid conditions.

gelenberg 2019, petrides 2001, Prudic 2004

Individualized Dosing

Sufficient stimulation is needed to produce a seizure, but any stimulation above the threshold only increases side effects.

A dose for one patient may be too much or insufficient for another.

Typically the seizure threshold rises over the several weeks of the ECT course, as the brain responds to the seizure and attempts to prevent future ones.

ECT is a medical procedure involving repeated sessions of general anesthesia and is estimated to have a mortality rate similar to minor surgery or childbirth. american 2001

High rate of cardiac arrhythmias in the immediate postictal period* (most events are benign and resolve quickly).

Cognitive impairment can linger for minutes to hours and can lead to delirium in some patients (e.g., elderly).

Safety Considerations

Retrograde amnesia is common while long-term memory impairment remains a point of controversy.

Headaches are the most common (up to 45%) physical symptom following ECT; some severe enough to induce nausea / vomiting

*Patients with preexisting cardiac disease are at greatest risk for developing irregular rhythms.

ECT continuation and maintenance considerations:

Despite the remarkable acute efficacy with ECT, the long-term benefits are difficult to sustain. The relapse rate is particularly high after the sessions are discontinued. Continuation of some antidepressant treatment after the course of ECT is indicated. (reference needed))

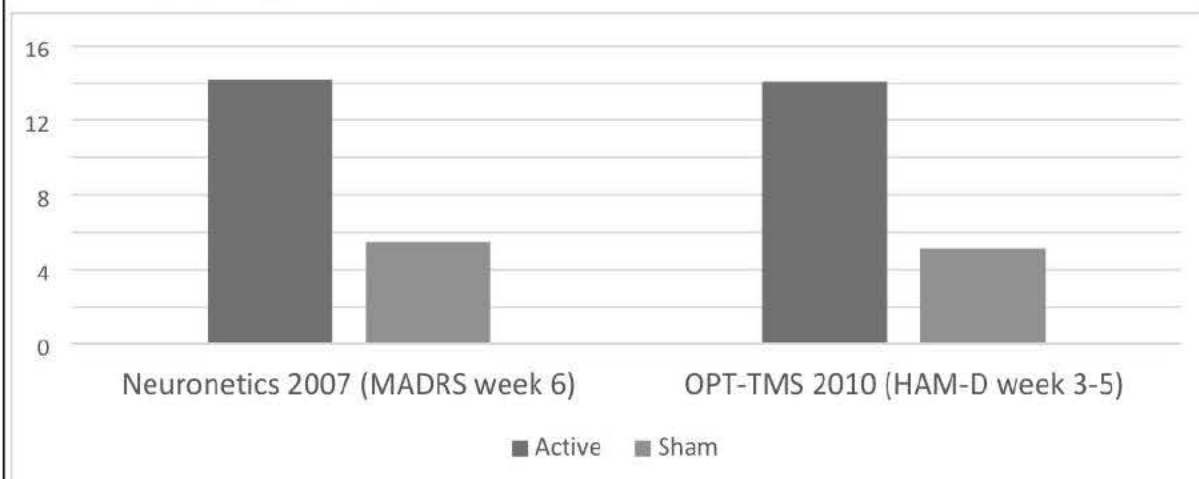
ECT should be considered in patients with MDD who cannot tolerate or have not responded to several trials of antidepressant treatment; patients with more severe symptoms may benefit from earlier application of this treatment modality.

Repetitive Transcranial Magnetic Stimulation (rTMS)

Repetitive Transcranial Magnetic Stimulation (rTMS) is approved for the treatment of Major Depressive Disorder in adults who have failed to achieve satisfactory improvement from at least one prior course of antidepressant medication. *VA/Do, Connolly 2012*

Figure X. TMS is Superior to Sham For Both Response and Remission For TRD

O'Reardon et al. (2017), George et al. (2010)



Neuronetics, randomized 301 medication free patients to active or sham treatment. Participants were treated with 10Hz rTMS at 120% of their motor threshold (MT) for 3000 pulses per session, 5 days a week for a total of 4-6 weeks. Minimal side effects reported ($p < 0.05$ vs. sham). OPT-TMS randomized 190 medication free patients who were treated days a week using 10Hz rTMS at 120% MT. They received a total of 3000 pulses per session for 3 weeks and non-remitters continued for an additional 3 weeks. Active rTMS group improved depressive symptoms ($p = 0.02$ vs. sham) with minimal side effects.

rTMS has been shown to be effective for both response and remission of MDD and is well tolerated. (Kozel et al. (2017), Conolea et al (2017), O'Reardon et al. (2007), George et al. (2010))

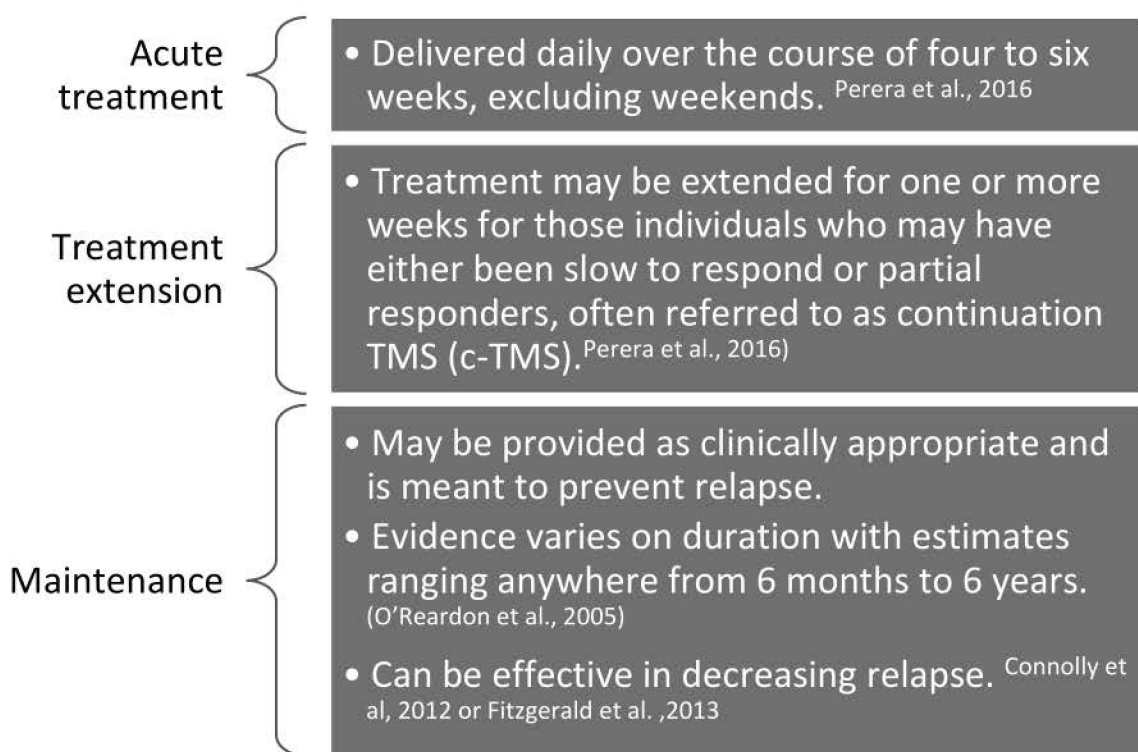
Compared to using electroconvulsive therapy (ECT), rTMS has fewer side effects but lower remission rates and longer time response. O'Reardon et al., 2007; Rossi et al., 2009; & George et al., 2010

Common side effects from TMS

- Headache
- Discomfort at treatment site
- Light-headedness
- Facial tingling

to
Chail

Figure X. rTMS Administration



Consider offering treatment with rTMS for treatment during a major depressive episode in patients with treatment-resistant depression.

Table X. Treatment Considerations for ECT vs. TMS VA/DoD, 2016, O'Reardon et al. (2007), George et al. (2010), Levkovitz et al. (2015); Zolezzi 2016

	Pros	Cons	Relative Contraindications	Discussion
ECT	- Higher remission rate	- More side effects - Need for sedation / anesthesia - Higher risk, more complex procedure	- Cardiovascular disease - Space-occupying intracranial lesion with the evidence of elevated intracranial pressure - Recent cerebral hemorrhage or stroke - Bleeding or otherwise unstable vascular aneurysm - Severe pulmonary disease	Appropriate for acute and severe MDD including psychotic depression or catatonia
rTMS	- Fewer side effects	- Lower remission rates - Longer time to response - Minimal risks and side effects	- Epilepsy - Bipolar disorder - Active substance use disorder - Tumor or other neuroanatomical abnormality near treatment site - Cochlear implants - Deep brain stimulators - Pacemakers - Presence of any ferromagnetic material in the head - Medications that decrease seizure threshold*	Appropriate for patients with severe, chronic or recurrent MDD who are treatment resistant

*Should a clinician decide to treat individuals who are on one of these medications, it is recommended that careful monitoring and regular re-determination of the motor threshold be considered.

Vagus Nerve Stimulation (VNS)

Although vagus nerve stimulation is FDA approved for treatment-resistant depression, there is no current evidence that supports its routine use in the treatment of MDD and it is not widely available.^{Va/dod dep} When discussing this as a treatment option it is important to indicate that the risk of harm is high with a 5% chance of serious side effects (voice alteration, dysphagia, dyspnea, infection, dizziness, asthenia, chest pains, palpitations, and vocal cord paralysis) and lack of evidence showing benefit.^{Va/dod dep}

Treatment Strategies for MDD^{va/dod dep}, Gelenberg 2010

PHQ-9 Score

Functional impairment

Initial Strategy

10-14

Mild

- Watchful waiting, supportive counseling
- If no improvement after 1 month, then consider brief psychotherapy or antidepressant

15-19

Moderate

- Start psychotherapy or antidepressant

≥ 20

Severe

- Start psychotherapy AND antidepressant

Psychoeducation and self-management should be provided for all severity levels

Partial response

Nonresponse

Increase dose (Unless dose is at max approved or tolerated)
OR combine with bupropion, mirtazapine or buspirone
AND add psychotherapy *

Switch to an alternative antidepressant
AND add psychotherapy*

Partial or nonresponse

Partial response

Consider augmentation with bupropion, mirtazapine, or buspirone
or
Switch to an alternative antidepressant
AND add psychotherapy*

Partial or nonresponse

Consider augmentation with bupropion, mirtazapine, buspirone, T3, lithium, or an atypical antipsychotic
AND add psychotherapy*

Partial or nonresponse

Consider previous options or switch antidepressant to a TCA or MAO-I
AND Consider ECT or rTMS or IV Ketamine or IN esketamine
AND add psychotherapy*

Partial or nonresponse

Partial or nonresponse

Consider an alternative drug combo not used previously*

Remission – Continue treatment for at least 6 months

*psychotherapy addition depends upon patient preferences and available times for weekly therapist – patient sessions. T3 = Triiodothyronine; TCA = Tricyclic Antidepressant; MAO-I = Monoamine Oxidase Inhibitor; ECT = Electroconvulsive Therapy; rTMS = Repetitive Transcranial Magnetic Stimulation

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From:	Wells, Daina L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2256099A3577421182C5516B56F40815-WELLS, DAIN (b6) va.gov>
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Subject:	TRD meeting today - next steps
Date:	2019/06/24 13:51:26
Importance:	High
Priority:	Urgent
Type:	Note

Hello,

Thanks again for taking the time to meet. As promised, attached is a copy of the 2012 TRD discussion handout we will be updating. I'll also provide a [link](#) to a more recent discussion handout on a different clinical topic so you can get an idea of the look and feel we're going for.

Here is a list of all participants in our group as well as what you volunteered to do for this TRD handout update on today's call. I have emailed those not present today to ask them if they would be willing to be a writer/reviewer and for what sections. Once they respond, I'll record what they will be doing and include them as needed.

SMEs	Role
Ilse Wiechers	Reviewer – all content
Dave Oslin	Reviewer – all content
(b6)	Writer – will review older document and determine what he can update
Matthew Fuller	Writer – pharmacotherapy
Michelle Madore	Writer and reviewer – rTMS section
Bruce Capehart	
William Gilmer	
Mark George	
Walter Dunn	Reviewer – rTMS, esketamine, ketamine
Gia Maramba	Writer and reviewer – psychotherapy

If you are a **writer**, please review the older attached TRD handout and begin reviewing the literature to determine what needs to be updated/added. I will be emailing the **writers** to set up a call in the next couple of weeks.

If you are a **reviewer only**, the writers will begin working on their sections and I will send out an email to all reviewers once we have a better idea of timeline for review.

If you have any questions, please don't hesitate to reach out.

Thank you.

Daina

Daina L. Wells, PharmD, MBA, BCPS, BCPP

National Clinical Program Manager

VA Academic Detailing Service, VACO PBM

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[ADS Inquiry and Request Portal](#)

Suicide Prevention is Everyone's Business.

#BeThere

Veterans in crisis, or their friends or family, can call the Veterans Crisis Line for confidential support 24 hours a day, seven days a week, 365 days a year at 1-800-273-8255 **and Press 1**, chat online at VeteransCrisisLine.net/Chat, or text to **838255**.

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Delivered Date:	2019/06/24 13:51:26

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Subject:	task list
Date:	2019/03/21 10:05:48
Priority:	Normal
Type:	Note

Due Date	Due time	Title	Assigned To	Update
3/21/2019		RE: HAC QFRs- Whole Health, Mental Health, Homelessness- Suspense: March 26th/ VIEWS 00194892	Cliff / SPP	Cliff - M 3. Dan, Pau Due to 1
3/21/2019	11:00 AM	FW: SMEs/Talking Points for Spravato® (esketamine)	Ilse	Please p Due to 1
3/21/2019	2:00 PM	FW: FY19 CTR - Substance Abuse Disorder Data (136734)	Trafton, Jodie	Please p Due to 1
3/21/2019	COB	"FW: 10NC and Mission Act" / "MISSION ACT"	Paula/Stacey	Please p Due to 1 Andrew,
3/22/2019	10:00 AM	RE: Sen. Young (IN) - RFI regarding clarification of Suicide Prevention statistics		SPP ser Due to 1
3/22/2019	12:00 PM	FW: Seattle Reporter Seeking OTH Info	Smith, Cliff	Please p
3/25/2019		FW: ITF Staff Meeting - Jan 2019	Loftis, Chris	Please s ITF Brief Due to 1
3/25/2019		RE: Case #: 00127165 - Due Date: 2019-02-21 17:00:00 - Action Requested - Provide Concurrence	NCPTSD	Please p
3/25/2019	COB	FW: 00199341: LRM: [RD-116-22] -- JUSTICE Report on Law Enforcement Mental Health Wellness	Marcia/VCL	Please re Due to 1

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Sent Date:	2019/03/21 10:05:39
Delivered Date:	2019/03/21 10:05:48

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Account Name	Account Number	McKesson Item Number	NDC	UPC	Generic Description	Dosage Strength	Manufacturer Size	Brand Description	Ordered Qty	Returned/Credited Quantity	Quantity Omitted	Net Qty	Total Dollars Purchased (Net)	Mfr/Supplier Name
VAMC IP 626 NASHVILLE	568355	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	2	0	0	2	\$785.58	JOM PHARMACEUTICAL
PETTIS IP LOMA LINDA CA	529437	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	4	0	0	4	\$2,359.72	JOM PHARMACEUTICAL
VA MED CTR - ALBUQ	722829	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	1	0	0	1	\$365.85	JOM PHARMACEUTICAL
VAMC IP 626 NASHVILLE	568355	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	2	0	0	2	\$1,179.86	JOM PHARMACEUTICAL
VA MED CTR - ALBUQ	722829	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	20	0	0	20	\$11,005.00	JOM PHARMACEUTICAL
VAMC IP 626 NASHVILLE	568355	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	1	0	0	1	\$393.39	JOM PHARMACEUTICAL
VA MED CT FAYETTEVILLE AR	447851	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	1	0	0	1	\$590.10	JOM PHARMACEUTICAL
VA MED CT FAYETTEVILLE AR	447851	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	1	0	0	1	\$590.10	JOM PHARMACEUTICAL
VA OP PHCY - BOSTON	303647	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	6	0	0	6	\$2,280.72	JOM PHARMACEUTICAL

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Date Selection: 05/01/2017 to 08/22/2019

Account Name	Account Number	McKesson Item Number	NDC	UPC	Generic Description	Dosage Strength	Manufacturer Size	Brand Description	Ordered Qty	Returned/Credited Quantity	Quantity Omitted	Net Qty	Total Dollars Purchased (Net)	Mfr/Supplier Name
VAMC IP 626 NASHVILLE	568355	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	2	0	0	2	\$785.58	JOM PHARMACEUTICAL
PETTIS IP LOMALINDA CA	529437	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	4	0	0	4	\$2,359.72	JOM PHARMACEUTICAL
VA MED CTR - ALBUQ	722829	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	1	0	0	1	\$365.85	JOM PHARMACEUTICAL
VAMC IP 626 NASHVILLE	568355	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	2	0	0	2	\$1,179.86	JOM PHARMACEUTICAL
VA MED CTR - ALBUQ	722829	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	20	0	0	20	\$11,005.00	JOM PHARMACEUTICAL
VAMC IP 626 NASHVILLE	568355	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	1	0	0	1	\$393.39	JOM PHARMACEUTICAL
VA MED CT FAYETTEVILLE AR	447851	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	1	0	0	1	\$590.10	JOM PHARMACEUTICAL
VA MED CT FAYETTEVILLE AR	447851	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	1	0	0	1	\$590.10	JOM PHARMACEUTICAL
VA OP PHCY - BOSTON	303647	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	6	0	0	6	\$2,280.72	JOM PHARMACEUTICAL

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Date Selection: 05/01/2017 to 08/22/2019

Account Name	Account Number	McKesson Item Number	NDC	UPC	Generic Description	Dosage Strength	Manufacturer Size	Brand Description	Ordered Qty	Returned/Credited Quantity	Quantity Omitted	Net Qty	Total Dollars Purchased (Net)	Mfr/Supplier Name
VAMC IP 626 NASHVILLE	568355	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	2	0	0	2	\$785.58	JOM PHARMACEUTICAL
PETTIS IP LOMA LINDA CA	529437	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	4	0	0	4	\$2,359.72	JOM PHARMACEUTICAL
VA MED CTR - ALBUQ	722829	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	1	0	0	1	\$365.85	JOM PHARMACEUTICAL
VAMC IP 626 NASHVILLE	568355	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	2	0	0	2	\$1,179.86	JOM PHARMACEUTICAL
VA MED CTR - ALBUQ	722829	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	20	0	0	20	\$11,005.00	JOM PHARMACEUTICAL
VAMC IP 626 NASHVILLE	568355	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	1	0	0	1	\$393.39	JOM PHARMACEUTICAL
VA MED CT FAYETTEVILLE AR	447851	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	1	0	0	1	\$590.10	JOM PHARMACEUTICAL
VA MED CT FAYETTEVILLE AR	447851	3635822	50458002803	35045802803	ESKETAMINE	84 MG	3	SPRAVATO 84MG DOSE KIT 3	1	0	0	1	\$590.10	JOM PHARMACEUTICAL
VA OP PHCY - BOSTON	303647	3635830	50458002802	35045802802	ESKETAMINE	56 MG	2	SPRAVATO 56MG DOSE KIT 2	6	0	0	6	\$2,280.72	JOM PHARMACEUTICAL

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Date Selection: 05/01/2017 to 08/22/2019

SPRAVATO™

(esketamine) nasal spray, CIII

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use **SPRAVATO™** safely and effectively. See full prescribing information for **SPRAVATO™**.

SPRAVATO™ (esketamine) nasal spray, CIII

Initial U.S. Approval: 1970 (ketamine)

WARNING: SEDATION; DISSOCIATION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS

See full prescribing information for complete boxed warning.

- Risk for sedation and dissociation after administration. Monitor patients for at least two hours after administration. (5.1, 5.2)
- Potential for abuse and misuse. Consider the risks and benefits of prescribing **SPRAVATO** prior to using in patients at higher risk of abuse. Monitor patients for signs and symptoms of abuse and misuse. (5.3)
- **SPRAVATO** is only available through a restricted program called the **SPRAVATO REMS**. (5.4)
- Increased risk of suicidal thoughts and behaviors in pediatric and young adult patients taking antidepressants. Closely monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors. **SPRAVATO** is not approved for use in pediatric patients. (5.5)

INDICATIONS AND USAGE

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults. (1)

Limitations of Use: **SPRAVATO** is not approved as an anesthetic agent. The safety and effectiveness of **SPRAVATO** as an anesthetic agent have not been established. (1)

DOSAGE AND ADMINISTRATION

- Administer **SPRAVATO** intranasally under the supervision of a healthcare provider. (2.1)
- Assess blood pressure prior to and after administration. (2.1)
- Evidence of therapeutic benefit should be evaluated at the end of the induction phase to determine need for continued treatment. (2.2)
- See Full Prescribing Information for recommended dosage during the induction and maintenance phases. (2.2)
- See Full Prescribing Information for important administration instructions. (2.3)

SPRAVATO™ (esketamine) nasal spray, CIII

DOSAGE FORMS AND STRENGTHS

Nasal Spray: 28 mg of esketamine per device. Each nasal spray device delivers two sprays containing a total of 28 mg of esketamine. (3)

CONTRAINDICATIONS

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial and peripheral arterial vessels) or arteriovenous malformation. (4)
- Intracerebral hemorrhage. (4)
- Hypersensitivity to esketamine, ketamine, or any of the excipients. (4)

WARNINGS AND PRECAUTIONS

- **Increases in Blood Pressure:** Patients with cardiovascular and cerebrovascular conditions and risk factors may be at an increased risk of associated adverse effects. (5.6)
- **Cognitive Impairment:** **SPRAVATO** may impair attention, judgment, thinking, reaction speed and motor skills. (5.7)
- **Impaired Ability to Drive and Operate Machinery:** Do not drive or operate machinery until the next day after a restful sleep. (5.8)
- **Embryo-fetal Toxicity:** May cause fetal harm. Consider pregnancy planning and prevention in females of reproductive potential. (5.10, 8.1, 8.3)

ADVERSE REACTIONS

The most commonly observed adverse reactions (incidence $\geq 5\%$ and at least twice that of placebo plus oral antidepressant) were dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk. (6)

To report **SUSPECTED ADVERSE REACTIONS**, contact Janssen Pharmaceuticals, Inc. at 1-800-JANSSEN (1-800-526-7736) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

USE IN SPECIFIC POPULATIONS

- Lactation: Breastfeeding not recommended. (8.2)

See 17 for **PATIENT COUNSELING INFORMATION** and Medication Guide.

Revised: 03/2019

FULL PRESCRIBING INFORMATION: CONTENTS*

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FULL PRESCRIBING INFORMATION

WARNING: SEDATION; DISSOCIATION; ABUSE AND MISUSE; and SUICIDAL THOUGHTS AND BEHAVIORS**Sedation**

- Patients are at risk for sedation after administration of SPRAVATO [see *Warnings and Precautions* (5.1)].

Dissociation

- Patients are at risk for dissociative or perceptual changes after administration of SPRAVATO [see *Warnings and Precautions* (5.2)].

Because of the risks of sedation and dissociation, patients must be monitored for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting [see *Warnings and Precautions* (5.1, 5.2)].

Abuse and Misuse

- SPRAVATO has the potential to be abused and misused. Consider the risks and benefits of prescribing SPRAVATO prior to use in patients at higher risk of abuse. Monitor patients for signs and symptoms of abuse and misuse [see *Warnings and Precautions* (5.3)].

Because of the risks of serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, SPRAVATO is only available through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the SPRAVATO REMS [see *Warnings and Precautions* (5.4)].

Suicidal Thoughts and Behaviors

Antidepressants increased the risk of suicidal thoughts and behavior in pediatric and young adult patients in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. SPRAVATO is not approved in pediatric patients [see *Warnings and Precautions* (5.5)].

1 INDICATIONS AND USAGE

SPRAVATO™ is indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults [see *Clinical Studies* (14.1)].

Limitations of Use:

SPRAVATO is not approved as an anesthetic agent. The safety and effectiveness of SPRAVATO as an anesthetic agent have not been established.

2 DOSAGE AND ADMINISTRATION**2.1 Important Considerations Prior to Initiating and During Therapy**

SPRAVATO must be administered under the direct supervision of a healthcare provider. A treatment session consists of nasal administration of SPRAVATO and post-administration observation under supervision.

Blood Pressure Assessment Before and After Treatment

- Assess blood pressure prior to dosing with SPRAVATO [see *Warnings and Precautions* (5.6)].
- If baseline blood pressure is elevated (e.g., >140 mmHg systolic, >90 mmHg diastolic), consider the risks of short term increases in blood pressure and benefit of SPRAVATO treatment in patients with TRD [see *Warnings and Precautions* (5.6)]. Do not administer SPRAVATO if an increase in blood pressure or intracranial pressure poses a serious risk [see *Contraindications* (4)].
- After dosing with SPRAVATO, reassess blood pressure at approximately 40 minutes (which corresponds with the C_{max}) and subsequently as clinically warranted.
- If blood pressure is decreasing and the patient appears clinically stable for at least two hours, the patient may be discharged at the end of the post-dose monitoring period; if not, continue to monitor [see *Warnings and Precautions* (5.6)].

Food and Liquid Intake Recommendations Prior to Administration

Because some patients may experience nausea and vomiting after administration of SPRAVATO [see *Adverse Reactions* (6.1)], advise patients to avoid food for at least 2 hours before administration and to avoid drinking liquids at least 30 minutes prior to administration.

Nasal Corticosteroid or Nasal Decongestant

Patients who require a nasal corticosteroid or nasal decongestant on a dosing day should administer these medications at least 1 hour before SPRAVATO [see *Clinical Pharmacology* (12.3)].

2.2 Recommended Dosage

Administer SPRAVATO in conjunction with an oral antidepressant (AD).

The recommended dosage for SPRAVATO is shown in Table 1. Dosage adjustments should be made based on efficacy and tolerability. Evidence of therapeutic benefit should be evaluated at the end of the induction phase to determine need for continued treatment.

Table 1: Recommended Dosage for SPRAVATO

		Adults
Induction Phase	Weeks 1 to 4:	Day 1 starting dose: 56 mg
	Administer twice per week	Subsequent doses: 56 mg or 84 mg
Maintenance Phase	Weeks 5 to 8:	Administer once weekly 56 mg or 84 mg
	Week 9 and after:	Administer every 2 weeks or once weekly*
	Administer every 2 weeks or once weekly*	56 mg or 84 mg

* Dosing frequency should be individualized to the least frequent dosing to maintain remission/response.

2.3 Administration Instructions

SPRAVATO is for nasal use only. The nasal spray device delivers a total of 28 mg of esketamine. To prevent loss of medication, do not prime the device before use. Use 2 devices (for a 56 mg dose) or 3 devices (for an 84 mg dose), with a 5-minute rest between use of each device. Follow these administration instructions and read the *Instructions for Use* before administration:

Nasal Spray Device

Each device delivers two sprays containing a total of 28 mg of esketamine.

Indicator

One device contains 2 sprays. (1 spray for each nostril)

2 green dots (0 mg delivered)



1 green dot



No green dots

Two sprays (28 mg) delivered

**Step 1 Get ready****Before first device only:**

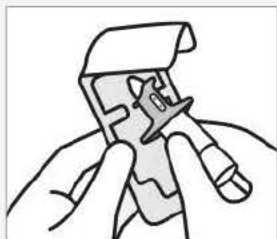
Instruct patient to blow nose **before first device only**.



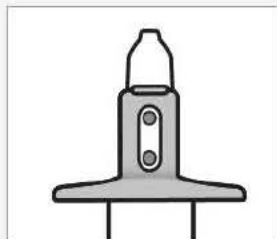
Confirm required number of devices.

56 mg = 2 devices

84 mg = 3 devices

Step 2 Prepare device**Healthcare professional:**

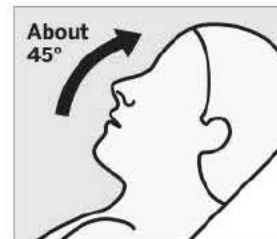
- Check expiration date ("EXP"). If expired, get a new device.
- Peel blister and remove device.

**Healthcare professional:**

- **Do not prime device.** This will result in a loss of medication.
- Check that indicator shows **2 green dots**. If not, dispose of device and get a new one.
- Hand device to patient.

Step 3 Prepare patient**Instruct the patient to:**

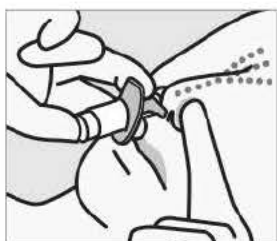
- Hold device as shown with the thumb gently supporting the plunger.
- **Do not** press the plunger.

**Instruct the patient to:**

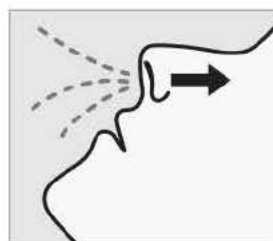
- Recline head at about **45 degrees** during administration to keep medication inside the nose.

Step 4 Patient sprays once into each nostril**Instruct the patient to:**

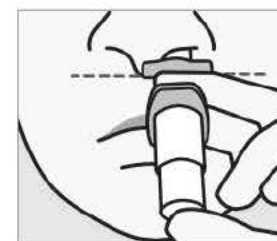
- Insert tip straight into the **first nostril**.
- Nose rest should touch the **skin between the nostrils**.

**Instruct the patient to:**

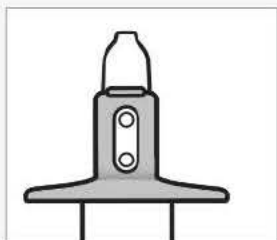
- Close opposite nostril.
- **Breathe in through nose** while pushing plunger all the way up until it stops.

**Instruct the patient to:**

- **Sniff gently** after spraying to keep medication inside nose.

**Instruct the patient to:**

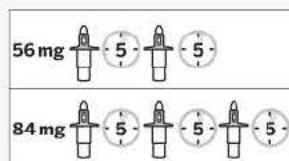
- Switch hands to insert tip into the **second nostril**.
- Repeat Step 4 to deliver second spray.

Step 5 Confirm delivery and rest**Healthcare professional:**

- Take device from patient.
- **Check that indicator shows no green dots.** If you see a green dot, have patient spray again into the second nostril.
- Check indicator again to confirm device is empty.

**Instruct the patient to:**

- Rest in a comfortable position (preferably, semi-reclined) for **5 minutes after each device**.
- If liquid drips out, dab nose with a tissue.
- **Do not** blow nose.

Next device**Healthcare professional:**

- **Repeat Steps 2-5** for the next device.

IMPORTANT: Ensure that patient **waits 5 minutes after each device** to allow medication to absorb.

Disposal

Dispose of used device(s) per facility procedure for a Schedule III drug product and per applicable federal, state, and local regulations.

2.4 Post-Administration Observation

During and after SPRAVATO administration at each treatment session, observe the patient for at least 2 hours until the patient is safe to leave [see *Warnings and Precautions* (5.1, 5.2, 5.6, 5.8)]. Before SPRAVATO administration, instruct patients not to engage in potentially hazardous activities, such as driving a motor vehicle or operating machinery, until the next day after a restful sleep.

2.5 Missed Treatment Session(s)

If a patient misses treatment sessions and there is worsening of depression symptoms, per clinical judgement, consider returning to the patient's previous dosing schedule (i.e., every two weeks to once weekly, weekly to twice weekly; see Table 1).

3 DOSAGE FORMS AND STRENGTHS

Nasal Spray: 28 mg of esketamine per device. Each nasal spray device delivers two sprays containing a total of 28 mg esketamine.

4 CONTRAINDICATIONS

SPRAVATO is contraindicated in patients with:

- Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation [see *Warnings and Precautions* (5.5)]
- History of intracerebral hemorrhage [see *Warnings and Precautions* (5.5)]
- Hypersensitivity to esketamine, ketamine, or any of the excipients.

5 WARNINGS AND PRECAUTIONS

5.1 Sedation

In clinical trials, 49% to 61% of SPRAVATO-treated patients developed sedation based on the Modified Observer's Alertness/Sedation scale (MOAA/s) [see *Adverse Reactions* (6.1)], and 0.3% of SPRAVATO-treated patients experienced loss of consciousness (MOAA/s score of 0).

Because of the possibility of delayed or prolonged sedation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting [see *Dosage and Administration* (2.4)].

Closely monitor for sedation with concomitant use of SPRAVATO with CNS depressants [see *Drug Interaction* (7.1)].

SPRAVATO is available only through a restricted program under a REMS [see *Warnings and Precautions* (5.4)].

5.2 Dissociation

The most common psychological effects of SPRAVATO were dissociative or perceptual changes (including distortion of time, space and illusions), derealization and depersonalization (61% to 75% of SPRAVATO-treated patients developed dissociative or perceptual changes based on the Clinician Administered Dissociative Symptoms Scale) [see *Adverse Reactions* (6.1)]. Given its potential to induce dissociative effects, carefully assess patients with psychosis before administering SPRAVATO; treatment should be initiated only if the benefit outweighs the risk.

Because of the risks of dissociation, patients must be monitored by a healthcare provider for at least 2 hours at each treatment session, followed by an assessment to determine when the patient is considered clinically stable and ready to leave the healthcare setting [see *Dosage and Administration* (2.4)].

SPRAVATO is available only through a restricted program under a REMS [see *Warnings and Precautions* (5.4)].

5.3 Abuse and Misuse

SPRAVATO contains esketamine, a Schedule III controlled substance (CIII), and may be subject to abuse and diversion. Assess each patient's risk for abuse or misuse prior to prescribing SPRAVATO and monitor all patients receiving SPRAVATO for the development of these behaviors or conditions, including drug-seeking behavior, while on therapy. Contact local state professional licensing board or state-controlled substances authority for information on how to prevent and detect abuse or diversion of SPRAVATO. Individuals with a history of drug abuse or dependence are at greater risk; therefore, use careful consideration prior to treatment of individuals with a history of substance use disorder and monitor for signs of abuse or dependence. [see *Drug Abuse and Dependence* (9)].

SPRAVATO is available only through a restricted program under a REMS [see *Warnings and Precautions* (5.4)].

5.4 SPRAVATO Risk Evaluation and Mitigation Strategy (REMS)

SPRAVATO is available only through a restricted program under a REMS called the SPRAVATO REMS because of the risks of serious adverse outcomes from sedation, dissociation, and abuse and misuse [see *Boxed Warning and Warnings and Precautions* (5.1, 5.2, 5.3)].

Important requirements of the SPRAVATO REMS include the following:

- Healthcare settings must be certified in the program and ensure that SPRAVATO is:
 - Only dispensed in healthcare settings and administered to patients who are enrolled in the program.
 - Administered by patients under the direct observation of a healthcare provider and that patients are monitored by a healthcare provider for at least 2 hours after administration of SPRAVATO [see *Dosage and Administration* (2.4)].
- Pharmacies must be certified in the REMS and must only dispense SPRAVATO to healthcare settings that are certified in the program.

Further information, including a list of certified pharmacies is available at www.SPRAVATOrems.com or 1-855-382-6022.

5.5 Suicidal Thoughts and Behaviors in Adolescents and Young Adults

In pooled analyses of placebo-controlled trials of antidepressant drugs (SSRIs and other antidepressant classes) that included approximately 77,000 adult patients and 4,500 pediatric patients (SPRAVATO is not approved in pediatric patients), the incidence of suicidal thoughts and behaviors in patients age 24 years and younger was greater than in placebo-treated patients. There was considerable variation in risk of suicidal thoughts and behaviors among drugs, but there was an increased risk identified in young patients for most drugs studied. There were differences in absolute risk of suicidal thoughts and behaviors across the different indications, with the highest incidence in patients with major depressive disorder (MDD). The drug-placebo differences in the number of cases of suicidal thoughts and behaviors per 1000 patients treated are provided in Table 2.

Table 2: Risk Differences of the Number of Patients with Suicidal Thoughts or Behaviors in the Pooled Placebo-Controlled Trials of Antidepressants in Pediatric* and Adult Patients

Age Range (Years)	Drug-Placebo Difference in Number of Patients of Suicidal Thoughts or Behaviors per 1000 Patients Treated
Increases Compared to Placebo	
<18	14 additional patients
18-24	5 additional patients
Decreases Compared to Placebo	
25-64	1 fewer patient
≥65	6 fewer patients

* SPRAVATO is not approved in pediatric patients.

It is unknown whether the risk of suicidal thoughts and behaviors in children, adolescents, and young adults extends to longer-term use, i.e., beyond four months. However, there is substantial evidence from placebo-controlled maintenance studies in adults with MDD that antidepressants delay the recurrence of depression and that depression itself is a risk factor for suicidal thoughts and behaviors.

Monitor all antidepressant-treated patients for clinical worsening and emergence of suicidal thoughts and behaviors, especially during the initial few months of drug therapy and at times of dosage changes. Counsel family members or caregivers of patients to monitor for changes in behavior and to alert the healthcare provider. Consider changing the therapeutic regimen, including possibly discontinuing SPRAVATO and/or the concomitant oral antidepressant, in patients whose depression is persistently worse, or who are experiencing emergent suicidal thoughts or behaviors.

5.6 Increase in Blood Pressure

SPRAVATO causes increases in systolic and/or diastolic blood pressure (BP) at all recommended doses. Increases in BP peak approximately 40 minutes after SPRAVATO administration and last approximately 4 hours [see *Adverse Reactions* (6.1)].

Approximately 8% to 17% of SPRAVATO-treated patients and 1% to 3% of placebo-treated patients experienced an increase of more than 40 mmHg in systolic BP and/or 25 mmHg in diastolic BP in the first 1.5 hours after administration at least once during the first 4 weeks of treatment. A substantial increase in blood pressure could occur after any dose administered even if smaller blood pressure effects were observed with previous administrations. SPRAVATO is contraindicated in patients for whom an increase in BP or intracranial pressure poses a serious risk (e.g., aneurysmal vascular disease, arteriovenous malformation, history of intracerebral hemorrhage) [see *Contraindications* (4)]. Before prescribing SPRAVATO, patients with other cardiovascular and cerebrovascular conditions should be carefully assessed to determine whether the potential benefits of SPRAVATO outweigh its risks.

Assess BP prior to administration of SPRAVATO. In patients whose BP is elevated prior to SPRAVATO administration (as a general guide: >140/90 mmHg) a decision to delay SPRAVATO therapy should take into account the balance of benefit and risk in individual patients.

BP should be monitored for at least 2 hours after SPRAVATO administration [see *Dosage and Administration* (2.1, 2.4)]. Measure blood pressure around 40 minutes post-dose and subsequently as clinically warranted until values decline. If BP remains high, promptly seek assistance from practitioners experienced in BP management. Refer patients experiencing symptoms of a hypertensive crisis (e.g., chest pain, shortness of breath) or hypertensive encephalopathy (e.g., sudden severe headache, visual disturbances, seizures, diminished consciousness or focal neurological deficits) immediately for emergency care.

Closely monitor blood pressure with concomitant use of SPRAVATO with psychostimulants or monoamine oxidase inhibitors (MAOIs) [see *Drug Interactions* (7.2, 7.3)].

In patients with history of hypertensive encephalopathy, more intensive monitoring, including more frequent blood pressure and symptom assessment, is warranted because these patients are at increased risk for developing encephalopathy with even small increases in blood pressure.

5.7 Cognitive Impairment

Short-Term Cognitive Impairment

In a study in healthy volunteers, a single dose of SPRAVATO caused cognitive performance decline 40 minutes post-dose. Compared to placebo-treated subjects, SPRAVATO-treated subjects required a greater effort to complete cognitive tests at 40 minutes post-dose. Cognitive performance and mental effort were comparable between SPRAVATO and placebo at 2 hours post-dose. Sleepiness was comparable after 4 hours post-dose.

Long-Term Cognitive Impairment

Long-term cognitive and memory impairment have been reported with repeated ketamine misuse or abuse. No adverse effects of SPRAVATO nasal spray on cognitive functioning were observed in a one-year open-label safety study; however, the long-term cognitive effects of SPRAVATO have not been evaluated beyond one year.

5.8 Impaired Ability to Drive and Operate Machinery

Two placebo-controlled studies were conducted to assess the effects of SPRAVATO on the ability to drive [see *Clinical Studies* (14.3)]. The effects of SPRAVATO 84 mg were comparable to placebo at 6 hours and 18 hours post-dose. However, two SPRAVATO-treated subjects in one of the studies discontinued the driving test at 8 hours post-dose because of SPRAVATO-related adverse reactions.

Before SPRAVATO administration, instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination, such as driving a motor vehicle or operating machinery, until the next day following a restful sleep. Patients will need to arrange transportation home following treatment with SPRAVATO.

5.9 Ulcerative or Interstitial Cystitis

Cases of ulcerative or interstitial cystitis have been reported in individuals with long-term off-label use or misuse/abuse of ketamine. In clinical studies with SPRAVATO nasal spray, there was a higher rate of lower urinary tract symptoms (pollakiuria, dysuria, micturition urgency, nocturia, and cystitis) in SPRAVATO-treated patients than in placebo-treated patients [see *Adverse Reactions* (6)]. No cases of esketamine-related interstitial cystitis were observed in any of the studies, which included treatment for up to a year.

Monitor for urinary tract and bladder symptoms during the course of treatment with SPRAVATO, and refer to an appropriate healthcare provider as clinically warranted.

5.10 Embryo-fetal Toxicity

Based on published findings from pregnant animals treated with ketamine, the racemic mixture of arketamine and esketamine, SPRAVATO may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to an infant exposed to SPRAVATO *in utero*. Advise women of reproductive potential to consider pregnancy planning and prevention [see *Use in Specific Populations* (8.1, 8.3)].

6 ADVERSE REACTIONS

The following adverse reactions are discussed in more detail in other sections of the labeling:

- Sedation [see *Warnings and Precautions* (5.1)]
- Dissociation [see *Warnings and Precautions* (5.2)]
- Increase in Blood Pressure [see *Warnings and Precautions* (5.6)]
- Cognitive Impairment [see *Warnings and Precautions* (5.7)]
- Impaired Ability to Drive and Operate Machinery [see *Warnings and Precautions* (5.8)]
- Ulcerative or Interstitial Cystitis [see *Warnings and Precautions* (5.9)]
- Embryo-fetal Toxicity [see *Warnings and Precautions* (5.10)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Patient Exposure

SPRAVATO was evaluated for safety in 1709 patients diagnosed with treatment resistant depression (TRD) [see *Clinical Studies* (14.1, 14.2)] from five Phase 3 studies (3 short-term and 2 long-term studies) and one Phase 2 dose-ranging study. Of all SPRAVATO-treated patients in the completed Phase 3 studies, 479 (30%) received at least 6 months of treatment, and 178 (11%) received at least 12 months of treatment.

Adverse Reactions Leading to Discontinuation of Treatment

In short-term studies in adults < 65 years old (Study 1 pooled with another 4-week study), the proportion of patients who discontinued treatment because of an adverse reaction was 4.6% in patients who received SPRAVATO plus oral AD compared to 1.4% for patients who received placebo nasal spray plus oral AD. For adults ≥ 65 years old, the proportions were 5.6% and 3.1%, respectively. In Study 2, a long-term maintenance study, the discontinuation rates because of an adverse reaction were similar for patients receiving SPRAVATO plus oral AD and placebo nasal spray plus oral AD in the maintenance phase, at 2.6% and 2.1%, respectively. Across all phase 3 studies, adverse reactions leading to SPRAVATO discontinuation

in more than 2 patients were (in order of frequency): anxiety (1.2%), depression (0.9%), blood pressure increased (0.6%), dizziness (0.6%), suicidal ideation (0.5%), dissociation (0.4%), nausea (0.4%), vomiting (0.4%), headache (0.3%), muscular weakness (0.3%), vertigo (0.2%), hypertension (0.2%), panic attack (0.2%) and sedation (0.2%).

Most Common Adverse Reactions

The most commonly observed adverse reactions in TRD patients treated with SPRAVATO plus oral AD (incidence ≥5% and at least twice that of placebo nasal spray plus oral AD) were dissociation, dizziness, nausea, sedation, vertigo, hypoesthesia, anxiety, lethargy, blood pressure increased, vomiting, and feeling drunk. Table 3 shows the incidence of adverse reactions that occurred in TRD patients treated with SPRAVATO plus oral AD at any dose and greater than patients treated with placebo nasal spray plus oral AD.

Table 3: Adverse Reactions Occurring in ≥2% of TRD Patients Treated with SPRAVATO + Oral AD at Any Dose and at a Greater Rate than Patients Treated with Placebo Nasal Spray + Oral AD

	SPRAVATO + Oral AD (N=346)	Placebo + Oral AD (N=222)
Cardiac disorders		
Tachycardia*	6 (2%)	1 (0.5%)
Ear and labyrinth disorders		
Vertigo*	78 (23%)	6 (3%)
Gastrointestinal disorders		
Constipation	11 (3%)	3 (1%)
Diarrhea	23 (7%)	13 (6%)
Dry mouth	19 (5%)	7 (3%)
Nausea	98 (28%)	19 (9%)
Vomiting	32 (9%)	4 (2%)
General disorders and administration site conditions		
Feeling abnormal	12 (3%)	0 (0%)
Feeling drunk	19 (5%)	1 (0.5%)
Investigations		
Blood pressure increased*	36 (10%)	6 (3%)
Nervous system disorders		
Dizziness*	101 (29%)	17 (8%)
Dysarthria*	15 (4%)	0 (0%)
Dysgeusia*	66 (19%)	30 (14%)
Headache*	70 (20%)	38 (17%)
Hypoesthesia*	63 (18%)	5 (2%)
Lethargy*	37 (11%)	12 (5%)
Mental impairment	11 (3%)	2 (1%)
Sedation*	79 (23%)	21 (9%)
Tremor	12 (3%)	2 (1%)
Psychiatric disorders		
Anxiety*	45 (13%)	14 (6%)
Dissociation*	142 (41%)	21 (9%)
Euphoric mood	15 (4%)	2 (1%)
Insomnia	29 (8%)	16 (7%)
Renal and urinary disorders		
Pollakiuria	11 (3%)	1 (0.5%)
Respiratory, thoracic and mediastinal disorders		
Nasal discomfort*	23 (7%)	11 (5%)
Oropharyngeal pain	9 (3%)	5 (2%)
Throat irritation	23 (7%)	9 (4%)
Skin and subcutaneous tissue disorders		
Hyperhidrosis	14 (4%)	5 (2%)

* The following terms were combined:

Anxiety includes: agitation; anticipatory anxiety; anxiety; fear; feeling jittery; irritability; nervousness; panic attack; tension

Blood pressure increased includes: blood pressure diastolic increased; blood pressure increased; blood pressure systolic increased; hypertension

Dissociation includes: delusional perception; depersonalization/derealization disorder; derealization; diplopia; dissociation; dysesthesia; feeling cold; feeling hot; feeling of body temperature change; hallucination; hallucination, auditory; hallucination, visual; hyperacusis; illusion; ocular discomfort; oral dysesthesia; paresthesia; paresthesia oral; pharyngeal paresthesia; photophobia; time perception altered; tinnitus; vision blurred; visual impairment

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Dizziness includes: dizziness; dizziness exertional; dizziness postural; procedural dizziness

Dysarthria includes: dysarthria; slow speech; speech disorder

Dysgeusia includes: dysgeusia; hypogeusia

Headache includes: headache; sinus headache

Hypoesthesia includes: hypoesthesia; hypoesthesia oral, hypoesthesia teeth, pharyngeal hypoesthesia

Lethargy includes: fatigue; lethargy

Nasal discomfort includes: nasal crusting; nasal discomfort; nasal dryness; nasal pruritus

Sedation includes: altered state of consciousness; hypersomnia; sedation; somnolence

Tachycardia includes: extrasystoles; heart rate increased; tachycardia

Vertigo includes: vertigo; vertigo positional

Sedation

Sedation was evaluated by adverse event reports and using the Modified Observer's Alertness/Sedation scale (MOAA/s). In the MOAA/s scale, 5 means "responds readily to name spoken in normal tone" and 0 means "no response after painful trapezius squeeze." Any decrease in MOAA/s from pre-dose is considered to indicate presence of sedation, and such a decrease occurred in a higher number of patients on esketamine than placebo during the short-term trials (Table 4). Dose-related increases in the incidence of sedation were observed in a fixed-dose study [see *Warnings and Precautions* (5.1)].

Table 4: Incidence of Sedation (MOAA/s <5) in Double-Blind, Randomized, Placebo-Controlled Fixed-Dose Study with Patients < 65 Years of Age and Double-Blind, Randomized, Placebo-Controlled Flexible-Dose Study with Patients ≥65 years

	Patients <65 years		Patients ≥65 years	
	Placebo + Oral AD	SPRAVATO + Oral AD	Placebo + Oral AD	SPRAVATO + Oral AD
		56 mg 84 mg		28 to 84 mg
Number of patients*	N=112	N=114 N=114	N=63	N=72
Sedation (MOAA/s <5)	11%	50% 61%	19%	49%

*Patients who were evaluated with MOAA/s

Dissociation/Perceptual Changes

SPRAVATO can cause dissociative symptoms (including derealization and depersonalization) and perceptual changes (including distortion of time and space, and illusions). In clinical trials, dissociation was transient and occurred on the day of dosing. Dissociation was evaluated by adverse event reports and the Clinician-Administered Dissociative States Scale (CADSS) questionnaire. A CADSS total score of more than 4 indicates presence of dissociative symptoms, and such an increase to a score of 4 or more occurred in a higher number of patients on esketamine compared to placebo during the short-term trials (see Table 5). Dose-related increases in the incidence of dissociative symptoms (CADSS total score >4) were observed in a fixed-dose study. Table 5 shows the incidence of dissociation (CADSS total score >4) in a double-blind, randomized, placebo-controlled, fixed-dose study in adults <65 years of age and a double-blind, randomized, placebo-controlled, flexible-dose study with patients ≥ 65 years of age.

Table 5: Incidence of Dissociation (CADSS Total Score >4) in Double-Blind, Randomized, Placebo-Controlled Studies (Fixed-Dose Study with Patients <65 Years and Flexible-Dose Study with Patients ≥65 Years)

	Patients <65 years		Patients ≥65 years	
	Placebo + Oral AD	SPRAVATO + Oral AD	Placebo + Oral AD	SPRAVATO + Oral AD
		56 mg 84 mg		28 to 84 mg
Number of patients	N=113	N=113 N=116	N=65	N=72
CADSS total score >4 and change >0	5%	61% 69%	12%	75%

* Number of patients who were evaluated with CADSS

Increase in Blood Pressure

The mean placebo-adjusted increases in systolic and diastolic blood pressure (SBP and DBP) over time were about 7 to 9 mmHg in SBP and 4 to 6 mmHg in DBP at 40 minutes post-dose and 2 to 5 mmHg in SBP and 1 to 3 mmHg in DBP at 1.5 hours post-dose in patients receiving SPRAVATO plus oral antidepressants (Table 6).

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Table 6: Increases in Blood Pressure in Double-blind, Randomized-controlled, Short-term Trials of SPRAVATO + Oral AD Compared to Placebo Nasal Spray + Oral AD in the Treatment of TRD

	Patients <65 years		Patients ≥65 years	
	SPRAVATO + Oral AD	Placebo + Oral AD	SPRAVATO + Oral AD	Placebo + Oral AD
	N=346	N=222	N=72	N=65
Systolic blood pressure				
≥180 mmHg	9 (3%)	---	2 (3%)	1 (2%)
≥40 mmHg increase	29 (8%)	1 (0.5%)	12 (17%)	1 (2%)
Diastolic blood pressure				
≥110 mmHg	13 (4%)	1 (0.5%)	---	---
≥25 mmHg increase	46 (13%)	6 (3%)	10 (14%)	2 (3%)

Nausea and Vomiting

SPRAVATO can cause nausea and vomiting (Table 7). Most of these events occurred on the day of dosing and resolved the same day, with the median duration not exceeding 1 hour in most subjects across dosing sessions. Rates of reported nausea and vomiting decreased over time across dosing sessions from the first week of treatment in the short-term studies, as well as over time with long-term treatment (Table 7).

Table 7: Incidence and Severity of Nausea and Vomiting in Double-blind, Randomized-controlled Fixed-dose Study

Treatment (+ Oral AD)	Nausea			Vomiting	
	N	All	Severe	All	Severe
SPRAVATO 56 mg	115	31 (27%)	0	7 (6%)	0
SPRAVATO 84 mg	116	37 (32%)	4 (3%)	14 (12%)	3 (3%)
Placebo Nasal Spray	113	12 (11%)	0	2 (2%)	0

Sense of Smell

Sense of smell was assessed over time; no difference was observed between patients treated with SPRAVATO plus oral AD and those treated with placebo nasal spray plus oral AD during the double-blind maintenance phase of Study 2 [see *Clinical Studies* (14.2)].

7 DRUG INTERACTIONS

7.1 Central Nervous System Depressants

Concomitant use with CNS depressants (e.g., benzodiazepines, opioids, alcohol) may increase sedation [see *Warnings and Precautions* (5.1)]. Closely monitor for sedation with concomitant use of SPRAVATO with CNS depressants.

7.2 Psychostimulants

Concomitant use with psychostimulants (e.g., amphetamines, methylphenidate, modafinil, armodafinil) may increase blood pressure [see *Warnings and Precautions* (5.6)]. Closely monitor blood pressure with concomitant use of SPRAVATO with psychostimulants.

7.3 Monoamine Oxidase Inhibitors (MAOIs)

Concomitant use with monoamine oxidase inhibitors (MAOIs) may increase blood pressure [see *Warnings and Precautions* (5.6)]. Closely monitor blood pressure with concomitant use of SPRAVATO with MAOIs.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to antidepressants, including SPRAVATO, during pregnancy. Healthcare providers are encouraged to register patients by contacting the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>.

Risk Summary

SPRAVATO is not recommended during pregnancy. There are insufficient data on SPRAVATO use in pregnant women to draw conclusions about any drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. Based on published findings from pregnant animals treated with ketamine, the racemic mixture of arketamine and esketamine, SPRAVATO may cause fetal harm when administered to pregnant women (see *Data*). Advise pregnant women of the potential risk to an infant exposed to SPRAVATO *in utero*. There are risks to the mother associated with untreated depression in pregnancy (see *Clinical Considerations*). If a woman becomes pregnant while being treated with SPRAVATO, treatment with esketamine should be discontinued and the patient should be counseled about the potential risk to the fetus.

Published studies in pregnant primates demonstrate that the administration of drugs that block N-methyl-D-aspartate (NMDA) receptors during the period of peak brain development increases neuronal apoptosis in the developing brain of the offspring. There are no data on pregnancy exposures in primates corresponding to periods prior to the third trimester in humans [see *Use in Specific Populations* (8.2)].

In an embryo-fetal reproduction study in rabbits, skeletal malformations were noted at maternally toxic doses when ketamine was intranasally administered with a No Observed Adverse Effect Level (NOAEL) at estimated esketamine exposures 0.3 times the exposures at the maximum recommended human dose (MRHD) of 84 mg/day. In addition, intranasal administration of esketamine to pregnant rats during pregnancy and lactation at exposures that were similar to those at the MRHD resulted in a delay in sensorimotor development in pups during the preweaning period and a decrease in motor activity in the post-weaning period.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Clinical Considerations

Disease-Associated Maternal and/or Embryo-Fetal Risk

A prospective, longitudinal study followed 201 pregnant women with a history of major depressive disorder who were euthymic and taking antidepressants at the beginning of pregnancy. The women who discontinued antidepressants during pregnancy were more likely to experience a relapse of major depression than women who continued antidepressants. Consider the risk of untreated depression when discontinuing or changing treatment with antidepressant medication during pregnancy and postpartum.

Data

Animal Data

Based on published data, when female monkeys were treated intravenously with racemic ketamine at anesthetic dose levels in the third trimester of pregnancy, neuronal cell death was observed in the brains of their fetuses. This period of brain development translates into the third trimester of human pregnancy. The clinical significance of these findings is not clear; however, studies in juvenile animals suggest neuroapoptosis correlates with long-term cognitive deficits.

Racemic ketamine was administered intranasally to pregnant rats during the period of organogenesis at doses of 15, 50, and 150 mg/kg/day. The No Observed Adverse Effect Level (NOAEL) for embryo-fetal toxicity in rats was the highest dose of 150 mg/kg/day. Estimating 50% of the exposure to be from esketamine, the NOAEL associated with esketamine plasma exposure (AUC) is 12-times the AUC exposure at the MRHD of 84 mg/day. In pregnant rabbits, racemic ketamine was administered intranasally from gestational day 6 to 18 at doses of 10, 30, and 100 mg/kg/day. The high dose was lowered from 100 to 50 mg/kg after 5 days of dosing due to excessive mortality in the pregnant rabbits. Skeletal malformations were observed at doses ≥ 30 mg/kg/day, which were maternally toxic. The NOAEL for skeletal malformations was associated with a plasma esketamine exposure (AUC) that was 0.3 times the AUC exposure at MRHD of 84 mg/day.

Administration of esketamine to pregnant rats during pregnancy and lactation at intranasal doses equivalent to 4.5, 15, and 45 mg/kg/day (based on a 200-gram rat) produced AUC exposures 0.07, 0.5, and 0.7 times the MRHD of 84 mg/day, respectively. Maternal toxicity was observed at doses ≥ 15 mg/kg/day. In addition, a dose-dependent delay in the age of attainment of Preyer response reflex was observed in pups at all doses during the preweaning period. This sensory/motor developmental measure was tested starting on postnatal day (PND) 9, and the effect normalized by PND 19 in treatment groups as compared with PND 14 for the majority of the control animals. There is no NOAEL for this delay in sensory/motor response observed in pups during the preweaning period. During the postweaning period, a decrease in motor activity was observed at doses ≥ 15 mg/kg which is 0.5-times the human exposure at the MRHD of 84 mg/day. The NOAEL for maternal toxicity and decreased motor activity during the postweaning period was 4.5 mg/kg/day which was associated with a plasma exposure (AUC) that was 0.07-times the AUC exposure at MRHD of 84 mg/day.

8.2 Lactation

Risk Summary

Esketamine is present in human milk. There are no data on the effects of SPRAVATO on the breastfed infant or on milk production. Published studies in juvenile animals report neurotoxicity (see *Data*). Because of the potential for neurotoxicity, advise patients that breast-feeding is not recommended during treatment with SPRAVATO.

Data

Published juvenile animal studies demonstrate that the administration of drugs that block NMDA receptors, such as ketamine, during the period of rapid brain growth or synaptogenesis, results in widespread neuronal and oligodendrocyte

cell loss in the developing brain and alterations in synaptic morphology and neurogenesis. Based on comparisons across species, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life, but this window may extend out to approximately 3 years of age in humans.

8.3 Females and Males of Reproductive Potential

Contraception

Based on published animal reproduction studies, SPRAVATO may cause embryo-fetal harm when administered to a pregnant woman [see *Warnings and Precautions* (5.10) and *Use in Specific Populations* (8.1)]. However, it is not clear how these animal findings relate to females of reproductive potential treated with the recommended clinical dose. Consider pregnancy planning and prevention for females of reproductive potential during treatment with SPRAVATO.

8.4 Pediatric Use

The safety and effectiveness of SPRAVATO in pediatric patients have not been established.

8.5 Geriatric Use

Of the total number of patients in Phase 3 clinical studies exposed to SPRAVATO, (N=1601), 194 (12%) were 65 years of age and older, and 25 (2%) were 75 years of age and older. No overall differences in the safety profile were observed between patients 65 years of age and older and patients younger than 65 years of age.

The mean esketamine C_{max} and AUC values were higher in elderly patients compared with younger adult patients [see *Clinical Pharmacology* (12.3)].

The efficacy of SPRAVATO for the treatment of TRD in geriatric patients was evaluated in a 4-week, randomized, double-blind study comparing flexibly-dosed intranasal SPRAVATO plus a newly initiated oral antidepressant compared to intranasal placebo plus a newly initiated oral antidepressant in patients ≥ 65 years of age. SPRAVATO was initiated at 28 mg twice weekly and could be titrated to 56 mg or 84 mg administered twice-weekly. At the end of four weeks, there was no statistically significant difference between groups on the primary efficacy endpoint of change from baseline to Week 4 on the Montgomery-Asberg Depression Rating Scale (MADRS).

8.6 Hepatic Impairment

The mean esketamine AUC and $t_{1/2}$ values were higher in patients with moderate hepatic impairment compared to those with normal hepatic function [see *Clinical Pharmacology* (12.3)]. SPRAVATO-treated patients with moderate hepatic impairment may need to be monitored for adverse reactions for a longer period of time.

SPRAVATO has not been studied in patients with severe hepatic impairment (Child-Pugh class C). Use in this population is not recommended [see *Clinical Pharmacology* (12.3)].

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

SPRAVATO contains esketamine hydrochloride, the (S)-enantiomer of ketamine and a Schedule III controlled substance under the Controlled Substances Act.

9.2 Abuse

Individuals with a history of drug abuse or dependence may be at greater risk for abuse and misuse of SPRAVATO. Abuse is the intentional, non-therapeutic use of a drug, even once, for its psychological or physiological effects. Misuse is the intentional use, for therapeutic purposes, of a drug by an individual in a way other than prescribed by a health care provider or for whom it was not prescribed. Careful consideration is advised prior to use of individuals with a history of substance use disorder, including alcohol.

SPRAVATO may produce a variety of symptoms including anxiety, dysphoria, disorientation, insomnia, flashback, hallucinations, and feelings of floating, detachment and to be "spaced out". Monitoring for signs of abuse and misuse is recommended.

Abuse Potential Study

A cross-over, double-blind abuse potential study of SPRAVATO and ketamine was conducted in recreational polydrug users (n=34) who had experience with perception-altering drugs, including ketamine. Ketamine, the racemic mixture of arketamine and esketamine, is a Schedule III controlled substance and has known abuse potential. In this study, the mean "Drug Liking at the Moment" and "Take Drug Again" scores for single doses of intranasal SPRAVATO (84 mg and 112 mg – the maximum recommended dose and 1.3 times the maximum recommended dose, respectively) were similar to these scores in the intravenous ketamine (0.5 mg/kg infused over 40 minutes) control group. However, these scores were greater in the SPRAVATO and ketamine groups compared to the placebo group. The 112 mg dose of intranasal SPRAVATO was associated with significantly higher scores for "Hallucinating," "Floating," "Detached," and "Spaced Out" than the 84 mg dose of intranasal SPRAVATO and the intravenous ketamine dose.

9.3 Dependence

Physical dependence has been reported with prolonged use of ketamine. Physical dependence is a state that develops as a result of physiological adaptation in response to repeated drug use, manifested by withdrawal signs and symptoms after abrupt discontinuation or significant dosage reduction of a drug. There were no withdrawal symptoms captured up to 4 weeks after cessation of esketamine treatment. Withdrawal symptoms have been reported after the discontinuation of frequently used (more than weekly) large doses of ketamine for long periods of time. Such withdrawal symptoms are likely to occur if esketamine were similarly abused. Reported symptoms of withdrawal associated with daily intake of large doses of ketamine include craving, fatigue, poor appetite, and anxiety. Therefore, monitor SPRAVATO-treated patients for symptoms and signs of physical dependence upon the discontinuation of the drug.

Tolerance has been reported with prolonged use of ketamine. Tolerance is a physiological state characterized by a reduced response to a drug after repeated administration (i.e., a higher dose of a drug is required to produce the same effect that was once obtained at a lower dose). Similar tolerance would be expected with prolonged use of esketamine.

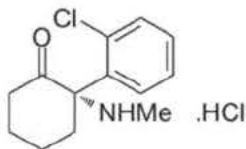
10 OVERDOSAGE

Management of Overdose

There is no specific antidote for esketamine overdose. In the case of overdose, the possibility of multiple drug involvement should be considered. Contact a Certified Poison Control Center for the most up to date information on the management of overdose (1-800-222-1222 or www.poison.org).

11 DESCRIPTION

SPRAVATO contains esketamine hydrochloride, a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist. Esketamine is the S-enantiomer of racemic ketamine. The chemical name is (S)-2-(o-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride. Its molecular formula is $C_{13}H_{16}ClNO \cdot HCl$ and its molecular weight is 274.2. The structural formula is:



Esketamine hydrochloride is a white or almost white crystalline powder that is freely soluble in water and in methanol, and soluble in ethanol.

SPRAVATO nasal spray is intended for nasal administration. Esketamine hydrochloride is contained as a solution in a stoppered glass vial within the nasal spray device. Each device delivers two sprays with a total of 32.3 mg of esketamine hydrochloride (equivalent to 28 mg of esketamine) in 0.2 mL of a clear, colorless aqueous solution with a pH of 4.5.

The inactive ingredients are citric acid monohydrate, edetate disodium, sodium hydroxide, and water for injection.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Esketamine, the S-enantiomer of racemic ketamine, is a non-selective, non-competitive antagonist of the N-methyl-D-aspartate (NMDA) receptor, an ionotropic glutamate receptor. The mechanism by which esketamine exerts its antidepressant effect is unknown. The major circulating metabolite of esketamine (noresketamine) demonstrated activity at the same receptor with less affinity.

12.2 Pharmacodynamics

Cardiac Electrophysiology

The effect of SPRAVATO (84 mg nasal spray and 0.8 mg/kg esketamine intravenously infused over 40 minutes) on the QTc interval was evaluated in a randomized, double-blind, placebo-, and positive-controlled (moxifloxacin 400 mg), 4-period, crossover study in 60 healthy subjects. A large increase in heart rate (i.e. >10 bpm) was observed in both intranasal and intravenous esketamine treatment groups. The totality of evidence from the nonclinical and clinical data indicates a lack of clinically relevant QTc prolongation at the therapeutic dose of esketamine.

12.3 Pharmacokinetics

Esketamine exposure increases with dose from 28 mg to 84 mg. The increase in C_{max} and AUC values was less than dose-proportional between 28 mg and 56 mg or 84 mg, but it was nearly dose proportional between 56 mg and 84 mg. No accumulation of esketamine in plasma was observed following twice a week administration.

Absorption

The mean absolute bioavailability is approximately 48% following nasal spray administration.

The time to reach maximum esketamine plasma concentration is 20 to 40 minutes after the last nasal spray of a treatment session.

The inter-subject variability of esketamine ranges from 27% to 66% for C_{max} and 18% to 45% for AUC_{∞} . The intra-subject variability of esketamine is approximately 15% for C_{max} and 10% for AUC_{∞} .

Distribution

The mean steady-state volume of distribution of esketamine administered by the intravenous route is 709 L.

Protein binding of esketamine was approximately 43% to 45%.

The brain-to-plasma ratio of noresketamine is 4- to 6-times lower than that of esketamine.

Elimination

After C_{max} was reached following intranasal administration, the decline in plasma esketamine concentrations was biphasic, with rapid decline for the initial 2 to 4 hours and a mean terminal half-life ($t_{1/2}$) that ranged from 7 to 12 hours. The mean clearance of esketamine is approximately 89 L/hour following intravenous administration. The elimination of the major metabolite, noresketamine, from plasma is slower than esketamine. The decline of noresketamine plasma concentrations is biphasic, with rapid decline for the initial 4 hours and a mean terminal $t_{1/2}$ of approximately 8 hours.

Metabolism

Esketamine is primarily metabolized to noresketamine metabolite via cytochrome P450 (CYP) enzymes CYP2B6 and CYP3A4 and to a lesser extent CYP2C9 and CYP2C19. Noresketamine is metabolized via CYP-dependent pathways and certain subsequent metabolites undergo glucuronidation.

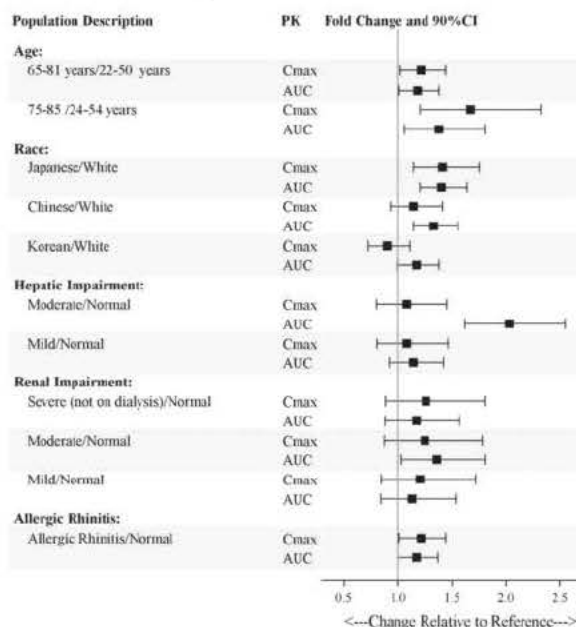
Excretion

Less than 1% of a dose of nasal esketamine is excreted as unchanged drug in urine. Following intravenous or oral administration, esketamine-derived metabolites were primarily recovered in urine ($\geq 78\%$ of a radiolabeled dose) and to a lesser extent in feces ($\leq 2\%$ of a radiolabeled dose).

Specific Populations

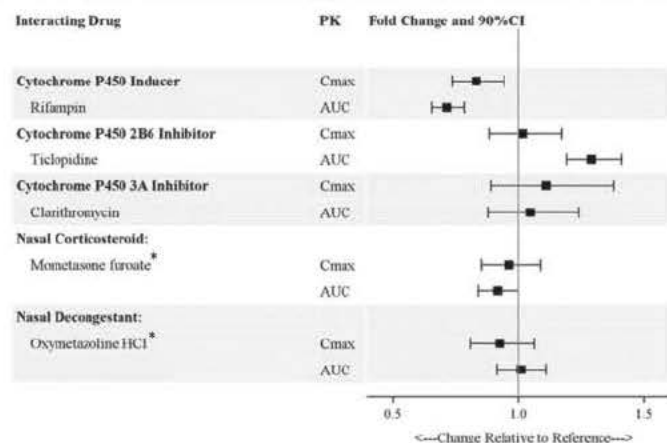
Exposures of esketamine in specific populations are summarized in Figure 1. No significant differences in the pharmacokinetics of SPRAVATO nasal spray were observed for sex and total body weight (>39 to 170 kg) based on population PK analysis. There is no clinical experience with SPRAVATO nasal spray in patients on renal dialysis or with severe (Child-Pugh class C) hepatic impairment.

Figure 1: Effect of Specific Populations on the Pharmacokinetics of Esketamine

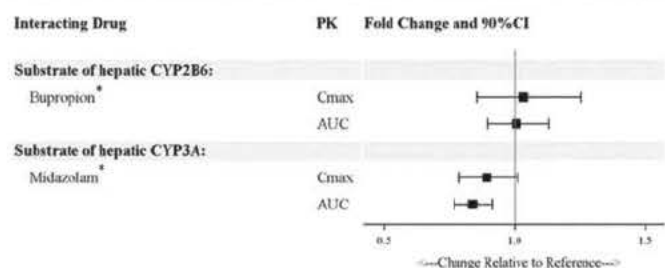


Drug Interaction Studies

The effect of other drugs on the exposures of intranasally administered esketamine are summarized in Figure 2. The effect of SPRAVATO on the exposures of other drugs are summarized in Figure 3. Based on these results, none of the drug-drug interactions are clinically significant.

Figure 2: Effect of Co-administered Drugs on the Pharmacokinetics of Esketamine

*Administered 1 hour before intranasal esketamine

Figure 3: Effect of Esketamine on the Pharmacokinetics of Co-Administered Drugs

* The potential for cytochrome P450 induction by esketamine was assessed. Intranasal esketamine (84 mg) was administered twice weekly for 2 weeks. Bupropion or midazolam was administered at baseline and 24 hours after the last dose of esketamine.

In Vitro Studies

Enzyme Systems: Esketamine has modest induction effects on CYP2B6 and CYP3A4 in human hepatocytes. Esketamine and its major metabolites do not induce CYP1A2. Esketamine and its major circulating metabolites did not show inhibition potential against CYPs and UGTs, except for a weak reversible inhibition of noreketamine on CYP3A4.

Transporter Systems: Esketamine is not a substrate of transporters P-glycoprotein (P-gp; multidrug resistance protein 1), breast cancer resistance protein (BCRP), or organic anion transporter (OATP) 1B1, or OATP1B3. Esketamine and its major circulating metabolites do not inhibit these transporters or multi-drug and toxin extrusion 1 (MATE1) and MATE2-K, or organic cation transporter 2 (OCT2), OAT1, or OAT3.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Once-daily intranasal administration of esketamine at doses equivalent to 4.5, 15, and 45 mg/kg/day (based on a 200-gram rat) did not increase the incidence of tumors in a 2-year rat carcinogenicity study. At the highest dose, the AUC exposure to esketamine was lower than the human exposure (AUC) at the maximum recommended human dose (MRHD) of 84 mg. Once-daily subcutaneous administration of esketamine up to 75 mg/kg/day (reduced to 40 mg/kg/day during week 17) did not increase the incidence of tumors in a 6-month study in transgenic (Tg.rash2) mice.

Mutagenesis

Racemic ketamine was not mutagenic with or without metabolic activation in the Ames test, but was positive in an *in vitro* mouse lymphoma test in the presence of metabolic activation. Intraperitoneally-injected ketamine did not show genotoxic properties in an *in vivo* bone marrow micronucleus test in mice.

Genotoxic effects with esketamine were seen in a screening *in vitro* micronucleus test in the presence of metabolic activation. However, intravenously-administered esketamine was devoid of genotoxic properties in an *in vivo* Comet assay in rat liver cells.

Impairment of Fertility

Esketamine was administered intranasally to both male and female rats before mating, throughout the mating period, and up to day 7 of gestation at doses equivalent to 4.5, 15, and 45 mg/kg/day (based on a 200-gram rat), which are approximately 0.05, 0.3, and 0.6-times the maximum recommended human dose (MRHD) of 84 mg/day based on mean AUC exposures, respectively. Estrous cycle irregularities were observed at the high dose of 45 mg/kg/day and increased time to mate was observed at doses ≥ 15 mg/kg/day without an overall effect on mating or fertility indices. The No Observed Adverse Effect Level (NOAEL) for mating and fertility is 45 mg/kg/day which is 0.6 times the esketamine exposures at MRHD of 84 mg/day.

13.2 Animal Toxicology and/or Pharmacology

Neurotoxicity

In a single-dose neuronal toxicity study where esketamine was administered intranasally to adult female rats, there were no findings of neuronal vacuolation in the brain up to an estimated dose equivalent of 45 mg/kg for a 200-gram rat with a safety margin of 1.8 and 4.5 times the clinical exposures for AUC and C_{max}, respectively, to the MRHD of 84 mg/day. In a second single dose neurotoxicity study conducted with intranasally administered esketamine to adult female rats, there were no findings of neuronal necrosis up to a dose equivalent of 270 mg/kg for a 200-gram rat which has a safety margin of 18-fold and 23-fold, respectively, to AUC and C_{max} exposures at the MRHD of 84 mg/day. Neuronal vacuolation was not examined in this study.

In a single-dose neuronal toxicity study in adult rats, subcutaneously administered racemic ketamine caused neuronal vacuolation in layer I of the retrosplenial cortex of the brain without neuronal necrosis at a dose of 60 mg/kg. The NOAEL for vacuolation in this study was 15 mg/kg. Estimating 50% of the exposure to be from esketamine, the NOAEL for neuronal vacuolation is 1.6-times and 4.5-times and the NOAEL for neuronal necrosis is 10-times and 16-times exposures, respectively, for AUC and C_{max} to the clinical exposure at the MRHD of 84 mg/day. The relevance of these findings to humans is unknown.

14 CLINICAL STUDIES

14.1 Treatment Resistant Depression

Short-Term Study

SPRAVATO was evaluated in a randomized, placebo-controlled, double-blind, multicenter, short-term (4-week), Phase 3 study (Study 1; NCT02418585) in adult patients 18 to <65 years old with treatment-resistant depression (TRD). Patients in Study 1 met DSM-5 criteria for major depressive disorder (MDD) and in the current depressive episode, had not responded adequately to at least two different antidepressants of adequate dose and duration. After discontinuing prior antidepressant treatments, patients in Study 1 were randomized to receive twice weekly doses of intranasal SPRAVATO (flexible dose; 56 mg or 84 mg) or intranasal placebo. All patients also received open-label concomitant treatment with a newly initiated daily oral antidepressant (AD) (duloxetine, escitalopram, sertraline, or extended-release venlafaxine as determined by the investigator based on patient's prior treatment history). SPRAVATO could be titrated up to 84 mg starting with the second dose based on investigator discretion.

The demographic and baseline disease characteristics of patients in Study 1 were similar for the SPRAVATO and placebo nasal spray groups. Patients had a median age of 47 years (range 19 to 64 years) and were 62% female, 93% Caucasian, and 5% Black. The newly initiated oral AD was an SSRI in 32% of patients and an SNRI in 68% of patients.

In Study 1, the primary efficacy measure was change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score at the end of the 4-week double-blind induction phase. The MADRS is a ten-item, clinician-rated scale used to assess severity of depressive symptoms. Scores on the MADRS range from 0 to 60, with higher scores indicating more severe depression. SPRAVATO plus a newly initiated oral AD demonstrated statistical superiority on the primary efficacy measure compared to placebo nasal spray plus a newly initiated oral AD (see Table 8).

Table 8: Primary Efficacy Results for Change from Baseline in MADRS Total Score at Week 4 in Patients with TRD in Study 1 (MMRM)

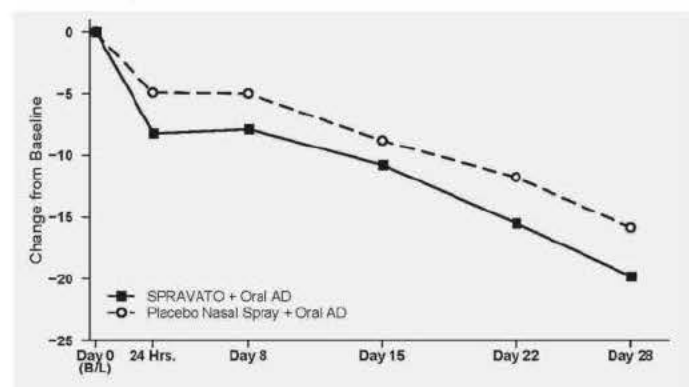
Treatment Group	Number of Patients	Mean Baseline Score (SD)	LS Mean (SE) Change from Baseline to end of Week 4	LS Mean Difference (95% CI)*
SPRAVATO (56 mg or 84 mg) + Oral AD†	114	37.0 (5.7)	-19.8 (1.3)	-4.0 (-7.3; -0.6)
Placebo nasal spray + Oral AD	109	37.3 (5.7)	-15.8 (1.3)	-

MMRM=mixed model for repeated measures; SD=standard deviation; SE=standard error; LS Mean=least-squares mean; CI=confidence interval; AD=antidepressant
 * Difference (SPRAVATO + Oral AD minus Placebo nasal spray + Oral AD) in least-squares mean change from baseline

† SPRAVATO + Oral AD was statistically significantly superior to placebo nasal spray + oral AD

Time Course of Treatment Response

Figure 4 shows the time course of response for the primary efficacy measure (MADRS) in Study 1. Most of SPRAVATO's treatment difference compared to placebo was observed at 24 hours. Between 24 hours and Day 28, both the SPRAVATO and placebo groups continued to improve; the difference between the groups generally remained but did not appear to increase over time through Day 28. At Day 28, 67% of the patients randomized to SPRAVATO were receiving 84 mg twice weekly.

Figure 4: Least Squares Mean Change from Baseline in MADRS Total Score Over Time in Patients with TRD in Study 1* (Full Analysis Set) – MMRM Analysis

* Note: In this flexible-dose study, dosing was individualized based on efficacy and tolerability. Few subjects (<10%) had reduction in SPRAVATO dosage from 84 mg to 56 mg twice weekly.

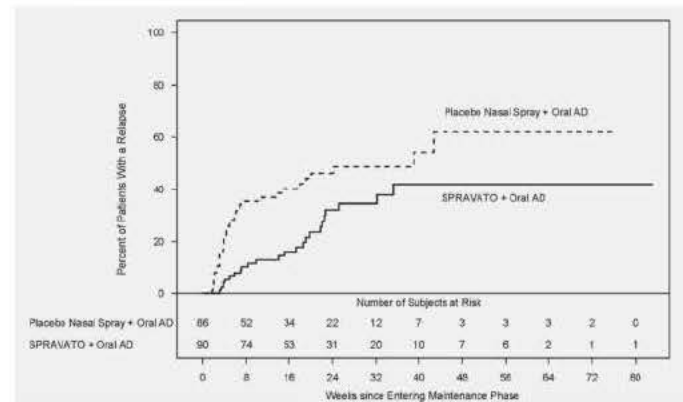
14.2 Treatment-Resistant Depression – Long-term Study

Study 2 (NCT02493868) was a long-term randomized, double-blind, parallel-group, multicenter maintenance-of-effect study in adults 18 to <65 years of age who were known remitters and responders to SPRAVATO. Patients in this study were responders in one of two short-term controlled trials (Study 1 and another 4-week study) or in an open-label direct-enrollment study in which they received flexibly-dosed SPRAVATO (56 mg or 84 mg twice weekly) plus daily oral AD in an initial 4-week phase.

Stable remission was defined as a MADRS total score ≤ 12 for at least 3 of the last 4 weeks. Stable response was defined as a MADRS total score reduction ≥ 50% for at least 3 of the last 4 weeks and not in remission. After at least 16 initial weeks of treatment with SPRAVATO and an oral AD, stable remitters and stable responders were randomized separately to continue intranasal treatment with SPRAVATO or switch to placebo nasal spray, in both cases with continuation of their oral AD. The primary study endpoint was time to relapse in the stable remitter group. Relapse was defined as a MADRS total score ≥ 22 for 2 consecutive weeks or hospitalization for worsening depression or any other clinically relevant event indicative of relapse.

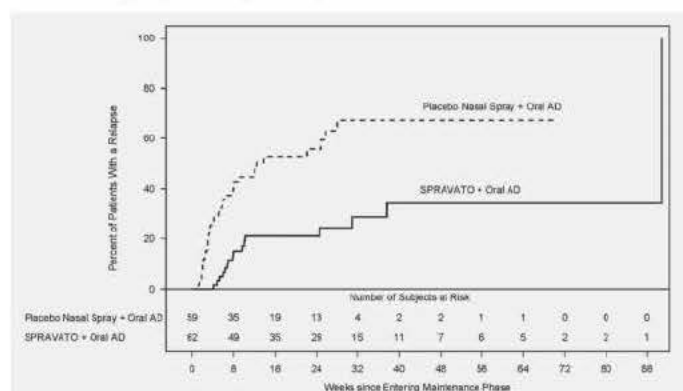
The demographic and baseline disease characteristics of the two groups were similar. Patients had a median age of 48 years (range 19 to 64 years) and were 66% female, 90% Caucasian, and 4% Black.

Patients in stable remission who continued treatment with SPRAVATO plus oral AD experienced a statistically significantly longer time to relapse of depressive symptoms than did patients on placebo nasal spray plus an oral AD (see Figure 5).

Figure 5: Time to Relapse in Patients with TRD in Stable Remission in Study 2* (Full Analysis Set)

* Note: The estimated hazard ratio (95% CI) of SPRAVATO + Oral AD relative to Placebo nasal spray + Oral AD based on weighted estimates was 0.49 (95% CI: 0.29, 0.84). However, the hazard ratio did not appear constant throughout the trial.

Time to relapse was also significantly delayed in the stable responder population. These patients experienced a statistically significantly longer time to relapse of depressive symptoms than patients on placebo nasal spray plus oral AD (see Figure 6).

Figure 6: Time to Relapse in Patients in Stable Response in TRD Patients in Study 2* (Full Analysis Set)

* Note: The estimated hazard ratio (95% CI) of SPRAVATO + Oral AD relative to Placebo nasal spray + Oral AD based on Cox proportional hazards model was 0.30 (95% CI: 0.16, 0.55).

In Study 2, based on depressive symptomatology, the majority of stable remitters (69%) received every-other-week dosing for the majority of time during the maintenance phase; 23% of stable remitters received weekly dosing. Among stable responders, 34% received every-other-week dosing and 55% received weekly dosing the majority of time during the maintenance phase. Of the patients randomized to SPRAVATO, 39% received the 56 mg dose and 61% received the 84 mg dose.

14.3 Effects on Driving

Two studies were conducted to assess the effects of SPRAVATO on driving skills; one study in adult patients with major depressive disorder (Study 3) and one study in healthy subjects (Study 4). On-road driving performance was assessed by the mean standard deviation of the lateral position (SDLP), a measure of driving impairment.

A single-blind, placebo-controlled study in 25 adult patients with major depressive disorder evaluated the effects of a single 84-mg dose of intranasal SPRAVATO on next day driving and the effect of repeated administration of 84 mg of intranasal SPRAVATO on same-day driving performance (Study 3). For the single dose treatment phase, an ethanol-containing beverage was used as a positive control. The SDLP after administration of single 84-mg dose of SPRAVATO nasal spray was similar to placebo 18 hours post-dose. For the multiple dose treatment phase, the SDLP after repeated administration of 84 mg intranasal SPRAVATO was similar to placebo 6 hours post-dose on Day 11, Day 18, and Day 25.

A randomized, double-blind, cross-over, placebo-controlled study in 23 healthy subjects evaluated the effects of a single 84-mg dose of esketamine nasal spray on driving (Study 4). Mirtazapine (30 mg) was used as a positive control. Driving performance was assessed at 8 hours after SPRAVATO or mirtazapine administration. The SDLP 8 hours after SPRAVATO nasal spray administration was similar to placebo. Two subjects discontinued the driving test after receiving SPRAVATO because of a perceived inability to drive after experiencing post-dose adverse reactions; one subject reported pressure behind the eyes and paresthesia of the hands and feet, the other reported headache with light sensitivity and anxiety.

16 HOW SUPPLIED/STORAGE AND HANDLING

SPRAVATO nasal spray is available as an aqueous solution of esketamine hydrochloride in a stoppered glass vial within a nasal spray device. Each nasal spray device delivers two sprays containing a total of 28 mg of esketamine (supplied as 32.3 mg of esketamine hydrochloride).

SPRAVATO is available in the following presentations:

- 56 mg Dose Kit: Unit-dose carton containing two 28 mg nasal spray devices (56 mg total dose) (NDC 50458-028-02).
- 84 mg Dose Kit: Unit-dose carton containing three 28 mg nasal spray devices (84 mg total dose) (NDC 50458-028-03).

Within each kit, each 28 mg device is individually packaged in a sealed blister (NDC 50458-028-00).

Storage

Store at 20° to 25°C (68° to 77°F); excursions permitted from 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

Disposal

SPRAVATO nasal spray devices must be handled with adequate security, accountability, and proper disposal, per facility procedure for a Schedule III drug product, and per applicable federal, state, and local regulations.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide).

Sedation and Dissociation

Inform patients that SPRAVATO has potential to cause sedation, dissociative symptoms, perception disturbances, dizziness, vertigo, and anxiety. Advise patients that they will need to be observed by a healthcare provider until these effects resolve [see Boxed Warning, Warnings and Precautions (5.1), Warnings and Precautions (5.2)].

Potential for Abuse, Misuse, and Dependence

Advise patients that SPRAVATO is a federally controlled substance because it can be abused or lead to dependence [see Warnings and Precautions (5.3), Drug Abuse and Dependence (9)].

SPRAVATO Risk Evaluation and Mitigation Strategy (REMS)

SPRAVATO is available only through a restricted program called the SPRAVATO REMS [see Warnings and Precautions (5.4)]. Inform the patient of the following notable requirements:

- Patients must be enrolled in the SPRAVATO REMS Program prior to administration.
- SPRAVATO must be administered under the direct observation of a healthcare provider.
- Patients must be monitored by a healthcare provider for at least 2 hours after administration of SPRAVATO.

Suicidal Thoughts and Behaviors

Advise patients and caregivers to look for the emergence of suicidality, especially early during treatment and when the dosage is adjusted [see Boxed Warning and Warnings and Precautions (5.5)].

Increases in Blood Pressure

Advise patients that SPRAVATO can cause increases in blood pressure. Inform patients that after treatment sessions they should be advised that they may need to be observed by a healthcare provider until these effects resolve [see Warnings and Precautions (5.6)].

Impaired Ability to Drive and Operate Machinery

Caution patients that SPRAVATO may impair their ability to drive or operate machinery. Instruct patients not to engage in potentially hazardous activities requiring complete mental alertness and motor coordination such as driving a motor vehicle or operating machinery until the next day after a restful sleep. Advise patients that they will need someone to drive them home after each treatment session [see Warnings and Precautions (5.8)].

Pregnancy

Advise pregnant women and women of reproductive potential of the potential risk to a fetus. Advise patients to notify their healthcare provider if they are pregnant or intend to become pregnant during treatment with SPRAVATO. Advise patients that there is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to SPRAVATO during pregnancy. [See Use in Specific Populations (8.1)].

Lactation

Advise women not to breastfeed during treatment with SPRAVATO [see Use in Specific Populations (8.2)].

Manufactured by:
Renaissance Lakewood LLC
Lakewood, NJ 08701

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

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MEDICATION GUIDE
SPRAVATO™ (sprah vah' toe) CIII
(esketamine)
nasal spray

What is the most important information I should know about SPRAVATO?

SPRAVATO can cause serious side effects including:

- **Sedation and dissociation.** SPRAVATO may cause sleepiness (sedation), fainting, dizziness, spinning sensation, anxiety, or feeling disconnected from yourself, your thoughts, feelings, space and time (dissociation).
 - Tell your healthcare provider right away if you feel like you cannot stay awake or if you feel like you are going to pass out.
 - Your healthcare provider must monitor you for serious side effects for at least 2 hours after taking SPRAVATO. Your healthcare provider will decide when you are ready to leave the healthcare setting.
- **Abuse and misuse.** There is a risk for abuse and physical and psychological dependence with SPRAVATO treatment. Your healthcare provider should check you for signs of abuse and dependence before and during treatment with SPRAVATO.
 - Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
 - Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **SPRAVATO Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, and abuse and misuse, SPRAVATO is only available through a restricted program called the SPRAVATO Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO can only be administered at healthcare settings certified in the SPRAVATO REMS Program and to patients enrolled in the program.
- **Increased risk of suicidal thoughts or actions.** SPRAVATO may cause worsening of depression and suicidal thoughts and behaviors, especially during the first few months of treatment and when the dose is changed. Depression and other serious mental illnesses are the most important causes of suicidal thoughts and actions. Some people may have a higher risk of having suicidal thoughts or actions. These include people who have (or have a family history of) depression or a history of suicidal thoughts or actions.

How can I watch for and try to prevent suicidal thoughts and actions?

- Pay close attention to any changes, especially sudden changes, in mood, behavior, thoughts, or feelings, or if you develop suicidal thoughts or actions.
- Tell your healthcare provider right away if you have any new or sudden changes in mood, behavior, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled. Call your healthcare provider between visits as needed, especially if you have concerns about symptoms.

Tell your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:

- | | |
|-----------------------------------|---|
| ◦ attempts to commit suicide | ◦ worsening depression |
| ◦ thoughts about suicide or dying | ◦ other unusual changes in behavior or mood |

SPRAVATO is not for use in children.

What is SPRAVATO?

SPRAVATO is a prescription medicine, used along with an antidepressant taken by mouth, for treatment-resistant depression (TRD) in adults.

SPRAVATO is not for use as a medicine to prevent or relieve pain (anesthetic). It is not known if SPRAVATO is safe or effective as an anesthetic medicine.

It is not known if SPRAVATO is safe and effective in children.

Do not take SPRAVATO if you:

- have blood vessel (aneurysmal vascular) disease (including in the brain, chest, abdominal aorta, arms and legs)
- have an abnormal connection between your veins and arteries (arteriovenous malformation)
- have a history of bleeding in the brain
- are allergic to esketamine, ketamine, or any of the other ingredients in SPRAVATO. See the end of this Medication Guide for a complete list of ingredients in SPRAVATO.

If you are not sure if you have any of the above conditions, talk to your healthcare provider before taking SPRAVATO.

Before you take SPRAVATO, tell your healthcare provider about all of your medical conditions, including if you:

- have heart or brain problems, including:
 - high blood pressure (hypertension)
 - slow or fast heartbeats that cause shortness of breath, chest pain, lightheadedness, or fainting
 - history of heart attack
 - history of stroke
 - heart valve disease or heart failure
 - history of brain injury or any condition where there is increased pressure in the brain
- have liver problems
- have ever had a condition called “psychosis” (see, feel, or hear things that are not there, or believe in things that are not true).
- are pregnant or plan to become pregnant. SPRAVATO may harm your baby. You should not take SPRAVATO if you are pregnant.
 - Tell your healthcare provider right away if you become pregnant during treatment with SPRAVATO.
 - If you are able to become pregnant, talk to your healthcare provider about methods to prevent pregnancy during treatment with SPRAVATO.
 - There is a pregnancy registry for women who are exposed to SPRAVATO during pregnancy. The purpose of the registry is to collect information about the health of women exposed to SPRAVATO and their baby. If you become pregnant during treatment with SPRAVATO, talk to your healthcare provider about registering with the National Pregnancy Registry for Antidepressants at 1-844-405-6185 or online at <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/antidepressants/>.
- are breastfeeding or plan to breastfeed. You should not breastfeed during treatment with SPRAVATO.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Taking SPRAVATO with certain medicine may cause side effects. Especially tell your healthcare provider if you take Central Nervous System (CNS) depressants, psychostimulants, or Monoamine oxidase inhibitors (MAOIs) medicines.

How will I take SPRAVATO?

- You will take SPRAVATO nasal spray yourself, under the supervision of a healthcare provider in a healthcare setting. Your healthcare provider will show you how to use the SPRAVATO nasal spray device
- Your healthcare provider will tell you how much SPRAVATO you will take and when you will take it.
- Follow your SPRAVATO treatment schedule exactly as your healthcare provider tells you to.
- During and after each use of the SPRAVATO nasal spray device, you will be checked by a healthcare provider who will decide when you are ready to leave the healthcare setting.
- You will need to plan for a caregiver or family member to drive you home after taking SPRAVATO.
- If you miss a SPRAVATO treatment, your healthcare provider may change your dose and treatment schedule.
- Some people taking SPRAVATO get nausea and vomiting. You should not eat for at least 2 hours before taking SPRAVATO and not drink liquids at least 30 minutes before taking SPRAVATO.
- If you take a nasal corticosteroid or nasal decongestant medicine take these medicines at least 1 hour before taking SPRAVATO.

What should I avoid while taking SPRAVATO?

- **Do not** drive, operate machinery, or do anything where you need to be completely alert after taking SPRAVATO. **Do not** take part in these activities until the next day following a restful sleep. See **“What is the most important information I should know about SPRAVATO?”**

What are the possible side effects of SPRAVATO?

SPRAVATO may cause serious side effects including:

- See **"What is the most important information I should know about SPRAVATO"**
- **Increased blood pressure.** SPRAVATO can cause a temporary increase in your blood pressure that may last for about 4 hours after taking a dose. Your healthcare provider will check your blood pressure before taking SPRAVATO and for at least 2 hours after you take SPRAVATO. Tell your healthcare provider right away if you get chest pain, shortness of breath, sudden severe headache, change in vision, or seizures after taking SPRAVATO.
- **Problems with thinking clearly.** Tell your healthcare provider if you have problems thinking or remembering.
- **Bladder problems.** Tell your healthcare provider if you develop trouble urinating, such as a frequent or urgent need to urinate, pain when urinating, or urinating frequently at night.

The most common side effects of SPRAVATO when used along with an antidepressant taken by mouth include:

- | | |
|--|----------------------------|
| • dissociation | • anxiety |
| • dizziness | • lack of energy |
| • nausea | • increased blood pressure |
| • sedation | • vomiting |
| • spinning sensation | • feeling drunk |
| • reduced sense of touch and sensation | |

If these common side effects occur, they usually happen right after taking SPRAVATO and go away the same day.

These are not all the possible side effects of SPRAVATO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of SPRAVATO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about SPRAVATO that is written for health professionals.

What are the ingredients in SPRAVATO?

Active ingredient: esketamine hydrochloride

Inactive ingredients: citric acid monohydrate, edetate disodium, sodium hydroxide, and water for injection

Manufactured by: Renaissance Lakewood LLC, Lakewood, NJ 08701

Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560

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For more information, go to www.SPRAVATO.com or call 1-800-526-7736.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: 03/2019

cp-79818v1

MEDICATION GUIDE
SPRAVATO™ (sprah vah' toe) CIII
(esketamine)
nasal spray

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 - Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines, or street drugs.
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- **SPRAVATO Risk Evaluation and Mitigation Strategy (REMS).** Because of the risks for sedation, dissociation, and abuse and misuse, SPRAVATO is only available through a restricted program called the SPRAVATO Risk Evaluation and Mitigation Strategy (REMS) Program. SPRAVATO can only be administered at healthcare settings certified in the SPRAVATO REMS Program and to patients enrolled in the program.
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 - history of heart attack
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 - heart valve disease or heart failure
 - history of brain injury or any condition where there is increased pressure in the brain
- have liver problems
- have ever had a condition called “psychosis” (see, feel, or hear things that are not there, or believe in things that are not true).
- are pregnant or plan to become pregnant. SPRAVATO may harm your baby. You should not take SPRAVATO if you are pregnant.
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- are breastfeeding or plan to breastfeed. You should not breastfeed during treatment with SPRAVATO.

Tell your healthcare provider about all the medicines that you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. Taking SPRAVATO with certain medicine may cause side effects. Especially tell your healthcare provider if you take Central Nervous System (CNS) depressants, psychostimulants, or Monoamine oxidase inhibitors (MAOIs) medicines.

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- **Do not** drive, operate machinery, or do anything where you need to be completely alert after taking SPRAVATO. **Do not** take part in these activities until the next day following a restful sleep. See “**What is the most important information I should know about SPRAVATO?**”

What are the possible side effects of SPRAVATO?

SPRAVATO may cause serious side effects including:

- See **"What is the most important information I should know about SPRAVATO"**
- **Increased blood pressure.** SPRAVATO can cause a temporary increase in your blood pressure that may last for about 4 hours after taking a dose. Your healthcare provider will check your blood pressure before taking SPRAVATO and for at least 2 hours after you take SPRAVATO. Tell your healthcare provider right away if you get chest pain, shortness of breath, sudden severe headache, change in vision, or seizures after taking SPRAVATO.
- **Problems with thinking clearly.** Tell your healthcare provider if you have problems thinking or remembering.
- **Bladder problems.** Tell your healthcare provider if you develop trouble urinating, such as a frequent or urgent need to urinate, pain when urinating, or urinating frequently at night.

The most common side effects of SPRAVATO when used along with an antidepressant taken by mouth include:

- | | |
|--|----------------------------|
| • dissociation | • anxiety |
| • dizziness | • lack of energy |
| • nausea | • increased blood pressure |
| • sedation | • vomiting |
| • spinning sensation | • feeling drunk |
| • reduced sense of touch and sensation | |

If these common side effects occur, they usually happen right after taking SPRAVATO and go away the same day.

These are not all the possible side effects of SPRAVATO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of SPRAVATO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about SPRAVATO that is written for health professionals.

What are the ingredients in SPRAVATO?

Active ingredient: esketamine hydrochloride

Inactive ingredients: citric acid monohydrate, edetate disodium, sodium hydroxide, and water for injection

Manufactured by: Renaissance Lakewood LLC, Lakewood, NJ 08701

Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560

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For more information, go to www.SPRAVATO.com or call 1-800-526-7736.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: 03/2019

cp-79819v1

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b6) va.gov>
Subject:	Spravato update
Date:	2019/03/13 15:32:05
Priority:	Normal
Type:	Note

Tom & Maria –

I just sent the draft 10N memo to 10NC5 Action and to our SMEs for review and input. I've asked for feedback by tomorrow 10 AM, so I should have you a document to review by midday ET.

As a heads up, the pieces are coming together in my head right now as I've laid out in the notes below. I think this will be memo #1 of 2, with a second memo and further instruction to follow in ~ 2 weeks time. I'm awaiting input from OMHSP leadership to see what they think about how I've outlined things below (and in the memo draft), but wanted to keep you in the loop on my thought process.

Turning to informed consent this afternoon, more on that to follow.

Ilse

(b) (5)

(b) (5)

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)

email: (b6) @va.gov (b6) @yale.edu

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Sent Date:	2019/03/13 15:32:03
Delivered Date:	2019/03/13 15:32:05

Instructions for Use

SPRAVATO™

(SPRAH VAH' TOE) (esketamine)



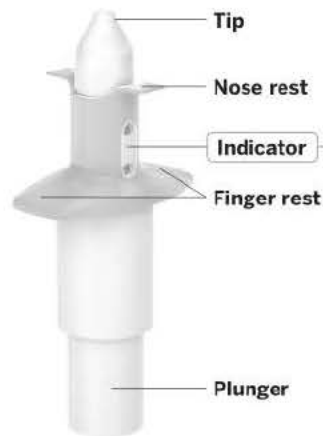
Important

This device is intended for administration by the patient, **under supervision of a healthcare professional.** Read this Instructions for Use in full before training and supervising patient.

Need help?

For additional assistance or to share your feedback call 800-JANSSEN (800-526-7736).

Nasal Spray Device

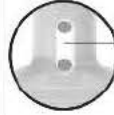


Each device delivers two sprays containing a total of 28 mg of esketamine.

Indicator

One device contains 2 sprays. (1 spray for each nostril)

2 green dots (0 mg delivered)



Device full

1 green dot



One spray delivered

No green dots

Two sprays (28 mg) delivered



Device empty

Step 1 Get ready

Before first device only:



Instruct patient to blow nose **before first device only.**

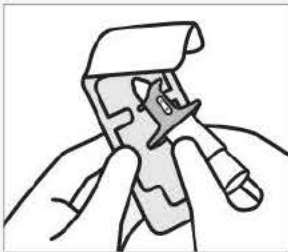


Confirm required number of devices.

56 mg = 2 devices

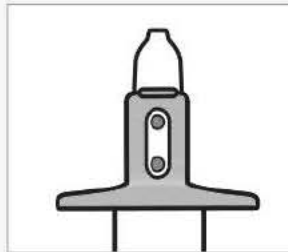
84 mg = 3 devices

Step 2 Prepare device



Healthcare professional:

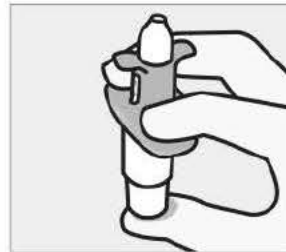
- Check expiration date ('EXP'). If expired, get a new device.
- Peel blister and remove device.



Healthcare professional:

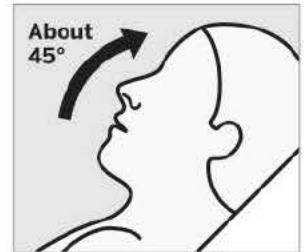
- **Do not prime device.** This will result in a loss of medication.
- Check that indicator shows **2 green dots**. If not, dispose of device and get a new one.
- Hand device to patient.

Step 3 Prepare patient



Instruct the patient to:

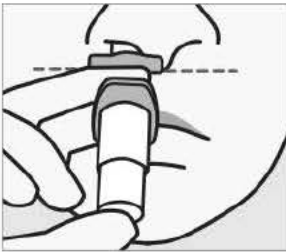
- Hold device as shown with the thumb gently supporting the plunger.
- **Do not** press the plunger.



Instruct the patient to:

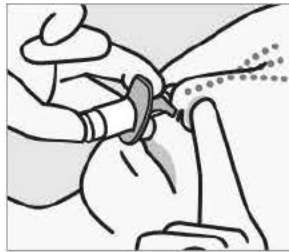
- Recline head at about **45 degrees** during administration to keep medication inside the nose.

Step 4 Patient sprays once into each nostril



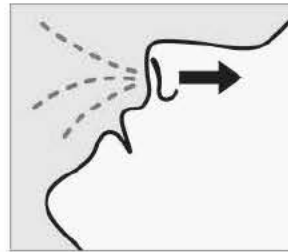
Instruct the patient to:

- Insert tip straight into the **first nostril**.
- Nose rest should touch the **skin between the nostrils**.



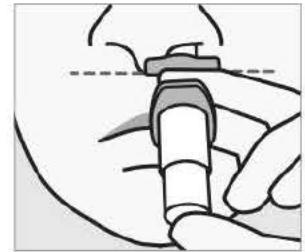
Instruct the patient to:

- Close opposite nostril.
- **Breathe in through nose** while pushing plunger all the way up until it stops.



Instruct the patient to:

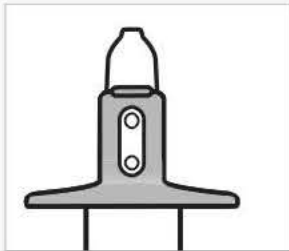
- **Sniff gently** after spraying to keep medication inside nose.



Instruct the patient to:

- Switch hands to insert tip into the **second nostril**.
- Repeat Step 4 to deliver second spray.

Step 5 Confirm delivery and rest



Healthcare professional:

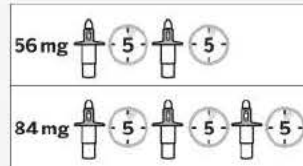
- Take device from patient.
- **Check that indicator shows no green dots.** If you see a green dot, have patient spray again into the second nostril.
- Check indicator again to confirm device is empty.



Instruct the patient to:

- Rest in a comfortable position (preferably, semi-reclined) for **5 minutes after each device**.
 - If liquid drips out, dab nose with a tissue.
- ⚠ Do not blow nose.**

Next device



Healthcare professional:

- **Repeat Steps 2-5** for the next device.

IMPORTANT: Ensure that patient **waits 5 minutes after each device** to allow medication to absorb.

Disposal

Dispose of used device(s) per facility procedure for a Schedule III drug product and per applicable federal, state, and local regulations.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Renaissance Lakewood LLC
Lakewood, NJ 08701

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Revised: March 2019
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cp-81317v1



From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER ((b6)) va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen ((b6)) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I ((b6)) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, ((b6)) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da ((b6)) va.gov>
Subject:	Spravato Follow-up briefing with Dr. Stone
Date:	2019/03/21 13:19:00
Priority:	Normal
Type:	Note

Just FYI...We received a calendar invite that the follow-up briefing has been moved to April 8th.

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <((b6)) va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen ((b6)) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I ((b6)) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, ((b6)) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da ((b6)) va.gov>
Sent Date:	2019/03/21 13:18:58
Delivered Date:	2019/03/21 13:19:00

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
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Subject:	Spravato FAQ
Date:	2019/03/12 10:56:37
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Appointment
Location:	Skype Meeting

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
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Date:	2019/03/12 10:56:00
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	Skype Meeting
Attendees:	Llorente, Maria D.; Wiechers, Ilse

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Sent Date:	2019/03/12 10:56:44

Delivered Date: 2019/03/12 10:56:00

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Subject:	Spravato FAQ
Date:	2019/03/12 10:56:47
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	Skype Meeting
Attendees:	Llorente, Maria D.; Wiechers, Ilse

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Sent Date: 2019/03/12 10:56:47

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER (b6) va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b6) va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) va.gov>
Subject:	Spravato FAQ
Date:	2019/03/12 10:56:47
Start Date:	2019/03/12 15:00:00
End Date:	2019/03/12 16:00:00
Priority:	Normal
Type:	Schedule.Meeting.Request
Location:	Skype Meeting
Attendees:	Llorente, Maria D.; Wiechers, Ilse

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER (b6) va.gov>
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Sent Date:	2019/03/12 10:56:44
Delivered Date:	2019/03/12 10:56:47

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96B44E7AE2C94C43B55D094-EMMENDORFER-(b6) va.gov>
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Type:	Appointment
Location:	Skype Meeting
Attendees:	Llorente, Maria D.; Wiechers, Ilse

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844-358-7954,,80749027# (North)	English (United States)
844-210-0201,,80749027# (North)	English (United States)
844-894-0415,,80749027# (North)	English (United States)

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PLEASE NOTE WE HAVE NEW PHONE NUMBERS You might want to make your attendees aware of the change.

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96B44E7AE2C94C43B55D094-EMMENDORFER-(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer

(b6)
<(b6)@va.gov>;
Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M
(b6)@va.gov>;
Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I
(b6)@va.gov>

Sent Date: 2019/03/12 10:56:47

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From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
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To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>
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Sent Date:	2019/03/12 10:56:47

From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Carroll, David (VACO) (b6) va.gov>
Subject:	Spravato Cleared Statement
Date:	2019/06/18 09:09:00
Priority:	Normal
Type:	Note

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

David Carroll, PhD
 Executive Director, Office of Mental Health and Suicide Prevention (10NC5)
 (b6)
 Suicide Prevention is Everyone's Business. *#BeThere.*



[cid:image003.jpg@01D34E71.BBA06B80](#)

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Carroll, David (VACO) (b6) va.gov>
Sent Date:	2019/06/18 09:09:40
Delivered Date:	2019/06/18 09:09:00

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From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) [REDACTED] va.gov>
To:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>
Subject:	SPRAVATO
Date:	2019/03/08 09:31:04
Start Date:	2019/03/08 14:30:00
End Date:	2019/03/08 15:00:00
Priority:	Normal
Type:	Appointment
Location:	VACO Room 818
Attendees:	Emmendorfer, Thomas (PBM)

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) [REDACTED] va.gov>
Recipient:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>
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SentVia:	Agyekum, Latonya /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9671CCACFB04489ABD71A1EE95B5A586-AGYEKUM, LA <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/08 09:31:01
Delivered Date:	2019/03/08 09:31:04

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) [REDACTED]@va.gov>
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SentVia:	Agyekum, Latonya /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9671CCACFB04489ABD71A1EE95B5A586-AGYEKUM, LA <(b6) [REDACTED] va.gov>
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From:	Oliva, Elizabeth M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B9CF68B788A948B8981FFB7558BDD309-OLIVA, ELIZ<(b6)>va.gov>
	VHASTORM /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74acb59abef6400e86680c046441e53b-VHASTORM <VHASTORM@va.gov>; VHA OEND /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=22224d066f9a4418860e31a2f4801a8f-VHA OEND <VHAOEND@va.gov>; VHA National Buprenorphine /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a47ef0f5cb684d4dbceb6db64498457a-VHA Nationa <VHANTtB@va.gov>; VHA National Opioid /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f689f4575ad643279b18c14094da64c8-VHA Nationa <VHANationalOpioid@med.va.gov>; VHAPBM Opioid Safety Initiative Dashboard End Users /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d3cde9bc5cba453bbe3b2537c1b1df4a-VHAPBH Opio <OpioidSafetyInitiativeDashboardEndUsers@va.gov>; VHA Clinical Pharmacists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feeeb2640db54aeebeeb57c1e0f534ea-VHA Clinica <vha.clinical.pharmacists@va.gov>; VHA Psychiatric Pharmacists /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90cb74f2975346fc8ad14f8c9a05a521-VHA Psychia <PsychiatricPharmacists@va.gov>; VHAPBM Academic Detailing Collaboration /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08f999dbd97248e5903e3f600de27b56-VHAPBH Acad <AcademicDetailingCllaboration@va.gov>; To: VHA Primary Care Chiefs-Directors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2091da205245400eb916406cb3029696-VHA Primary <VHAPrimaryCare@va.gov>; 'VHA Primary Care Operations VISN POC' <VHAPrimaryCareOperationsVISNPOC@va.vgov>; VHA PACT (PCMH) Pharmacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df566dbf1094869a55bb7b2dfca8510-VHA PACT (P <VHAPACTPCMHPharmacy@va.gov>; VHA PACT Centers of Excellence /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cbd6dec17374085a772b80316b9ee48-VHA PACT Ce <VHAPACTCentersofExcellence@va.gov>; VHA PACT Coordinators /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5ba0b99696d4c2e85f47f5f4b68752c-VHA PACT Co <VHAPACT@med.va.gov>; VHA CO All Inclusive MH First Friday Call /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df92a6c6708346d5865b96c0223e59fb-VHA CO All <VHACOAllInclusiveMHFirstFridayCall@va.gov>; NATIONAL MHR RTP GEN /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9518d2d40fd403ba21d2d9967474a43-NATIONAL MH <NATIONALMHR RTPGEN@va.gov>; VHA NATL FACILITY PAIN POC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d59b1354cfd4fa89de9ab0e6659319a-VHA NATL FA <VHANATL FACILITY PAIN POC@va.gov>; VHARIC SCAN-ECHO Pain /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38f1c34583e44b54ab9c0225ba23c0f1-VHARIC SCAN <VHARICSCAN-ECHOPain@va.gov>
CC:	Johnson, Kent /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=888ea64164a147609cd95cbbe8e3e93e-Johnson, Ke<(b6)>va.gov>
Subject:	REMINDER: TODAY'S VA Monthly OEND Call--International Overdose Awareness Day--learn about DoD OEND pilot efforts, MAT and OEND among homeless Veterans, ED-based MAT and OEND, and a novel simulation-based training for naloxone!!
Date:	2019/08/28 14:52:49
Priority:	Normal
Type:	Note

Hi all,

Just a reminder about today's VA Monthly OEND Call at the top of the hour. In honor of International Overdose Awareness Day on August 31st we will have a range of presentations touching upon various topics relevant to OEND. **We are excited to have guest speakers from DoD who will discuss a pilot study of OEND implementation in DoD as well as VA speakers discussing a recent study on OEND and MAT among homeless Veterans highlighting opportunities for improvement, an update on ED MAT implementation at the Syracuse VA and the Interdisciplinary Overdose Review team they are using to follow up on overdoses reported in the Suicide Behavior and Overdose Report, and finally a novel simulation-based naloxone training approach.** In recognition of International Overdose Awareness Day, I encourage staff to think about ways they can help Veterans at-risk for overdose—it will take a village to tackle the opioid crisis. Below is info that may be helpful:

- There have been some great presentations highlighting what VISNs and facilities have done in the past to increase overdose awareness among patients including booths, eboards, pins for staff to wear, etc. (e.g., VISN 22—see slides 22-46).
- VA also has great tools/resources for patients and providers on the VA Academic Detailing Services resources and campaigns page (e.g., OEND for patients prescribed opioids, OEND for patients with opioid use disorder, Am I At Risk for an Accidental Drug Poisoning, Fentanyl and Carfentanil brochure, Do You Know the Truth About Opioid Use Disorder?, Pain Informational Guide for Patients, Acute Pain Clinician's Guide, Chronic Pain Clinician's Guide, Opioid Taper Tool) and VA and DoD partnered for the Joint Pain Education Program to develop great pain educational videos.
- CDC has developed an interactive provider training series and an Rx Awareness Campaign: "Prescription opioids can be **addictive** and **dangerous**. It only takes a little to lose a lot."
- The Surgeon General has an Advisory on Naloxone and Opioid Overdose and an Opioid Overdose Prevention page
- SAMHSA also has an Opioid Overdose Prevention Toolkit that has useful resources

Hope these links help—thanks so much for your service to Veterans and I hope you can make the call today!!

Best,
Elizabeth

Today's VA Monthly OEND Call

- Call information:
 - **Link for attendees (unfortunately, no CEUs are available for this call):**
▪ <http://va-eerc-ees.adobeconnect.com/oend/>
 - **VANTS:** 800-767-1750; Participant Code: 44044
- **Agenda (in EST):**
 - 3:00-3:15—Nicholas A. Giordano, PhD, RN & Krista B. Highland, PhD, Defense & Veterans Center for Integrative Pain Management & Faye Curran, PhD, Research and

Development Directorate (J-9), *Opioid Overdose Education and Naloxone Distribution (OEND) Program: A Pilot Study*

- 3:15-3:30—Thomas Byrne, PhD, Investigator, Center for Healthcare Organization and Implementation Research, Edith Nourse Rogers Memorial Veterans Hospital, Bedford VA, *Opioid Use Disorder and Treatment among Veterans Accessing VA Specialized Homeless Programs*
- 3:30-3:45—Bryan Asher, LCSW, MAT Coordinator, Syracuse VAMC, *MAT Emergency Room Outcomes & Overdose Review Team*
- 3:45-4:00—Angela Hageman, MSN, RN, CNL, Clinical Nurse Leader & Kateri Gabriele, MS, RN, CHSE, Simulation Center Operations Manager, *A Simulation-based Approach to Naloxone Training at the Dayton VA Medical Center*
- VA Monthly OEND Calls are recorded and the presentations are also available on the [VA Monthly OEND Call page](#).

Diffusion of Excellence VHA Rapid Naloxone Initiative

• The [Diffusion of Excellence Initiative](#) is supporting implementation of the [VHA Rapid Naloxone Initiative](#) to prevent opioid-related death among Veterans. Based on a Diffusion of Excellence Gold Status Practice, there are three practice elements included in the VA Rapid Naloxone Initiative: (1) OEND to VA patients at-risk for opioid overdose, (2) VA Police Naloxone, and (3) AED Cabinet Naloxone. A DUSHOM memorandum supporting VA Police implementation following union approval was issued on December 1, 2017. More recently, on September 5, 2018 the DUSHOM released a [Rapid Naloxone Availability to Prevent Opioid-Related Death memorandum](#) to support implementation of the VA Rapid Naloxone Initiative VA-wide. As of early October 2018 there were 45 VA facilities that reported implementing VA Police naloxone and 20 facilities equipping select AEDs with naloxone. Pam Bellino gave an amazing [Ted-style Talk on her gold status practice that inspired this initiative](#) which includes inspirational testimonials from staff regarding saves with naloxone. The [VA Monthly OEND Call page](#) has more information and resources on how other sites have implemented in the past. **All resources pertaining to the VHA Rapid Naloxone Initiative, including comprehensive implementation toolkits for VA Police and AED cabinet components, can be found on the [VA National Center for Patient Safety Intranet site](#).** Thanks to the Diffusion of Excellence team for these wonderful resources to support implementation of this lifesaving innovation!

- <https://medium.com/vainnovation/spreading-innovations-across-va-9c9b15c314b2>
- <http://www.blogs.va.gov/VAntage/38858/nationwide-opioid-epidemic-prompts-va-to-implement-life-saving-idea/>
- https://www.youtube.com/watch?v=XkG_S83F8mQ&t=14s
- Questions about the initiative can be sent to VHARapidNaloxone@va.gov (I am part of the team that receives this email). *Nasal spray demos* are available from the pharmaceutical company to help train patients and staff in naloxone administration (info on ordering is below).

Requesting nasal spray demos

- There are limited numbers of nasal spray demos available through the pharmaceutical company (~300 allocated to VA per quarter) and they are equally distributed between reusable and water (one-time use) demos. The company is limiting requests to 1 demo per provider. If you/your site would like to request a demo unit, the company has requested that you send an email to the

following address (NOTE: A single requestor can submit a request for multiple providers, but be sure to include the names of the providers who are requesting demos):

narcancustomerservice@ebsi.com.

- Please provide the company with the name of the site, a contact person at the site, the mailing address, and the number of demos—with provider names—you are requesting. You can specify which type of demo you prefer; however, please note that supply is very limited so you may not be able to get the type or full quantity that you are asking for, but a waiting list is being kept and is first come, first serve. The demo units will then be shipped directly to the site if available.
 - PLEASE REMEMBER, the water demos are **one-time** use only. The VA Nasal Spray video—<https://youtu.be/0w-us7fQE3s>—demonstrates how you might be able to train patients with these single-use demos (e.g., give patients an opportunity to hold the demo and practice finger positioning) .

PBM's Free-to-Facilities Initiative

- I would like to thank PBM for their generous support of OEND since the inception of the national program in 2014 as well as recent CARA funding which combined have funded the national OEND program for the past almost 5 years. We currently have approximately \$7 million left for the initiative. After funds have been used, cost will shift to facilities.
- ***To allow the initiative to last as long as possible, remaining funds will go to purchasing the nasal spray*** (the current preferred option when clinically appropriate).
- The new 2 mg auto-injector formulation that has recently been added to VA National Formulary IS NOT PART OF THE Free-to-Facilities Initiative.
- Questions regarding the Free-to-Facilities update should be directed to your Chief of Pharmacy.

Naloxone copay exemptions have been implemented!!!

- CARA Section 915. ELIMINATION OF COPAYMENT REQUIREMENT FOR VETERANS RECEIVING OPIOID ANTAGONISTS OR EDUCATION ON USE OF OPIOID ANTAGONISTS exempts co-pays for naloxone medication and co-pays for education on naloxone (if visits were solely for education related to prevention and reversal of opioid overdose with naloxone). Communication is forthcoming about implementation, although information about an emergency patch to the clinic stop file to exempt co-pays for education was scheduled for March 15, 2017—please contact (b6) [REDACTED] [va.gov](mailto:[REDACTED]@va.gov) so that she can forward the emergency patch info to you which includes the appropriate new Stop Codes to be using when conducting education on naloxone (if visits were solely for education related to prevention and reversal of opioid overdose with naloxone). The naloxone medication copay exemption took effect on April 1st.
 - NOTE: [VA Pharmacy Benefits Management's Recommendations For Issuing Naloxone](#) includes clinical guidance and recommendations for offering naloxone, including ways to identify patients at-risk for overdose—e.g., the Risk Index for Overdose or Serious Opioid-induced Respiratory Depression—RIOSORD, which is incorporated into the [VA OEND Patient Risk Dashboard](#), as well as the [VA Stratification Tool for Opioid Risk Mitigation](#) (STORM), and [Opioid Therapy Risk Report](#) (OTRR).

Familiarize Yourself With Tools and Resources to Support OEND Implementation

- **Updated VA Academic Detailing OEND SharePoint—one-stop shop with key resources needed to implement OEND (e.g., patient education brochures and DVDs for patients that can be ordered through depot)**
 - Identify patients for OEND using VA Academic Detailing's OEND Patient Risk Dashboard
 - Displays subpopulations of patients prescribed opioids who may be at increased risk for an opioid overdose (e.g., patients with opioid and benzodiazepine prescriptions, patients with ≥ 50 MEDD, patients in RIOSORD Risk Class ≥ 8 , patients with Opioid Use Disorder, patients with a possible overdose in the past 3 years, etc.).
- **Updated patient education, reflect two FDA-approved formulations (AD Depot)**
 - Brief—Standard tri-fold that covers 3-pronged approach to OEND—how to *prevent, recognize, and respond* to an opioid overdose
 - Brochure for patients prescribed opioids—ENGLISH and SPANISH
 - Brochure for patients with opioid use disorders—ENGLISH and SPANISH
 - Detailed—Re-formatted “kit” brochures to allow for standard printing
 - Nasal Spray/Auto-injector—Pocket cards that cover 1 of 3 prongs to OEND (*response*)
 - Opioid Safety—Standard tri-fold that covers other 2 prongs (*prevention and recognition*)
- **VA National Opioid Overdose Education and Naloxone Distribution (OEND) SharePoint Site**
<https://vaww.portal2.va.gov/sites/mentalhealth/OEND/default.aspx>
- **VA OEND Videos (links to all VA OEND videos)**
 - Intro for People with Opioid Use Disorders <https://youtu.be/-qYXZDzo3cA>
 - Intro for People Taking Prescribed Opioids <https://youtu.be/NFzhz-PCzPc>
 - How to Use the VA Naloxone Nasal Spray <https://youtu.be/0w-us7fQE3s>
 - How to Use the VA Auto-Injector Naloxone Kit <https://youtu.be/-DQBCnrAPBY>
- **Panel Management Tools**
 - OEND Patient Risk Dashboard; Stratification Tool for Opioid Risk Mitigation; Opioid Therapy Risk Reduction Report
- **Accredited TMS training: TMS trainings 27440 and 27441**
 - Available outside VA on www.train.org: <https://www.train.org/main/course/1064943>
- **VA TMS training 37795: How to Use Naloxone Nasal Spray (Narcan®)**

Call to Action—Only ~1 in 3 Veterans with OUD is getting life-changing, evidence-based Medication Assisted Treatment

(MAT)—lets work together to CHANGE lives with MAT as we save them with OEND!!!

- As we head into FY18, it is time to start taking a closer look at our Veterans with opioid use disorder (OUD) and getting medication assisted treatment (MAT) to those who need it. We currently are prescribing MAT to about 35% of our patients with OUD. To truly address the opioid epidemic, we need to get patients with OUD the help they need and MAT is the answer for most! To do this, we will need the following:
 1. More providers to receive training so they can obtain a DEA X-waiver to prescribe buprenorphine/naloxone (Suboxone; see attached flier for training opportunities)
 2. To examine how we can support providers with an X-waiver who are not currently prescribing MAT to begin prescribing MAT (see below—65% of X-waivered VA providers are NOT prescribing buprenorphine!)
 - a. e.g., work on local facility level barriers that may prevent waived providers from prescribing MAT to Veterans

Let's make a commitment to increasing access for this life-changing and life-saving treatment to our Veterans with OUD!!!

- Check out the [VA Academic detailing resources](#) and use these to support your efforts!
- Contact the National Academic Detailing Service if you would like more assistance:
PharmacyAcademicDetailingProgram@va.gov

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Phone: 650-493-5000 (1-2) (b6)
Fax: 650-617-2736
(b6) [va.gov](#)

VA National Opioid Overdose Education and Naloxone Distribution (OEND) SharePoint Site:
<https://vaww.portal2.va.gov/sites/mentalhealth/OEND/default.aspx>

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Date:	2019/03/12 13:05:22
Priority:	Urgent
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Smith, Monica (VACO) would like to recall the message, "HHS bought a nasal spray for depression - DRAFT News Release".

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Delivered Date:	2019/03/12 13:05:22

From:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI (b6)@va.gov>
To:	VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a29ff0f0291a4a708de0731733c726c0-VHAPBH VISN <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bdd525bd2340749ff69f86d2e657f0-VHAPBH Phar <PharmacyChiefs@va.gov>; VHAPBM PMO /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03349ada043546d4b1c1543f977bfa89-VHAPBH PMO <PMO@va.gov>
Subject:	Recall: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 14:22:15
Priority:	Urgent
Type:	Outlook.Recall

Sales, Marie would like to recall the message, "Frequently Asked Questions (FAQ): Esketamine (Spravato®) ".

Sender:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI (b6)@va.gov>
Recipient:	VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a29ff0f0291a4a708de0731733c726c0-VHAPBH VISN <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bdd525bd2340749ff69f86d2e657f0-VHAPBH Phar <PharmacyChiefs@va.gov>; VHAPBM PMO /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03349ada043546d4b1c1543f977bfa89-VHAPBH PMO <PMO@va.gov>
Sent Date:	2019/03/15 14:22:10
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From: Butler, Brooke /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C01305E4FE24027828970A10090E946-BUTLER, BRO <(b6)@va.gov>

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Hobbs, Deborah /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f927338db84e46dbc32de9fcfc2772b-Hobbs, Debo <(b6)@va.gov>;
Blalock, Meredith J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=049248ff499341cd951ebde4dca87bd7-Blalock, Me <(b6)@va.gov>;
VHA National Psychiatry Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb44f48927b74432829cd2cc99374596-VHA Nationa <VHANationalPsychiatryChiefs@va.gov>;
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Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>;
Shiroma, Paulo R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cae9fb698bb245669c11a3564784e24e-Shiroma, Pa <(b6)@va.gov>;
McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446dd7379-McGuire, Ma <(b6)@va.gov>;
Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6)@va.gov>;

To: Pomerantz, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6)@va.gov>;
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Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6)@va.gov>;
Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbbc-Cunningham, <(b6)@va.gov>;
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 Duncan, Erica MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=600b2f4d20cd4d6ab196263a4eb0ce43-Duncan, Eri <(b6)@va.gov>;
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Leinbach, Jonathan E DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9f36c898fc246d4bce7481a6432bd7a-Leinbach, J <(b6)@va.gov>;

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Chemerinski, Eran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43736f282fa449efa089ab0a1f9a7d44-Chemerinski <(b6)@va.gov>;

Hillier, Shannon L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe2ecc57908c45df800c3d1b6a6a317b-Hillier, Sh <(b6)@va.gov>;

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Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave <(b6)@va.gov>;

VISN 23 MH Site Directors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=842e607324d840a3923c726939d9e6c1-VISN 23 MH <VISN23MHSiteDirectors@med.va.gov>;

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Minor, Donna /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4dc64cbd8dec441f8ae0339df64f1499-Minor, Donn <(b6)@va.gov>;

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Hiett, Erica H /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d1ed7782f8d4c6fa1b6ce91cf86227e-Hiett, Eric <(b6)@va.gov>;

Brown, Keith L /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b477646e43b743838e962938bc9828b7-Brown, Keit <(b6)@va.gov>;

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Spollen, John J. III /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca8e20803a64a5c948bbf5cb6a16150-Spollen II <(b6)@va.gov>;

Dunn, Walter /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd06b6b345fe4e25871d6ff0e6b94471-Dunn, Walte <(b6)@va.gov>;

Poole, Ronald D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec692400f3ac4a518216aead7840e20f-Poole, Rona <(b6)@va.gov>;

Golier, Julia A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffef8d04a1a04d8d8ce3c4ff57351e34-Golier, Jul <(b6)@va.gov>;

David, Daniella (M:AMI VA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcb957d580094beb9adb7f0c8d196a2e-David, Dani <(b6)@va.gov>;

Siegel, Mary K /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a8499dd0c12414da6b0c2da6024310f-Siegel, Mar <(b6)@va.gov>;

Dev, Deepak /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2dc34710d9704695aa9c1ac6b6db2127-Dev, Deepak <(b6)@va.gov>;

McGuire, Kevin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f479026bf78d424482167fdf346800fc-McGuire, Ke <(b6)@va.gov>;

Lache, Daniel J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f68dc7b53f44f9e82cc5b4020131004-Lache, Dani <(b6)@va.gov>;

Sivak, Kim A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f72debca022442a921e59b6efe89def-Sivak, Kim

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 MacPhee, Edward R. /o=ExchangeLabs/ou=Exchange Administrative Group
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 Whittaker, Kevin C. /o=ExchangeLabs/ou=Exchange Administrative Group
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 Potoski, Laura M /o=ExchangeLabs/ou=Exchange Administrative Group

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 Webb, Thomas A (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a4d1a8e26de429fa9db915028b3533b-Webb, Thoma (b6) @va.gov>;
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 Dinero, Nancy E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=355401bc8d9f442f8310c793c3802421-Dinero, Nan (b6) @va.gov>;
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Holland, Jon Todd DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group

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 Roney, Dionne L. /o=ExchangeLabs/ou=Exchange Administrative Group
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Miller, Lacey J. /o=ExchangeLabs/ou=Exchange Administrative Group
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Bower, Theresa (Terri) (SPO) /o=ExchangeLabs/ou=Exchange Administrative Group
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Radtke, Michelle L. SAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group
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LeClerc, Sheena B. (Chillicothe) /o=ExchangeLabs/ou=Exchange Administrative Group
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Silvershein, Jamie /o=ExchangeLabs/ou=Exchange Administrative Group
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Sutherland, Trent T., Greenville HCC /o=ExchangeLabs/ou=Exchange Administrative Group
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Manning, Jane M (V20) /o=ExchangeLabs/ou=Exchange Administrative Group
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McArdle, Kaitlin /o=ExchangeLabs/ou=Exchange Administrative Group

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 Funk, Margo C. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=097b7de0d4f5443fae712628a10117f1-Funk, Margo (b6)@va.gov>;
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 Awan, Sundus S. FHCC Lovell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d9a6fd5a11b4c959ec441ff42af077d-Awan, Sundu (b6)@va.gov>;
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 Haake, Elizabeth R. VHAREN /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1aed21e0613f4a56a81f6106206e8840-Haake, Eliz (b6)@va.gov>;
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 Rodriguez, William E. (Miami VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e821a47d9bde4fbf97feecd75cc3f1ab-Rodriguez, (b6)@va.gov>;
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 Coakley, Christina /o=ExchangeLabs/ou=Exchange Administrative Group

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 MacWhorter, Carrie /o=ExchangeLabs/ou=Exchange Administrative Group
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Mathis, Erin R. RICVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3bb9414b07374da6ade4118c457f8afb-Mathis, Eri (b6)@va.gov>;

Wonson, Erica RICVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=554085a5b0e941499535dc943591b1fa-Wonson, Eri (b6)@va.gov>;

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Larew, Janel M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=966db83636d54396baacec107e642041-Larew, Jane (b6)@va.gov>;

Hershey, Benjamin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93e4df4816f6470ba374437765c53cec-Hershey, Be (b6)@va.gov>;

Praus, Julie M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd1cd015835f4bd69274c3fe4ea518af-Praus, Juli (b6)@va.gov>;

Nwokoro, Stella /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3eee5bb5cedf4687861e03426bd02471-Nwokoro, St (b6)@va.gov>;

Jackson, John K (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd716c33519c443990885e9d98901413-Jackson, Jo (b6)@va.gov>;

Genesio, Kimberly (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e847fbabe3d45f68f7703c70e5ab382-Genesio, Ki (b6)@va.gov>;

Kokett, Gerard J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4712280cbb0a40e1a83ea0a325ffce7e-Kokett, Ger (b6)@va.gov>;

Lundell, Ryan D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2acf994d9b14e0896dcb58077e5ff44-Lundell, Ry (b6)@va.gov>;

Barber, Joseph A. LEBVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a68defa939440f1b95b7d58f0bfd279-Barber, Jos (b6)@va.gov>;

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Summerville, Michele R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65d2381e616a4242b29ccdf38f434852-Summerville (b6)@va.gov>;

Miller, Christopher W. CMOVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6a9876dfb61494e8426184e63d8ad24-Miller, Chr (b6)@va.gov>;

(b6)@yale.edu>;

Monsour, Sophia A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e0464869f804b15aec43502ea1acf0d-Monsour, So (b6)@va.gov>;

Forman, Steven D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfe30d938d84447d8ada2c2d4381e18f-Forman, Ste (b6)@va.gov>;

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Carradine, Lauren E /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e8dbbc76a40e0a188602e1b4f28f2-Carradine,

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	(b6)@va.gov>; Turner, Ted J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99c54b54d3e6439788a7d8a1639d9754-Turner, Ted (b6)@va.gov>; Tuck, Katie A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a583aef83b9149e5876a670d68c28d34-Tuck, Katie (b6)a.gov>; Leeson, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84d6ff6d21ca4ec395709e7abbb1394d-Leeson, Mic <(b6)@va.gov>; Maksimowski, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34445a0c91cb4855840b26a480e84ca5-Maksimowski (b6)@va.gov>; Elliott, William J. FNC/AMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2852c3a5738e4ce387d821e68a806a1c-Elliott, Wi (b6):@va.gov>; Gossett, Anne K /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=951b12aacb3f490caef0dc923f62a673-Gossett, An (b6)@va.gov>; McCoy, Thomas /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=984ead03b0cc47feb7fa99b6a2b85016-McCoy, Thom (b6)@va.gov>; HESSLER, JAIME T. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac27619870054b1cba4284dbf58bd228-HESSLER, J (b6)@va.gov>; Owenby, Ryan K DURYAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b49385e7df3c44bd83b2560a78728e57-Owenby, Rya (b6)y@va.gov>; Duquaine, Susan M. (KCV) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ed1087561d1476f827e1033cd143d27-Duquaine, S (b6)@va.gov>; Hunt, Lindsey (Boise) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea600cc3c0184fb4b7239c7761ce5a91-Hunt, Linds <(b6)@va.gov>; Bahrey, Stephanie J., VHACIN /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=677ceb2cedf149bcb3c0d4c98e444645-Bahrey, Ste (b6)@va.gov>; Chau, Suzanne T. FHCC Lovell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8998a42271cc4a6782fb77ad88f2347a-Chau, Suzan (b6)@va.gov>
Subject:	Recall: Esketamine Community of Practice
Date:	2019/08/15 07:34:24
Priority:	Urgent
Type:	Outlook.Recall

Butler, Brooke would like to recall the message, "Esketamine Community of Practice".

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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)va.gov>; Hobbs, Deborah /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f927338db84e46dcbc32de9fcfc2772b-Hobbs, Debo <(b6)va.gov>; Bialock, Meredith J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=049248ff499341cd951ebde4dca87bd7-Bialock, Me <(b6)va.gov>; VHA National Psychiatry Chiefs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb44f48927b74432829cd2cc99374596-VHA Nationa <VHANationalPsychiatryChiefs@va.gov>;

VHACLE BVAC Group /o=ExchangeLabs/ou=Exchange Administrative Group
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VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group
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Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group
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Shiroma, Paulo R. /o=ExchangeLabs/ou=Exchange Administrative Group
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Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group
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Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group
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Mathew, Sanjay (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group
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Myrick, Donald L. (Hugh) /o=ExchangeLabs/ou=Exchange Administrative Group
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National Mental Health Facility Leaders /o=ExchangeLabs/ou=Exchange Administrative Group
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Duncan, Erica MD /o=ExchangeLabs/ou=Exchange Administrative Group
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Griffith, June /o=ExchangeLabs/ou=Exchange Administrative Group
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Alholail, Ayman M. (ROS) /o=ExchangeLabs/ou=Exchange Administrative Group
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Winder, Marquita Bracshaw /o=ExchangeLabs/ou=Exchange Administrative Group
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Beckey, Nick P /o=ExchangeLabs/ou=Exchange Administrative Group
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Ha, Allen RICYAMC /o=ExchangeLabs/ou=Exchange Administrative Group
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Maddix, Daniel S. /o=ExchangeLabs/ou=Exchange Administrative Group
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Dare, Donna C. /o=ExchangeLabs/ou=Exchange Administrative Group

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Chiao, Teresa B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf652f930b408290a05563f482ed5a-Chiao, Tere (b6)@va.gov>;
Morrow, Deborah J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6bc66f1bc9264d0b9d6ad639704a0323-Morrow, Deb (b6)@va.gov>;
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Ogden, Elaine M. (KCV A) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f660bfbe3e7c4e9b93a8f321ca7084c7-Ogden, Elai (b6)@va.gov>;
Short, Delmar D SAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ace8e0e4db84133b985450c1fa41b2b-Short, Delm (b6)a.gcv>;
Wormuth, Janelle /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30475070e3ab4f95b2d75040c4e81494-Wormuth, Ja (b6)@va.gov>;
V21 PBM Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc8c81b852c4d9980bd7bd56521e474-V21 PBM Sta (b6)V21PBMStaff@va.gov>;
Higgins, Diana Tovar (VHAMAC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=293dff64f7c54b0ab7c5691a55523de7-Higgins, Di (b6)@va.gov>;
Miller, Joy R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806d0b8ef6e846fe8086b59e1def9c15-Miller, Joy (b6)@va.gov>;
Hoffman, Jonathan D. (VISN 19) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18868437182141d18cd718d5f01be210-Hoffman, Jo (b6)@va.gov>;
Moore, Troy A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a133a6f0cf4cf2827b25433eb60b4c-Moore, Troy (b6)@va.gov>;
Mambourg, Scott VHAREN /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cc0e02a3f9c4b748574199266262b10-Mambourg, S (b6)@va.gov>;
Kaigle, Allie E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e216d56c3e04a00976e1df7dd9d655f-Kaigle, All (b6)@va.gov>;
Moody, Breanna L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f58bb25631b7496fb172634ecc432a1e-Moody, Brea (b6)@va.gov>;
Erwin, William FNCVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f1cc63a343b403b8d763e78106fda83-Erwin, Will (b6)@va.gov>;
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Patnaude, Lawrence A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbbd902adcd14c7bb1d1eb144e887865-Patnaude, L (b6)@va.gov>;
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Baugh, Terrence B /o=ExchangeLabs/ou=Exchange Administrative Group
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Strate, Margaret /o=ExchangeLabs/ou=Exchange Administrative Group

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Rosario-Vega, Maria N. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54944fe2937a492b9ff8cf2f7b6d4527-Rosario-Veg <(b6)>a@va.gov>;
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Gray, Jennifer M. HAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=abc033d43f2a46548b8c62d5b965f61c-Gray, Jenni (b6)>@va.gov>;
Schultz, Sarah R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9cc0c3d36dfc44fe91c5d7056af528c5-Schultz, Sa (b6)>@va.gov>;
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Vaughn, Kaitlin S. /o=ExchangeLabs/ou=Exchange Administrative Group
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Holm, Cynthia L. (Walla Walla) /o=ExchangeLabs/ou=Exchange Administrative Group
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Braddy, Kathryn A. /o=ExchangeLabs/ou=Exchange Administrative Group
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Saltz, Elizabeth A. /o=ExchangeLabs/ou=Exchange Administrative Group
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Beall, Andrea L. /o=ExchangeLabs/ou=Exchange Administrative Group
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Chapman, Amanda G. (FAV) /o=ExchangeLabs/ou=Exchange Administrative Group
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Hoeldtke, John /o=ExchangeLabs/ou=Exchange Administrative Group
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Boykin, Crystal M.HAMVAMC /o=ExchangeLabs/ou=Exchange Administrative Group
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Schofield, Brian A. (STL) /o=ExchangeLabs/ou=Exchange Administrative Group

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 Webb, Thomas A (NOLA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a4d1a8e26de429fa9db915028b3533b-Webb, Thoma (b6) :@va.gov>;
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 Dixon, David M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c061f638787478f9717af42ec0f980f-Dixon, Davi (b6) :@va.gov>;
 Henry, Jessica FNCVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac117265d5e54483902ae9b4dc6cdac4-Henry, Jess (b6) :a.gov>;
 Wilson, Christopher R /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc454be48fb435a99f864bfb786fd4-Wilson, Chr (b6) :@va.gov>;
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 Joseph, Lisa E. (Miami VA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=16cf31d9214a45ac9005068970e7d30d-Joseph, Lis (b6) :@va.gov>;
 McCree, Kevin M. (MRN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27750b2e9a364e6fbc494124b9bd904a-McCree, Kev (b6) :@va.gov>;
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 Finn, Danielle R. VHAREN /o=ExchangeLabs/ou=Exchange Administrative Group

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 Amin, Priti P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a520a24cfe46128a500d851ec9fdc8-Amin, Priti (b6) .gov>;
 Davis, Cassandra M. (Orlando-Pharmacy) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0a6c5b8472545beb895a2e295d57962-Clement, Ca (b6) @va.gov>;
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Lundell, Ryan D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2acff994d9b14e0896dcb58077e5ff44-Lundell, Ry (b6)@va.gov>;

Barber, Joseph A. LEVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a68defa939440f1b95b7d58f0bfd279-Barber, Jos (b6)@va.gov>;

Sanft, Ryan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef8f2f71a40c4923a22c1197201d4413-Sanft, Ryan (b6)@va.gov>;

Summerville, Michele R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65d2381e616a4242b29ccdf38f434852-Summerville (b6)@va.gov>;

Miller, Christopher W. CMOVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6a9876dfb61494e8426184e63d8ad24-Miller, Chr (b6)@va.gov>;

(b6)@yale.edu>;

Monsour, Sophia A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e0464869f804b15aec43502ea1acf0d-Monsour, So (b6)@va.gov>;

Forman, Steven D /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfe30d938d84447d8ada2c2d4381e18f-Forman, Ste (b6)@va.gov>;

Vajjhala, Vinay T /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb691463f280467c915e3ab6f3583c53-Vajjhala, V (b6)@va.gov>;

Carradine, Lauren E /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e8dbbc76a40e0a188602e1b4f28f2-Carradine, (b6)@va.gov>;

Speerhas, Lucy E /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e6fd3fd91484bb7ab816e9b9aebec86-Speerhas, L (b6)@va.gov>;

Bennett, Sevim /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ab26d69c30e49ee9b33d20af63268ff-Bennett, Se (b6)@va.gov>;

Forshee, Judith A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f974de8a39b74d1ab9dd676bc80c4689-Forshee, Ju (b6)@va.gov>;

Gaber, Lea M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51158c5321ba4e02b637b9f1b0ce7379-Gaber, Lea (b6)@va.gov>;

Smith, Jordan O /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c47e4df36d3b4fb99bdc36f5a1831ede-Smith, Jord

(b6)@va.gov>;
Vandaele, Madeline A. /o=ExchangeLabs/ou=Exchange Administrative Group
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(b6)@va.gov>;
Ali, Sarah S. /o=ExchangeLabs/ou=Exchange Administrative Group
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(b6)@va.gov>;
Roche, Jennifer (VHACLE) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0a7521712be942438d558649b8b0a6d0-Roche, Jenn
(b6)@va.gov>;
Allen, Sarah M. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=84c2e4187be8469891cb69fe5c8792f0-Allen, Sara
(b6)a.gov>;
Saeed, Mohammad A /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7952cb18c68b4359b06843c7d84d8b7b-Saeed, Moha
(b6)@va.gov>;
Jones, Ellen A. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=039c735e335946de89140f14af2bae82-Jones, Elle
(b6)s@va.gov>;
Fox, Mark /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=918cef8e5a65496b9e6ad1ba992eac17-Fox, Mark
(b6)@va.gov>;
Sophinos, Jeffrey /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a9608b24465949409a2c1b03e4bb2254-Sophinos, J
(b6)s@va.gov>;
Mitchell, Brian G. (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=26a0a4f77fd84c5eb8ad053c9cf6ebb3-Mitchell, B
(b6)l3@va.gov>;
Karow, Matthew J. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=59ab512a48b4444f85ff897f98d11b48-Karow, Matt
(b6)@va.gov>;
Campbell, Tamara, VHACIN /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5521dc4af7ca43bcb3dc10bd9a25f1c-Campbell, T
(b6)@va.gov>;
Lehrer, Douglas S., VHACIN /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1afbcfb2e29a46428c7595dbc695c5b9-Lehrer, Dou
(b6)@va.gov>;
Taxeras, Heather D. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d9fa56fe01ac4c79a1653e64fc244eec-Taxeras, He
(b6)@va.gov>;
Pencea, Viorica /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=71c62c083c1f46ada8bd3896c52e1909-Pencea, Vio
(b6)a@va.gov>;
Lipp, Sharon, DVHACS /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=797f702e5fab487eb12d8853d55c4eba-Lipp, Sharo
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Oshita, Monica I. /o=ExchangeLabs/ou=Exchange Administrative Group
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(b6)@va.gov>;
Jobin, Timothy /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5796677707394f6eae96fdb4417e93-Jobin, Timo
(b6)@va.gov>;
Turner, Ted J. /o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a583aef83b9149e5876a670d68c28d34-Tuck, Katie
(b6)@va.gov>;
Leeson, Michael /o=ExchangeLabs/ou=Exchange Administrative Group
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(b6)n@va.gov>;
Maksimowski, Michael /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=34445a0c91cb4855840b26a480e84ca5-Maksimowski
(b6)@va.gov>;
Elliott, William J. FNC/AMC /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2852c3a5738e4ce387d821e68a806a1c-Elliott, Wi

(b6)@va.gov>;
 Gossett, Anne K /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=951b12aacb3f490caef0dc923f62a673-Gossett, An
 <(b6)@va.gov>;
 McCoy, Thomas /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=984ead03b0cc47feb7fa99b6a2b85016-McCoy, Thom
 (b6)2@va.gov>;
 HEISSLER, JAIME T. /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac27619870054b1cba4284dbf58bd228-HEISSLER, J
 (b6)@va.gov>;
 Owenby, Ryan K DURYAMC /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=b49385e7df3c44bd83b2560a78728e57-Owenby, Rya
 (b6)@va.gov>;
 Duquaine, Susan M. (KCVA) /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ed1087561d1476f827e1033cd143d27-Duquaine, S
 (b6)@va.gov>;
 Hunt, Lindsey (Boise) /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=ea600cc3c0184fb4b7239c7761ce5a91-Hunt, Linds
 (b6)@va.gov>;
 Bahrey, Stephanie J., VHACIN /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=677ceb2cedf149bcb3c0d4c98e444645-Bahrey, Ste
 (b6)@va.gov>;
 Chau, Suzanne T. FHCC Lovell /o=ExchangeLabs/ou=Exchange Administrative Group
 (FYDIBOHF23SPDLT)/cn=Recipients/cn=8998a42271cc4a6782fb77ad88f2347a-Chau, Suzan
 (b6)@va.gov>

Sent Date: 2019/08/15 07:33:53

Delivered Date: 2019/08/15 07:34:24

From:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA <(b6)@va.gov>
To:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Subject:	Recall: esketamine briefing slides for clearance to present at ORD meeting
Date:	2019/08/23 16:01:39
Priority:	Urgent
Type:	Outlook.Recall

Stewart, Katharine E. would like to recall the message, "esketaamine briefing slides for clearance to present at ORD meeting".

Sender:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA <(b6)@va.gov>
Recipient:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Sent Date:	2019/08/23 16:01:38
Delivered Date:	2019/08/23 16:01:39

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Subject:	Read: HHS bought a rasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 15:46:03
Priority:	Normal
Type:	REPORT.IPM.Note.IPNRN

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
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Sent Date:	2019/03/14 15:46:03

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Subject:	Read: HHS bought a rasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 16:01:07
Priority:	Normal
Type:	REPORT.IPM.Note.IPNRN

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Sent Date:	2019/03/14 16:01:07

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Subject:	Read: HHS bought a rasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 15:37:59
Priority:	Normal
Type:	REPORT.IPM.Note.IPNRN

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Sent Date:	2019/03/14 15:37:59

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Subject:	Read: HHS bought a rasal spray for depression - DRAFT News Release - REVISED
Date:	2019/03/14 10:04:22
Priority:	Normal
Type:	REPORT.IPM.Note.IPNRN

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Sent Date:	2019/03/14 10:04:22

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b6) .gov>
Subject:	Read: FW: Spravato/esketamine approval
Date:	2019/06/24 11:18:06
Priority:	Normal
Type:	REPORT.IPM.Note.IPNRN

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b6) va.gov>
Sent Date:	2019/06/24 11:18:06

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Mole, Larry A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f4eed603a543398e4e0b0bbe52cf41-Mole, Larry (b6)@va.gov>
Subject:	RE:ketamine and Veterans, on CNN
Date:	2019/06/18 21:57:00
Priority:	Normal
Type:	Note

Hope it goes well.

From: Mole, Larry A.
Sent: Tuesday, June 18, 2019 8:56 PM
To: Llorente, Maria D. <(b6)@va.gov>
Subject: RE: ketamine and Veterans, on CNN

Thank you.

Sent with BlackBerry Work
www.blackberry.com

From: Llorente, Maria D. <(b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 6:01 PM
To: Mole, Larry A. (b6)@va.gov>
Subject: FW: ketamine and Veterans, on CNN

Hi Larry. Lu asked me to make you aware that a veteran received Esketamine this morning at the Boston VA for treatment resistant depression. He tolerated the procedure and was discharged with close follow up. We do not know yet if it was therapeutic. In case it comes up during your hearing

Sent with BlackBerry Work
www.blackberry.com

From: Beck, Lucille B. <(b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 4:30 PM
To: Llorente, Maria D. <(b6)@va.gov>, Law, Cassandra M. <(b6)@va.gov>
Subject: RE: ketamine and Veterans, on CNN

Please give Larry Mole a heads up as he is testifying about propose marijuana legislation and it May be raised.

OCLA should provide guidance on any statement.

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
VA Central Office
Phone: (b6)
Cell: (b6)

Sent with BlackBerry Work
(www.blackberry.com).

From: Llorente, Maria D. <(b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 5:28 PM
To: Beck, Lucille B. <(b6)@va.gov>, Law, Cassandra M. <(b6)@va.gov>
Subject: RE: ketamine and Veterans, on CNN

A veteran did successfully receive a treatment today at Boston VA. Don't know outcome, but he tolerated procedure well.

Sent with BlackBerry Work
(www.blackberry.com)

From: Beck, Lucille B. <(b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 12:55 PM
To: Llorente, Maria D. <(b6)@va.gov>, Law, Cassandra M. <(b6)@va.gov>
Subject: ketamine and Veterans, on CNN

Maria,

Just as you predicted, critical piece just aired about ketamine, Veterans, and J and J.

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
Veterans Health Administration (VHA)
Office: (b6)
Cell: (b6)

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Mole, Larry A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7f4eed603a543398e4e0b0bbe52cf41-Mole, Larry (b6)@va.gov>
Sent Date:	2019/06/18 21:57:18

Delivered Date: 2019/06/18 21:57:00

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett (b6) va.gov>; VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcbaf4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>
Subject:	RE: WOW, THIS WAS FAST
Date:	2019/06/24 11:53:14
Priority:	Normal
Type:	Note

Interesting point. Thanks for sending, Mike.

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Monday, Jun 24, 2019, 8:50 AM
To: Glassman, Peter A. ((b6) va.gov>, Lowe, Joette ((b6) va.gov>, VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>, VHAPBM MAP Committee <pbm.map@med.va.gov>
Subject: RE: WOW, THIS WAS FAST

Last Friday, VA provided the following statement to answer media inquiries:

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

So.....all of the articles published since Friday about VA's decision used this statement; some to say VA rejected it and others to say VA approved it. Fascinating.

Mike

From: Glassman, Peter A.
Sent: Monday, June 24, 2019 11:46 AM
To: Lowe, Joette <(b6) va.gov>; VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee <pbm.map@med.va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: WOW, THIS WAS FAST

Wow, indeed. Thanks for sending.

Sent with BlackBerry Work
(www.blackberry.com)

From: Lowe, Joette <(b6) va.gov>
Date: Monday, Jun 24, 2019, 6:05 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>, VHAPBM MAP Committee <pbm.map@med.va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: WOW, THIS WAS FAST

Hey Y'all,

This was really fast for media to get this story out so quickly. We haven't even posted the minutes yet. The title appears to be negative but the article was pretty fair I thought.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404

(b6)

Suicide Prevention is Everyone's Business. #BeThere.



[cid:image009.jpg@01D328A1.8C7B68A0](#)

<https://www.statnews.com/2019/06/21/va-declines-broad-coverage-for-new-jj-depression-drug-touted-by-trump/>

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P (b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett (b6) va.gov>; VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcbaf4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommtee@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>
Sent Date:	2019/06/24 11:53:13
Delivered Date:	2019/06/24 11:53:14
Message Flags:	Unread

From:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT (b6) va.gov>
To:	Martinez, Suzanne Q /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f20b6d10d1e9498e9136c60bd6842f35-Martinez, S (b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P (b6) va.gov>; VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcbaf4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>
Subject:	RE: WOW, THIS WAS FAST
Date:	2019/06/24 15:19:47
Priority:	Normal
Type:	Note

Ain't that the truth!!

Joette S. Lowe, PharmD

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Tuscaloosa, AL 35404

(b6)

Suicide Prevention is Everyone's Business. **#BeThere.**



cid:image009.jpg@01D328A1.8C7B68A0

From: Martinez, Suzanne Q

Sent: Monday, June 24, 2019 1:01 PM

To: Valentino, Michael (VACO) (b6) va.gov>; Glassman, Peter A.

(b6) va.gov>; Lowe, Joette (b6) va.gov>; VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee <pbm.map@med.va.gov>

Subject: RE: WOW, THIS WAS FAST

If only my diet worked so quickly.

From: Valentino, Michael (VACO)

Sent: Monday, June 24, 2019 11:51 AM

To: Glassman, Peter A. (b6) va.gov>; Lowe, Joette (b6) va.gov>; VHAPBM VPE

Formulary Committee <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee
<pbm.map@med.va.gov>

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VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

So.....all of the articles published since Friday about VA's decision used this statement; some to say VA rejected it and others to say VA approved it. Fascinating.

Mike

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Sent: Monday, June 24, 2019 11:46 AM

To: Lowe, Joette ((b6) [REDACTED] va.gov); VHAPBM VPE Formulary Committee
<VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee <pbm.map@med.va.gov>

Cc: Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>

Subject: RE: WOW, THIS WAS FAST

Wow, indeed. Thanks for sending.

Sent with BlackBerry Work
(www.blackberry.com)

From: Lowe, Joette ((b6) [REDACTED] va.gov)

Date: Monday, Jun 24, 2019, 6:05 AM

To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>, VHAPBM MAP Committee <pbm.map@med.va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
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(b6) [REDACTED]

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<https://www.statnews.com/2019/06/21/va-declines-broad-coverage-for-new-ji-depression-drug-touted-by-trump/>

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Sent Date:	2019/06/24 15:19:45
Delivered Date:	2019/06/24 15:19:47

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Subject:	RE: WOW, THIS WAS FAST
Date:	2019/06/24 10:39:57
Priority:	Normal
Type:	Note

Of course. I haven't seen any other articles but this one's content appeared to be pretty fair to me except for the title.

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cid:image009.jpg@01D328A1.8C7B68A0

From: Valentino, Michael (VACO)

Sent: Monday, June 24, 2019 8:44 AM

To: Leslie, Donna M. <(b6)@va.gov>; Lowe, Joette <(b6)@va.gov>

Subject: RE: WOW, THIS WAS FAST

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To: Lowe, Joette <(b6)@va.gov>

Cc: Valentino, Michael (VACO) <(b6)@va.gov>

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From: Lowe, Joette

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To: Mambourg, Scott VHAREN <(b6)@va.gov>; VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee <pbm.map@med.va.gov>

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Cc: Valentino, Michael (VACO) <(b6)@va.gov>

Subject: RE: WOW, THIS WAS FAST

Attachment?

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(www.blackberry.com)

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Date: Monday, Jun 24, 2019, 6:05 AM

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Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Leslie, Donna M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c658dca625d48eba1d7be8efb4caa5c-Leslie, Don <(b6) va.gov>
Sent Date:	2019/06/24 10:39:56
Delivered Date:	2019/06/24 10:39:57

From:	Leslie, Donna M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C658DCA625D48EBA1D7BE8EFB4CAA5C-LESLIE, DON (b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett (b6) va.gov>
Subject:	RE: WOW, THIS WAS FAST
Date:	2019/06/24 09:57:54
Priority:	Normal
Type:	Note

Yikes....Very interesting how they can spin the same statement.

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From: Mambourg, Scott VHAREN

Sent: Monday, June 24, 2019 8:10 AM

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<VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee <pbm.map@med.va.gov>

Cc: Valentino, Michael (VACO) <(b6)@va.gov>

Subject: RE: WOW, THIS WAS FAST

Attachment?

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Date: Monday, Jun 24, 2019, 6:05 AM

To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>, VHAPBM MAP Committee
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Cc: Valentino, Michael (VACO) <(b6)@va.gov>

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Sent Date:	2019/06/24 09:57:53
Delivered Date:	2019/06/24 09:57:54
Message Flags:	Unread

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Ribeiro, Maria /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47516f5f178c44bea9537d88d928af83-Ribeiro, Ma <(b6) va.gov>
Subject:	RE: WOW, THIS WAS FAST
Date:	2019/06/24 16:11:00
Priority:	Normal
Type:	Note

They were getting a lot of inquiries from the media and decided to have one statement they could use for all inquiries instead of doing a new statement for each inquiry

From: Ribeiro, Maria
Sent: Monday, June 24, 2019 4:10 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: WOW, THIS WAS FAST

Thank you.

Why are they placing so much emphasis on this?

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 4:04 PM
To: Ribeiro, Maria <(b6) va.gov>
Cc: Thule, Peter <(b6) va.gov>
Subject: RE: WOW, THIS WAS FAST

Hi Maria,

The statement in bold text below was released to the media by the VA Press Secretary last Friday.....

Mike

From: Ribeiro, Maria
Sent: Monday, June 24, 2019 4:02 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Cc: Thule, Peter <(b6) va.gov>
Subject: RE: WOW, THIS WAS FAST

The agenda has not even been approved yet.
Who informed the press?

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 11:51 AM

To: Glassman, Peter A. <(b6) [REDACTED]@va.gov>; Lowe, Joette <(b6) [REDACTED]@va.gov>; VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee <pbm.map@med.va.gov>

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This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

So.....all of the articles published since Friday about VA's decision used this statement; some to say VA rejected it and others to say VA approved it. Fascinating.

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Sent Date:	2019/06/24 16:11:14
Delivered Date:	2019/06/24 16:11:00

	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P <(b6) va.gov>; Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett <(b6) va.gov>; To: VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcba1f4b52e048838d3053091f54eb4e-VHAPBH VPE <VPEFormularyCommittee@va.gov>; VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBH MAP <pbm.map@med.va.gov>
Subject:	RE: WOW, THIS WAS FAST
Date:	2019/06/24 11:49:17
Priority:	Normal
Type:	Note

Last Friday, VA provided the following to answer any media inquiries:

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From: Lowe, Joette <(b6) [REDACTED] va.gov>
Date: Monday, Jun 24, 2019, 6:05 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>, VHAPBM MAP Committee <pbm.map@med.va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
Subject: WOW, THIS WAS FAST

Hey Y'all,

This was really fast for media to get this story out so quickly. We haven't even posted the minutes yet. The title appears to be negative but the article was pretty fair I thought.

Joette S. Lowe, PharmD
VISN 7 Pharmacy Executive (VPE)
3701 Loop Road East
Tuscaloosa, AL 35404

(b6) [REDACTED]
Suicide Prevention is Everyone's Business. #BeThere.



[cid:image009.jpg@01D328A1.8C7B68A0](#)

<https://www.statnews.com/2019/06/21/va-declines-broad-coverage-for-new-jj-depression-drug-touted-by-trump/>

Recipient:

Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P <(b6) [REDACTED] va.gov>;
Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett <(b6) [REDACTED] va.gov>;
VHAPBM VPE Formulary Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fcbaf4b52e048838d3053091f54eb4e-VHAPBM VPE <VPEFormularyCommittee@va.gov>;
VHAPBM MAP Committee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51be394a33f2409a9fb44ce631b751b3-VHAPBM MAP <pbm.map@med.va.gov>

Sent Date:	2019/06/24 11:49:23
Delivered Date:	2019/06/24 11:49:17
Message Flags:	Unread Unsent

From:	Goodman, Francine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EC164D1255644AC4BB4AF7B812F0A6FB-GOODMAN, FR <(b6) va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>
Subject:	RE: WOW
Date:	2019/08/21 10:49:22
Priority:	Normal
Type:	Note

OMG! That's a great example!

Francine Goodman | National Clinical Pharmacy Program Manager | VHA PBM Services (10P4P)

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, August 21, 2019 8:56 AM
To: Geraci, Mark <(b6) va.gov>; Tortorice, Kathy <(b6) va.gov>; Echevarria, Kelly <(b6) va.gov>; VHAPBM PBM Clinical Only <PBMClinicalOnly@va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Shank, Michelle D <(b6) va.gov>; Henriksen, Andrew L. <(b6) va.gov>
Subject: RE: WOW

Esketamine.....

From: Geraci, Mark
Sent: Wednesday, August 21, 2019 8:53 AM
To: Tortorice, Kathy <(b6) va.gov>; Echevarria, Kelly <(b6) va.gov>; VHAPBM PBM Clinical Only <PBMClinicalOnly@va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Shank, Michelle D <(b6) va.gov>; Henriksen, Andrew L. <(b6) va.gov>
Subject: RE: WOW

Well, that's another whole side to this story....

Mark C. Geraci, Pharm.D., BCOP
National PBM Clinical Pharmacy Program Manager
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue-1 Block North of Cermak (Bldg 37, Room 139)
Hines, IL 60141
Phone: (b6)
Fax: 708-786-7989

From: Tortorice, Kathy
Sent: Wednesday, August 21, 2019 7:51 AM
To: Geraci, Mark <(b6) va.gov>; Echevarria, Kelly <(b6) va.gov>; VHAPBM PBM

Clinical Only <PBMClinicalOnly@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Cc: Shank, Michelle D <(b6)@va.gov>; Henriksen, Andrew L. <(b6)@va.gov>
Subject: RE: WOW

(b6)

From: Geraci, Mark
Sent: Wednesday, August 21, 2019 7:50 AM
To: Echevarria, Kelly <(b6)@va.gov>; VHAPBM PBM Clinical Only <PBMClinicalOnly@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Cc: Shank, Michelle D <(b6)@va.gov>; Henriksen, Andrew L. <(b6)@va.gov>
Subject: RE: WOW

Very interesting but not surprised.

Mark C. Geraci, Pharm.D., BCOP
National PBM Clinical Pharmacy Program Manager
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue-1 Block North of Cermak (Bldg 37, Room 139)
Hines, IL 60141
Phone: (b6)
Fax: 708-786-7989

From: Echevarria, Kelly
Sent: Wednesday, August 21, 2019 7:47 AM
To: VHAPBM PBM Clinical Only <PBMClinicalOnly@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Cc: Shank, Michelle D <(b6)@va.gov>; Henriksen, Andrew L. <(b6)@va.gov>
Subject: WOW

This was super interesting

https://www.medscape.com/viewarticle/916873?nlid=131151_4822&src=WNL_mdplsfeat_190820_msc_pedit_phar&uac=75642AJ&spon=30&implD=2067592&faf=1

Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP
National Clinical Pharmacy Program Manager – Infectious Diseases
VHA Pharmacy Benefits Management
(b6)

ASTF SharePoint:
<https://vaww.pbmnat.va.gov/sites/PBM/ASTF/SitePages/Home.aspx>

Sender: Goodman, Francine /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EC164D1255644AC4BB4AF7B812F0A6FB-GOODMAN, FR (b6)@va.gov>
Recipient:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6)@va.gov>
Sent Date:	2019/08/21 10:49:21
Delivered Date:	2019/08/21 10:49:22
Message Flags:	Unread

From:	Itebejac, Ivan S. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8EA7279E6E9043D394CE89972A6152D2-ITEBEJAC, I (b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) va.gov>
CC:	Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis (b6) a.gov>
Subject:	RE: VPE MAP
Date:	2019/06/17 10:29:19
Priority:	Normal
Type:	Note

Thank you. I plan to be at as much as I can, for sure that discussion.
Best regards,
Ivan

From: Valentino, Michael (VACO) <(b6) va.gov>
Date: Monday, Jun 17, 2019, 9:51 AM
To: Itebejac, Ivan S. <(b6)@va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Torphy, Lisa <(b6) va.gov>
Subject: RE: VPE MAP

Sorry to hear the news Ivan. Of course it is no problem for you to miss the meeting. Jenn, can Lisa send the dial in codes?
Ivan, the issue that I believe may be the most interesting is esketamine.....you might want to make listening to that one a priority. If you can't listen in, you may want to let Jenn or Matt know your votes

Sent with BlackBerry Work
(www.blackberry.com)

From: Itebejac, Ivan S. (b6)@va.gov>
Date: Monday, Jun 17, 2019, 8:35 AM
To: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Cc: Torphy, Lisa <(b6) va.gov>
Subject: VPE MAP

Good morning,

I will be unable to travel for the meeting this week due to (b6). (b6)
For now it looks like I should be able to join
virtually this week, as (b6), but I expect
we will travel Friday.
If approved, please share a VANTS/Skype code with me so I can attend virtually.
I successfully cancelled the hotel reservation and all travel authorizations last evening without
penalty.
Thanks for considering. I apologize I am not able to attend in-person.
Ivan

Sender:	Itebejac, Ivan S. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8EA7279E6E9043D394CE89972A6152D2-ITEBEJAC, I (b6)@va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6)@va.gov>; Torphy, Lisa /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43ab37387c5c4ed6bae3006dcde84582-Torphy, Lis (b6)@va.gov>
Sent Date:	2019/06/17 10:29:18
Delivered Date:	2019/06/17 10:29:19

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6) [REDACTED]@va.gov>
To:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, (b6) [REDACTED]@va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) [REDACTED]@va.gov>; Downs, John R /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3b4cb66b5ad4057a546b04553edca2d-Downs, John <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>
CC:	Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B (b6) [REDACTED]@va.gov>
Subject:	RE: VA/DoD Bipolar Disorder CPG
Date:	2019/06/28 18:15:59
Priority:	Normal
Type:	Note

Thanks!

From: Schreiber, Matthew A.
Sent: Friday, June 28, 2019 3:02 PM
To: Glassman, Peter A. <(b6) [REDACTED]@va.gov>; Fuller, Matthew A. (PBM) <(b6) [REDACTED]@va.gov>; Downs, John R <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Cc: Capehart, Bruce P. DURVAMC <(b6) [REDACTED]@va.gov>
Subject: RE: VA/DoD Bipolar Disorder CPG

I don't think there would be a lot to add, personally. Matthew's summary is excellent, just that there isn't a lot of therapeutic advance in terms of utility in the newer medications, in my opinion.

(b6) [REDACTED]
 [REDACTED]
 [REDACTED] k! I guess I should take a look at it before casting aspersions, but....

In all seriousness, though—there don't seem to be a lot of changes in how we treat bipolar disorder since that guideline was retired (it's a very useful guideline, BTW). The APA hasn't even updated their guidelines since about 2002!

I'd like to hear Bruce's thoughts, and it wouldn't hurt to cast further out for more opinions. Maybe there would be some use for an addendum? This is what UK NICE guidelines sometimes seem to do in this kind of situation. But overall—not too strongly enthusiastic.

From: Glassman, Peter A.
Sent: Friday, June 28, 2019 2:56 PM
To: Fuller, Matthew A. (PBM) <(b6) [REDACTED] va.gov>; Downs, John R <(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>
Cc: Schreiber, Matthew A. <(b6) [REDACTED] va.gov>; Capehart, Bruce P. DURVAMC <(b6) [REDACTED] va.gov>
Subject: RE: VA/DoD Bipolar Disorder CPG

Thanks. Matt and Bruce what are your thoughts about a new guideline? Should we ask VACO folks too?

From: Fuller, Matthew A. (PBM)
Sent: Friday, June 28, 2019 1:58 PM
To: Glassman, Peter A. <(b6) [REDACTED] va.gov>; Downs, John R <(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>
Cc: Schreiber, Matthew A. <(b6) [REDACTED] va.gov>; Capehart, Bruce P. DURVAMC <(b6) [REDACTED] va.gov>
Subject: RE: VA/DoD Bipolar Disorder CPG

All,

The bipolar disorder CPG was completed in 2010 and included discussion of the following drugs: lithium, VPA, CBZ, LMT, oxcarbazepine, topiramate, gabapentin, olanzapine, olanzapine/fluoxetine, quetiapine, risperidone, aripiprazole, ziprasidone, haloperidol, clozapine and various antidepressants. Drugs approved for bipolar disorder not discussed in the CPG include: asenapine, cariprazine, chlorpromazine, and lurasidone. Drugs not approved for bipolar disorder but may be used clinically include: armodafinil, clonazepam, clonidine, esketamine, ketamine, levetiracetam, iloperidone, paliperidone, other first generation antipsychotics, tiagabine, and verapamil. Hope this helps with decision making.

Regards,

Matthew

From: Glassman, Peter A.
Sent: Friday, June 28, 2019 4:05 PM
To: Downs, John R <(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>
Cc: Fuller, Matthew A. (PBM) <(b6) [REDACTED] va.gov>; Schreiber, Matthew A. <(b6) [REDACTED] va.gov>; Capehart, Bruce P. DURVAMC <(b6) [REDACTED] va.gov>
Subject: RE: VA/DoD Bipolar Disorder CPG

There have been, to my knowledge, no new medications so I don't think so but then again I am not familiar if there have been changes in practice--let me add in Matt S and Matt F and Bruce for their thoughts.

From: Downs, John R
Sent: Friday, June 28, 2019 1:02 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>; Glassman, Peter A. <(b6) [REDACTED] va.gov>
Subject: VA/DoD Bipolar Disorder CPG

Jenn and Pete,

As the PBM rep to the VA/DoD EBPWG I am being asked to query whether PBM sees a need for an update of the VA/DoD Bipolar CPG. This CPG has been archived as of 2 years ago when there was little filed interest and no new medications. Todd Semla was the SME back then and he agreed. Do y'all see any issues from the PBM perspective that would warrant taking this one out of retirement and updating?

Best,

Rick

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6) va.gov>
Recipient:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Downs, John R /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3b4cb66b5ad4057a546b04553edca2d-Downs, John <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>
Sent Date:	2019/06/28 18:15:58
Delivered Date:	2019/06/28 18:15:59
Message Flags:	Unread

From:	Lane, Ca-Asia A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9D29E7CA0DC4FD0A6C963114D519B09-LANE, CA-AS <(b6)@va.gov>
To:	Tucker, Brooks /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24ae47cff629405aa8557cc2cc792903-Tucker, Bro <(b6)@va.gov>; Anderson, Christopher /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6975381a335487284adae636cc3d666-Anderson, C <(b6)@va.gov>; Haverstock, Cathy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c3c46a7ea634b5a8a6d0618028d0f89-Haverstock, C <(b6)@va.gov>
CC:	Johnson, Glenn /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c2def801948c4c68ba78aa2c5675bdf-Johnson, Gl <(b6)@va.gov>; Franklin, Keita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15ea4a5623c141d0a1d02611f7e975cd-Franklin, K <(b6)@va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b5745c8952a823b04dabff5-Carroll, Da <(b6)@va.gov>
Subject:	RE: VA's availability of Spravato (esketamine) linked to BeThere campaign
Date:	2019/06/18 11:05:38
Priority:	Normal
Type:	Note

Insight from Program Office:

(b) (5)

Program office (Dr. Carroll) recommends confining any comments to the below, which is previous cleared VA/VHA recent response to the recent media articles – see yellow highlight in the attached and I will include in our questions list.

Recommended response to any Ketamine questions that may come up during hearing:

- (b) (5)

(Thoughts)

Very Respectfully,
Ca-Asia A. Lane
Congressional Relations Officer
Office of Congressional & Legislative Affairs
Department of Veterans Affairs
(b6) [REDACTED] va.gov
Office: (b6) [REDACTED]
Work Cell: (b6) [REDACTED]

From: Tucker, Brooks
Sent: Tuesday, June 18, 2019 9:31 AM
To: Lane, Ca-Asia A. <(b6) [REDACTED] va.gov>; Anderson, Christopher <(b6) [REDACTED] va.gov>; Haverstock, Cathy <(b6) [REDACTED] va.gov>
Cc: Johnson, Glenn <(b6) [REDACTED] va.gov>
Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

Discussed with Secva this morning and we can go over it again at the prep.

Sent with BlackBerry Work
(www.blackberry.com)

From: Lane, Ca-Asia A. <(b6) [REDACTED] va.gov>
Date: Tuesday, Jun 18, 2019, 9:25 AM
To: Anderson, Christopher <(b6) [REDACTED] va.gov>, Haverstock, Cathy <(b6) [REDACTED] va.gov>, Tucker, Brooks (b6) [REDACTED] @va.gov>
Cc: Johnson, Glenn <(b6) [REDACTED] va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

Sir/Maam,

I haven't dug into the below just yet, but bringing to your attention to shape a ??? possibly. (Again, I've not reviewed it just yet).

From: Franklin, Keita
Sent: Tuesday, June 18, 2019 8:53 AM
To: Lane, Ca-Asia A. <(b6) [REDACTED] va.gov>; Carroll, David (VACO) <(b6) [REDACTED] va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lakso, Wendy
Sent: Tuesday, June 18, 2019 8:01 AM
To: Franklin, Keita (b6) [REDACTED] va.gov>

Cc: Actions <actions@dgccommunications.com>; Jones, Taunya (b6) va.gov>

Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

Dr. Franklin,

Head's up as the SVAC is tomorrow – the below link is an article on J&J about esketamine. I've added a paragraph I pulled from the article which mentions #BeThere and as part of the campaign it was mentioned in a PSA that J&J and the VA are undertaking a new clinical trial process....." This may come up in the hearing.

<https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans>

"While it was under development, J&J's and Janssen's relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson & Johnson joined the VA's suicide prevention campaign, #BeThere. A public service announcement on the campaign said J&J and the VA will "undertake new clinical trial processes in hopes of providing access to the latest and most innovative treatments to help veterans in need".

Wendy Lakso

Acting Deputy Director, Suicide Prevention Program

Office of Mental Health and Suicide Prevention

Veterans Health Administration

Cell: (b6)

Sender:	Lane, Ca-Asia A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F9D29E7CA0DC4FD0A6C963114D519B09-LANE, CA-AS <(b6) va.gov>
Recipient:	Tucker, Brooks /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=24ae47cff629405aa8557cc2cc792903-Tucker, Bro (b6) @va.gov>; Anderson, Christopher /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a6975381a335487284adae636cc3d666-Anderson, C <(b6) va.gov>; Haverstock, Cathy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c3c46a7ea634b5a8a6d0618028d0f89-Haverstock, <(b6) va.gov>; Johnson, Glenn /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c2def801948c4c68ba78aa2c5675bdfb-Johnson, Gl <(b6) va.gov>; Franklin, Keita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15ea4a5623c141d0a1d02611f7e975cd-Franklin, K (b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>
Sent Date:	2019/06/18 11:05:37
Delivered Date:	2019/06/18 11:05:38
From:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b6) va.gov>
To:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>;

	VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>
	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; CC: VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA CO 10N Support Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49641c3663c04aa58d87f8b7fa6dd515-VHA CO 10N <VHACO10NSS@va.gov>
Subject:	FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients
Date:	2019/06/07 09:05:35
Priority:	Normal
Type:	Note

Good Morning Mr. Greilsamer/VHA Communications,

On behalf of 10N/10NC, Ms. Christine Croteau clears the below response from 10NC5 to your inquiry.

Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist
Office of the ADUSH for Clinical Operations (10NC)
(b6) (office)
(b6) (cell)

From: Croteau, Christine
Sent: Friday, June 07, 2019 9:03 AM
To: Stewart, Katharine E. (l(b6) (b6)@va.gov); VHA 10NC Clearance <VHA10NCCclearance2@va.gov>
Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

10NC clears

From: Gavin, Stacy
Sent: Friday, June 07, 2019 8:58 AM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: Wiechers, Ilse <Ilse.Wiechers@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; Valentino, Michael (VACO) <(b6) (b6)@va.gov>
Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good morning,

Two weeks after the FDA approved intranasal esketamine for use in conjunction with an oral antidepressant for the treatment of treatment-resistant depression in adults, the VA announced the treatment would be made available to Veterans based on their individual medical needs combined with providers' clinical assessments. VA is now preparing a thoughtful, step-wise approach to clinical implementation of esketamine that puts Veteran safety first and ensures close, careful monitoring of potential adverse events, including the risk of addiction. This reflects our commitment to seek new ways to provide the best health care available for our nation's Veterans. Initial use of this treatment is anticipated for this summer at several sites across the country.

From: Greilsamer, Alan

Sent: Thursday, June 06, 2019 5:51 PM

To: Acree, Jill L. (b6) <(b6)@va.gov>

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>; Wiechers, Ilse (b6) <(b6)@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good afternoon,

VA Press Secretary has asked the VHA SME/program office to develop a two-sentence statement defending VA's decision to rapidly implement use of a drug that could pose significant life-long addiction risks.

Requesting a response to 10B2B by tomorrow (June 7) no later than 3 p.m. ET.

Thank you, Alan

—

Alan Greilsamer

Director, Media Relations (10B2B)

Office of Communications

Veterans Health Administration

P: (b6)

E: (b6)@va.gov

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Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>, VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>, VHA CO 10N Support Staff <VHACO10NSS@va.gov>

Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good afternoon,

On behalf of 10N/10NC, Christine Croteau clears the response below and attached submitted by 10NC5.

Thank you,

Jill L. Acree, M.A.
Health Systems Specialist
ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
Office: (b6)
Cell: (b6)

From: Croteau, Christine
Sent: Thursday, June 6, 2019 11:25 AM
To: Acree, Jill L. (b6) <(b6)@va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

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Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good morning,

In addition to Dr. Wiechers, 10NC5 recommends Jennifer Zacher or another SME from PBM participate.

Regarding side effects, we included the following in the iMed consent form for patients receiving esketamine:

- Sleepiness(sedation)
- fainting
- feeling disconnected from yourself, your thoughts, feelings, space & time(dissociation)
- dizziness
- nausea/vomiting
- spinning sensation
- anxiety
- blood pressure increase
- feeling drunk
- lack of energy
- numbness
- risk for abuse and physical and psychological dependence or addiction
- bladder problems
- problems thinking clearly
- increased risk of suicidal thoughts or actions

- full list available (see SPRAVATO Prescribing Information)

Attached is the referred to Spravato REMS Prescribing information document (also embedded in our iMed consent as a patient education document).

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Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>
Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Thanks – please send the information of the side effects when you can.

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Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>; VHA CO 10N Support Staff <VHACO10NSS@va.gov>
Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good Morning,

On behalf of 10N/10NC, Dr. Sherrie Schuldheis clears Dr. Wiechers to participate. Please see Dr. Schuldheis' response below.

Thank you,

Jill L. Acree, M.A.
Health Systems Specialist
ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
Office: (b6)
Cell: (b6)

From: Schuldheis, Sherrie L, Ph.D
Sent: Thursday, June 6, 2019 10:32 AM
To: Davis, Lashelle (VHACO) <(b6)@va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>
Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

10 NC clears Dr. Wiechers to participate; we can't clear the COS from a facility as that is a local decision.

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b5) (cell)
(b5) va.gov

From: Gavin, Stacy
Sent: Thursday, June 06, 2019 9:22 AM
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Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good morning,

10NC5 recommends Dr. Wiechers participate in this interview. We will send additional information on side effects later, as Dr. Wiechers is on pacific time.

Stacy

From: Greilsamer, Alan
Sent: Wednesday, June 05, 2019 5:37 PM
To: VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

10NC,

Please see below request. Does 10NC/10NC5 recommend that Dr. Wiechers participate in this interview? Additionally, will you provide information about the side effects that the reporter references.

Requesting a response by tomorrow (June 6) no later than 2 p.m. ET.

Thanks, Alan

—

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b6)
E: (b6) va.gov

From: Cashour, Curtis

Sent: Tuesday, June 4, 2019 5:51 PM

To: Hull, Candace <(b6)@va.gov>; Hutton, James <(b6)@va.gov>; Carter, Susan

<(b6)@va.gov>; Ballesteros, Mark <(b6)@va.gov>; Greilsamer, Alan

<(b6)@va.gov>; Screen, Gina <(b6)@va.gov>

Cc: Northstar, Jan <(b6)@va.gov>; Ruthman, Erika <(b6)@va.gov>; Thomas, Tom

<(b6)@va.gov>; Fluker, Paige <(b6)@va.gov>

Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Alan/Gina – what is your recommended response?

Curt Cashour

Press Secretary

Department of Veterans Affairs

(b6)

(b6)@va.gov

@curtcashour

From: Hull, Candace

Sent: Tuesday, June 4, 2019 1:00 PM

To: Cashour, Curtis <(b6)@va.gov>; Hutton, James <(b6)@va.gov>; Carter, Susan

<(b6)@va.gov>; Ballesteros, Mark <(b6)@va.gov>

Cc: Northstar, Jan <(b6)@va.gov>; Ruthman, Erika <(b6)@va.gov>; Thomas, Tom

<(b6)@va.gov>; Fluker, Paige <(b6)@va.gov>

Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Importance: High

Curt, please note the query below.

From: Fluker, Paige

Sent: Tuesday, June 4, 2019 12:40 PM

To: Northstar, Jan <(b6)@va.gov>; Hull, Candace <(b6)@va.gov>; Ruthman, Erika

<(b6)@va.gov>

Subject: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Importance: High

Please see below. The facility is recommending CO provides a response and VISN concurs. In part due to the reporter's ties with national outlets and also the controversy surrounding the topic.

Date of request: June 4, 2019

Subject: Esketamine rapid approval for use at VA

Outlet: Center for Public Integrity (Reporter states stories run in NY Times, Washington Post, USA Today and multiple online publications)

Reporter: Peter Cary

Phone: (b6) (office); (b6) (mobile)

E-mail: (b6) publicintegrity.org

Deadline: June 7, 2019

Projected publication date: June 20, 2019

Request: Reporter requests interview with Charleston VAMC Associate Chief of Staff for Mental Health Dr. Donald "Hugh" Myrick regarding esketamine use in VA patients. This drug was approved for use by FDA in March and approved for use in VA within two weeks, which was very rapid. While there has been a lot of discussion around the drug, there has been significant hesitations expressed by clinicians across the country regarding the side effects of the drug. Focus of the interview will be on efficacy, patient safety and VA's decision to rapidly implement use of a drug that could pose significant life-long addiction risks.

Background info: Reporter states he has contacted multiple physicians including other VA physicians and has submitted a FOIA request to VHA. Dr. Myrick is part of the national VA workgroup charged with rolling out the drug for use in VA; the reporter is not aware of this fact. Recommendation is for possible interview with Dr. Ilse Wiechers, chair of the VACO workgroup charged with rolling out the drug for use in VA or other appropriate national SME.

Thanks,

Paige Fluker, M.S., M.A.

U.S. Army Veteran

Deputy Public Affairs Officer | Stakeholder Relations

VA Southeast Network (VISN 7)

3700 Crestwood Pkwy Duluth, GA

Office: (b6)

Cell: (b6)

Inside VA Southeast Network

Sender:	Stewart, Katharine E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=182805D689894DA4B2D00810DA5E305C-STEWART, KA (b6)@va.gov>
Recipient:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fb5c68c590d58fa4b-Greilsamer, <(b6)@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>; VHA CO 10N Support Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49641c3663c04aa58d87f8b7fa6dd515-VHA CO 10N <VHACO10NSS@va.gov>

Sent Date:	2019/06/07 09:05:34
Delivered Date:	2019/06/07 09:05:35

From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Franklin, Keita /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15ea4a5623c141d0a1d02611f7e975cd-Franklin, K <(b6) va.gov>; Lane, Ca-Asia A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9d29e7ca0dc4fd0a6c963114d519b09-Lane, Ca-As <(b6) va.gov>
Subject:	RE: VA's availability of Spravato (esketamine) linked to BeThere campaign
Date:	2019/06/18 09:08:00
Priority:	Normal
Type:	Note

It might be good to discuss strategy for responding at the prep session today – should this come up at the hearing. Although J&J did have a partnership (MOA?) with VA at the time, the development of Spravato was NOT explicitly part of it in any way. Recommend confining any response/comment to what we wrote and cleared recently in response to the recent media articles – see yellow highlight in the attached.

From: Franklin, Keita
Sent: Tuesday, June 18, 2019 8:53 AM
To: Lane, Ca-Asia A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lakso, Wendy
Sent: Tuesday, June 18, 2019 8:01 AM
To: Franklin, Keita <(b6) va.gov>
Cc: Actions <actions@dgccommunications.com>; Jones, Taunya <(b6) va.gov>
Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

Dr. Franklin,
Head's up as the SVAC is tomorrow – the below link is an article on J&J about esketamine. I've added a paragraph I pulled from the article which mentions #BeThere and as part of the campaign it was mentioned in a PSA that J&J and the VA are undertaking a new clinical trial process.....” This may come up in the hearing.

<https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans>

“While it was under development, J&J’s and Janssen’s relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson & Johnson joined the VA’s suicide prevention campaign, #BeThere. A public service announcement on the campaign said J&J and the VA will “undertake new

clinical trial processes in hopes of providing access to the latest and most innovative treatments to help veterans in need”.

Wendy Lakso
Acting Deputy Director, Suicide Prevention Program
Office of Mental Health and Suicide Prevention
Veterans Health Administration
Cell: (b6)

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
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Thank you,

Katie Stewart, MSW, LCSW
Health Systems Specialist

Office of the ADUSH for Clinical Operations (10NC)

(b6) (office)

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Office of Communications
Veterans Health Administration
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Thank you,

Jill L. Acree, M.A.
Health Systems Specialist
ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
Office: (b6)
Cell: (b6)

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- problems thinking clearly
- increased risk of suicidal thoughts or actions
- full list available (see SPRAVATO Prescribing Information)

Attached is the referred to Spravato REMS Prescribing information document (also embedded in our iMed consent as a patient education document).

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Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>; VHA CO 10N Support Staff

<VHACO10NSS@va.gov>

Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good Morning,

On behalf of 10N/10NC, Dr. Sherrie Schuldheis clears Dr. Wiechers to participate. Please see Dr. Schuldheis' response below.

Thank you,

Jill L. Acree, M.A.
Health Systems Specialist
ADUSH for Clinical Operations (10NC)
810 Vermont Ave. NW
Washington, D.C. 20420
Office: (b6)
Cell: (b6)

From: Schuldheis, Sherrie L, Ph.D
Sent: Thursday, June 6, 2019 10:32 AM
To: Davis, Lashelle (VHACO) (b6) @va.gov; VHA 10NC Clearance
<VHA10NCClearance2@va.gov>
Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

10 NC clears Dr. Wiechers to participate; we can't clear the COS from a facility as that is a local decision.

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b5) (cell)
(b5) va.gov

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Sent: Thursday, June 06, 2019 9:22 AM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov
Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Good morning,

10NC5 recommends Dr. Wiechers participate in this interview. We will send additional information on side effects later, as Dr. Wiechers is on pacific time.

Stacy

From: Greilsamer, Alan
Sent: Wednesday, June 05, 2019 5:37 PM
To: VHA 10NC Action <vha10ncaction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

10NC,

Please see below request. Does 10NC/10NC5 recommend that Dr. Wiechers participate in this interview? Additionally, will you provide information about the side effects that the reporter references.

Requesting a response by tomorrow (June 6) no later than 2 p.m. ET.

Thanks, Alan

—

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b6)
E: (b6) va.gov

From: Cashour, Curtis
Sent: Tuesday, June 4, 2019 5:51 PM
To: Hull, Candace <(b6) va.gov>; Hutton, James ((b6) va.gov>; Carter, Susan <(b6) va.gov>; Ballesteros, Mark ((b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>
Cc: Northstar, Jan <(b6) va.gov>; Ruthman, Erika <(b6) va.gov>; Thomas, Tom ((b6) va.gov>; Fluker, Paige (b6) @va.gov>
Subject: RE: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients

Alan/Gina – what is your recommended response?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Hull, Candace
Sent: Tuesday, June 4, 2019 1:00 PM
To: Cashour, Curtis <(b6) va.gov>; Hutton, James <(b6) va.gov>; Carter, Susan (b6) va.gov>; Ballesteros, Mark (b6) @va.gov>

Cc: Northstar, Jan <(b6) va.gov>; Ruthman, Erika <(b6) va.gov>; Thomas, Tom (b6) va.gov>; Fluker, Paige <(b6) @va.gov>

Subject: FW: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients
Importance: High

Curt, please note the query below.

From: Fluker, Paige

Sent: Tuesday, June 4, 2019 12:40 PM

To: Northstar, Jan <(b6) va.gov>; Hull, Candace <(b6) va.gov>; Ruthman, Erika <(b6) va.gov>

Subject: Charleston MEDIA QUERY - Center for Public Integrity, Esketamine use in VA patients
Importance: High

Please see below. The facility is recommending CO provides a response and VISN concurs. In part due to the reporter's ties with national outlets and also the controversy surrounding the topic.

Date of request: June 4, 2019

Subject: Esketamine rapid approval for use at VA

Outlet: Center for Public Integrity (Reporter states stories run in NY Times, Washington Post, USA Today and multiple online publications)

Reporter: Peter Cary

Phone: (b6) (office); (b6) (mobile)

E-mail: (b6) [publicintegrity.org](mailto:(b6)@publicintegrity.org)

Deadline: June 7, 2019

Projected publication date: June 20, 2019

Request: Reporter requests interview with Charleston VAMC Associate Chief of Staff for Mental Health Dr. Donald "Hugh" Myrick regarding esketamine use in VA patients. This drug was approved for use by FDA in March and approved for use in VA within two weeks, which was very rapid. While there has been a lot of discussion around the drug, there has been significant hesitations expressed by clinicians across the country regarding the side effects of the drug. Focus of the interview will be on efficacy, patient safety and VA's decision to rapidly implement use of a drug that could pose significant life-long addiction risks.

Background info: Reporter states he has contacted multiple physicians including other VA physicians and has submitted a FOIA request to VHA. Dr. Myrick is part of the national VA workgroup charged with rolling out the drug for use in VA; the reporter is not aware of this fact. Recommendation is for possible interview with Dr. Ilse Wiechers, chair of the VACO workgroup charged with rolling out the drug for use in VA or other appropriate national SME.

Thanks,

Paige Fluker, M.S., M.A.

U.S. Army Veteran
Deputy Public Affairs Officer | Stakeholder Relations
VA Southeast Network (VISN 7)
3700 Crestwood Pkwy Duluth, GA
Office: (b6)
Cell: (b6)
Inside VA Southeast Network

Sender:	Stewart, Katharine E. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=182805d689894da4b2d00810da5e305c-Stewart, Ka <(b6) va.gov>
Recipient:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFHSSs@va.gov>; VHA CO 10N Support Staff /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=49641c3663c04aa58d87f8b7fa6dd515-VHA CO 10N <VHACO10NSS@va.gov>
Sent Date:	2019/06/07 09:05:34
Delivered Date:	2019/06/07 09:05:35

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P <(b6)@va.gov>
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
Subject:	RE: VA's availability of Spravato (esketamine) linked to BeThere campaign
Date:	2019/06/18 12:00:29
Priority:	Normal
Type:	Note

Just got word from m Dr Witcher's that this med was administered at Boston VA. Would we want to mention that?

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 10:48 AM
To: Hastings, Patricia R. <(b6)@va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6)@va.gov>, Llorente, Maria D. <(b6)@va.gov>
Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

Hi Pat, looks good. Except we are meeting tomorrow and Thursday, not next week. Just called and left you a voicemail with me cell (b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Brooks, Aja <(b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 10:36 AM
To: Hastings, Patricia R. <(b6)@va.gov>, VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) <(b6)@va.gov>, Emmendorfer, Thomas (PBM) <(b6)@va.gov>, Llorente, Maria D. <(b6)@va.gov>, VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

OCLA acknowledges receipt.

v/r AJ

From: Hastings, Patricia R.

Sent: Tuesday, June 18, 2019 11:13 AM

To: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>

Cc: Valentino, Michael (VACO) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Brooks, Aja (l(b6)@va.gov>; Llorente, Maria D. <(b6)@va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>

Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

10P4 Actions, 10P Actions,

This is a short notice request from the Assistant Secretary for VA's Office of Congressional and Legislative Affairs regarding bullets for the medication Esketamine. Cleared for submission to 10P. Please let me know if you need additional information.

- • VA is an advocate for Veterans with injuries arising from military service.
- • Some of those needs are due to the hidden injuries of war.
- • VA constantly seeks to provide Veterans with mental health needs, such as PTSD, suicidal ideation and depression with effective treatments.
 - • This search involves the review of new treatment possibilities and findings grounded in evidence-based medicine, best practices and research.
 - • Esketamine is a medication approved by the FDA for treatment-resistant depression in adults who failed on other antidepressant medicines.
- • The VA Formulary Committees meets next week and will discuss Esketamine (trade name, Spravato), to review clinical efficacy, safety and parameters for use.
- • VA has many other new, experimental or recently developed therapies in review for treatment of maladies that have had limited improvement with traditional modes of treatment. (Examples: Stellate Ganglion Block, yoga, acupuncture, new medicines, Cognitive Behavior Therapy).

V/R

Dr. Patricia R. Hastings

Acting Deputy Chief Patient Care Services Officer

Deputy Chief Consultant for Post-Deployment Health Services (10P4Q)

Patient Care Services, 810 Vermont Ave NW, Washington, DC 20420

O: (b6)

O: (b6)

C: (b6) 1

F: 202-495-5973

(b6)@va.gov

VA Motto: ICARE [Integrity-Commitment-Advocacy-Respect-Excellence]

From: Lane, Ca-Asia A.
Sent: Tuesday, June 18, 2019 10:04 AM
To: Franklin, Keita <(b6) va.gov>
Cc: Brooks, Aja <(b6) va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

Thanks maam.

Brooks mentioned that we should probably spend a moment discussing just to bring the Sec. into awareness of our J&J relationship as well.....

Also including my colleague Aja to reach out to her portfolio folks to ensure its FDA, irregularity etc.....

Very Respectfully,
Ca-Asia A. Lane
Congressional Relations Officer
Office of Congressional & Legislative Affairs
Department of Veterans Affairs
(b6) va.gov
Office: (b6)
Work Cell: (b6)

From: Franklin, Keita
Sent: Tuesday, June 18, 2019 8:53 AM
To: Lane, Ca-Asia A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lakso, Wendy
Sent: Tuesday, June 18, 2019 8:01 AM
To: Franklin, Keita <(b6) va.gov>
Cc: Actions <actions@dcgcommunications.com>; Jones, Taunya <(b6) va.gov>
Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

Dr. Franklin,
Head's up as the SVAC is tomorrow – the below link is an article on J&J about esketamine. I've added a paragraph I pulled from the article which mentions #BeThere and as part of the campaign it was mentioned in a PSA that J&J and the VA are undertaking a new clinical trial process.....” This may come up in the hearing.

<https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans>

“While it was under development, J&J’s and Janssen’s relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson & Johnson joined the VA’s suicide prevention campaign, #BeThere. A public service announcement on the campaign said J&J and the VA will “undertake new clinical trial processes in hopes of providing access to the latest and most innovative treatments to help veterans in need”.

Wendy Lakso
Acting Deputy Director, Suicide Prevention Program
Office of Mental Health and Suicide Prevention
Veterans Health Administration
Cell: (b6) 78

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Hastings, Patricia R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a504fbfe766048a5a65461c45f28e9de-Hastings, P <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/06/18 12:00:28
Delivered Date:	2019/06/18 12:00:29

From:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) va.gov>
Subject:	RE: VA's availability of Spravato (esketamine) linked to BeThere campaign
Date:	2019/06/18 11:38:23
Priority:	Normal
Type:	Note

Mike,

Can you call me at (b6)

pat

From: Valentino, Michael (VACO)
Sent: Tuesday, June 18, 2019 11:34 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Hastings, Patricia R. (b6) va.gov>
Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

Is there an "ask" here or just for awareness?

Sent with BlackBerry Work
www.blackberry.com

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 9:22 AM
To: Hastings, Patricia R. (b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Brooks, Aja
Sent: Tuesday, June 18, 2019 10:07 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lane, Ca-Asia A.
Sent: Tuesday, June 18, 2019 10:04 AM

To: Franklin, Keita <(b6) [REDACTED] va.gov>
Cc: Brooks, Aja <(b6) [REDACTED] va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

Thanks maam.

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Also including my colleague Aja to reach out to her portfolio folks to ensure its FDA, irregularity etc.....

Very Respectfully,
Ca-Asia A. Lane
Congressional Relations Officer
Office of Congressional & Legislative Affairs
Department of Veterans Affairs
(b6) [REDACTED] va.gov
Office: (b6) [REDACTED]
Work Cell: (b6) [REDACTED]

From: Franklin, Keita
Sent: Tuesday, June 18, 2019 8:53 AM
To: Lane, Ca-Asia A. <(b6) [REDACTED] va.gov>; Carroll, David (VACO) <(b6) [REDACTED] va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lakso, Wendy
Sent: Tuesday, June 18, 2019 8:01 AM
To: Franklin, Keita <(b6) [REDACTED] va.gov>
Cc: Actions <actions@dgccommunications.com>; Jones, Taunya <(b6) [REDACTED] va.gov>
Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

Dr. Franklin,
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<https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans>

“While it was under development, J&J’s and Janssen’s relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson & Johnson joined the VA’s suicide prevention campaign,

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Wendy Lakso
Acting Deputy Director, Suicide Prevention Program
Office of Mental Health and Suicide Prevention
Veterans Health Administration
Cell: (b6)

Sender:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b6)@va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6)@va.gov>
Sent Date:	2019/06/18 11:38:22
Delivered Date:	2019/06/18 11:38:23

From:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b6) va.gov>
To:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) va.gov>; Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja (b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b6) va.gov>; VHA 10P4 PCS Clearance /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fff83d687b9d4fa78cd996960409675b-VHA 10P4 PC <VHA10P4PCSClearance@va.gov>
Subject:	RE: VA's availability of Spravato (esketamine) linked to BeThere campaign
Date:	2019/06/18 12:08:47
Priority:	Normal
Type:	Note

Adding a note from Dr. Llorente:

This morning VHA provided the first treatment with esketamine. The Veteran tolerated the treatment well and was discharged home with close outpatient follow up plans.

From: Hastings, Patricia R.
Sent: Tuesday, June 18, 2019 11:13 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Brooks, Aja (b6) va.gov>; Maria D. Llorente ((b6) va.gov) <(b6) va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

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- Some of those needs are due to the hidden injuries of war.

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V/R

Dr. Patricia R. Hastings

Acting Deputy Chief Patient Care Services Officer

Deputy Chief Consultant for Post-Deployment Health Services (10P4Q)

Patient Care Services, 810 Vermont Ave NW, Washington, DC 20420

O: (b6)

(b6)

(b6)

(b6)

(b6) [va.gov](mailto:(b6)@va.gov)

VA Motto: ICARE [Integrity-Commitment-Advocacy-Respect-Excellence]

From: Lane, Ca-Asia A.

Sent: Tuesday, June 18, 2019 10:04 AM

To: Franklin, Keita <(b6)@va.gov>

Cc: Brooks, Aja <(b6)@va.gov>

Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

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Also including my colleague Aja to reach out to her portfolio folks to ensure its FDA, irregularity etc.....

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Ca-Asia A. Lane

Congressional Relations Officer

Office of Congressional & Legislative Affairs

Department of Veterans Affairs

(b6) [REDACTED] va.gov

Office: (b6) [REDACTED]

Work Cell: (b6) [REDACTED]

From: Franklin, Keita

Sent: Tuesday, June 18, 2019 8:53 AM

To: Lane, Ca-Asia A. <(b6) [REDACTED] va.gov>; Carroll, David (VACO) <(b6) [REDACTED] va.gov>

Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lakso, Wendy

Sent: Tuesday, June 18, 2019 8:01 AM

To: Franklin, Keita <(b6) [REDACTED] va.gov>

Cc: Actions <actions@dcgcommunications.com>; Jones, Taunya <(b6) [REDACTED] va.gov>

Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

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“While it was under development, J&J’s and Janssen’s relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson & Johnson joined the VA’s suicide prevention campaign, #BeThere. A public service announcement on the campaign said J&J and the VA will “undertake new clinical trial processes in hopes of providing access to the latest and most innovative treatments to help veterans in need”.

Wendy Lakso

Acting Deputy Director, Suicide Prevention Program

Office of Mental Health and Suicide Prevention

Veterans Health Administration

Cell: (b6) [REDACTED]

Sender:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b6) [REDACTED] va.gov>
Recipient:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>;

VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act
<VHA10PAActions@va.gov>;
Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino,
<(b6)@va.gov>;
Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer
<(b6)@va.gov>;
Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja
<(b6)@va.gov>;
Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M
<(b6)@va.gov>;
VHA 10P4 PCS Clearance /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fff83d687b9d4fa78cd996960409675b-VHA 10P4 PC
<VHA10P4PCSClearance@va.gov>

Sent Date: 2019/06/18 12:08:46

Delivered Date: 2019/06/18 12:08:47

From:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>
CC:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b6) va.gov>
Subject:	RE: VA's availability of Spravato (esketamine) linked to BeThere campaign
Date:	2019/06/18 12:14:54
Priority:	Normal
Type:	Note

Yes, Sir, Tom told me it was this week, but this way there is time for a thoughtful reply.
pat

From: Valentino, Michael (VACO)
Sent: Tuesday, June 18, 2019 11:49 AM
To: Hastings, Patricia R. (b6) va.gov>
Cc: Emmendorfer, Thomas (PBM) (b6) va.gov>; Llorente, Maria D. (b6) va.gov>
Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

Hi Pat, looks good. Except we are meeting tomorrow and Thursday, not next week.

Just called and left you a voicemail with me cell. (b6)

Sent with BlackBerry Work
www.blackberry.com

From: Brooks, Aja (b6) va.gov>
Date: Tuesday, Jun 18, 2019, 10:36 AM
To: Hastings, Patricia R. (b6) va.gov>, VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>
Cc: Valentino, Michael (VACO) (b6) va.gov>, Emmendorfer, Thomas (PBM) (b6) va.gov>, Llorente, Maria D. (b6) va.gov>, VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>
Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

OCLA acknowledges receipt.

v/r AJ

From: Hastings, Patricia R.

Sent: Tuesday, June 18, 2019 11:13 AM

To: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>

Cc: Valentino, Michael (VACO) <(b6)@va.gov>; Emmendorfer, Thomas (PBM)

<(b6)@va.gov>; Brooks, Aja (l(b6)@va.gov); Llorente, Maria D.

<(b6)@va.gov>; VHA 10P4 PCS Clearance <VHA10P4PCSClearance@va.gov>

Subject: RE: VA's availability of Spravato (esketamine) linked to BeThere campaign

10P4 Actions, 10P Actions,

This is a short notice request from the Assistant Secretary for VA's Office of Congressional and Legislative Affairs regarding bullets for the medication Esketamine. Cleared for submission to 10P. Please let me know if you need additional information.

- • VA is an advocate for Veterans with injuries arising from military service.
- • Some of those needs are due to the hidden injuries of war.
- • VA constantly seeks to provide Veterans with mental health needs, such as PTSD, suicidal ideation and depression with effective treatments.
 - • This search involves the review of new treatment possibilities and findings grounded in evidence-based medicine, best practices and research.
 - • Esketamine is a medication approved by the FDA for treatment-resistant depression in adults who failed on other antidepressant medicines.
- • The VA Formulary Committees meets next week and will discuss Esketamine (trade name, Spravato), to review clinical efficacy, safety and parameters for use.
- • VA has many other new, experimental or recently developed therapies in review for treatment of maladies that have had limited improvement with traditional modes of treatment. (Examples: Stellate Ganglion Block, yoga, acupuncture, new medicines, Cognitive Behavior Therapy).

V/R

Dr. Patricia R. Hastings

Acting Deputy Chief Patient Care Services Officer

Deputy Chief Consultant for Post-Deployment Health Services (10P4Q)

Patient Care Services, 810 Vermont Ave NW, Washington, DC 20420

O: (b6)

O: (b6)

C: (b6)

F: 2(b6)

(b6)@va.gov

VA Motto: ICARE [Integrity-Commitment-Advocacy-Respect-Excellence]

From: Lane, Ca-Asia A.
Sent: Tuesday, June 18, 2019 10:04 AM
To: Franklin, Keita <(b6) va.gov>
Cc: Brooks, Aja (b6) va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

Thanks maam.

Brooks mentioned that we should probably spend a moment discussing just to bring the Sec. into awareness of our J&J relationship as well.....

Also including my colleague Aja to reach out to her portfolio folks to ensure its FDA, irregularity etc.....

Very Respectfully,
Ca-Asia A. Lane
Congressional Relations Officer
Office of Congressional & Legislative Affairs
Department of Veterans Affairs
(b6) va.gov
Office: (b6)
Work Cell: (b6)

From: Franklin, Keita
Sent: Tuesday, June 18, 2019 8:53 AM
To: Lane, Ca-Asia A. <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>
Subject: FW: VA's availability of Spravato (esketamine) linked to BeThere campaign

From: Lakso, Wendy
Sent: Tuesday, June 18, 2019 8:01 AM
To: Franklin, Keita <(b6) va.gov>
Cc: Actions <actions@dgccommunications.com>; Jones, Taunya <(b6) va.gov>
Subject: VA's availability of Spravato (esketamine) linked to BeThere campaign

Dr. Franklin,
Head's up as the SVAC is tomorrow – the below link is an article on J&J about esketamine. I've added a paragraph I pulled from the article which mentions #BeThere and as part of the campaign it was mentioned in a PSA that J&J and the VA are undertaking a new clinical trial process.....” This may come up in the hearing.

<https://www.theguardian.com/us-news/2019/jun/17/spravato-ketamine-like-drug-that-experts-doubt-and-trump-is-pushing-on-veterans>

“While it was under development, J&J’s and Janssen’s relationships at the VA deepened. As trials for the drug went forward in late 2017, Johnson & Johnson joined the VA’s suicide prevention campaign, #BeThere. A public service announcement on the campaign said J&J and the VA will “undertake new clinical trial processes in hopes of providing access to the latest and most innovative treatments to help veterans in need”.

Wendy Lakso
Acting Deputy Director, Suicide Prevention Program
Office of Mental Health and Suicide Prevention
Veterans Health Administration
Cell: (b6)

Sender:	Hastings, Patricia R. /o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P (b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b6) va.gov>
Sent Date:	2019/06/18 12:14:53
Delivered Date:	2019/06/18 12:14:54

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6)@va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA
Date:	2019/03/18 13:52:09
Priority:	Normal
Type:	Note

Thank you all for your speedy replies – will move it forward.

From: Carroll, David (VACO)
Sent: Monday, March 18, 2019 1:51 PM
To: Llorente, Maria D. <(b6)@va.gov>; Smith, Monica (VACO) <(b6)@va.gov>;
Wiechers, Ilse <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>;
Valentino, Michael (VACO) <(b6)@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Thx

From: Llorente, Maria D.
Sent: Monday, March 18, 2019 1:45 PM
To: Smith, Monica (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>;
Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Carroll, David (VACO) <(b6)@va.gov>;
Valentino, Michael (VACO) <(b6)@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Agree. Thank you!

Sent with BlackBerry Work
www.blackberry.com

From: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>
Date: Monday, Mar 18, 2019, 12:30 PM
To: Wiechers, Ilse (b6) [REDACTED]@va.gov>, Llorente, Maria D. <(b6) [REDACTED]@va.gov>, Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>, Carroll, David (VACO) <(b6) [REDACTED]@va.gov>, Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Got it, thanks for that catch, Ilse.

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:29 PM
To: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Carroll, David (VACO) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

No, we need to continue to include the language on abuse and misuse.

Proposed New: (b) (5) [REDACTED]
[REDACTED]
m [REDACTED].

From: Smith, Monica (VACO)
Sent: Monday, March 18, 2019 10:28 AM
To: Llorente, Maria D. <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>; Carroll, David (VACO) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Sure will....how's this?

New: (b) (5) [REDACTED]
[REDACTED]
[REDACTED].

Old:

(b) (5) [REDACTED]
[REDACTED]
[REDACTED].

From: Llorente, Maria D.
Sent: Monday, March 18, 2019 1:23 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Wiechers, Ilse

(b6) @va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Monica, will you make the change?

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>

Date: Monday, Mar 18, 2019, 12:21 PM

To: Wiechers, Ilse (b6) @va.gov>, Llorente, Maria D. <(b6) va.gov>, Smith, Monica (VACO) <(b6) va.gov>, Carroll, David (VACO) <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

agree

From: Wiechers, Ilse

Sent: Monday, March 18, 2019 1:15 PM

To: Llorente, Maria D. <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

agree

From: Llorente, Maria D.

Sent: Monday, March 18, 2019 10:15 AM

To: Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

(b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>
Date: Monday, Mar 18, 2019, 11:35 AM
To: Carroll, David (VACO) <(b6) [REDACTED]@va.gov>, Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>, Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>, Wiechers, Ilse (b6) [REDACTED]@va.gov>, Llorente, Maria D. <(b6) [REDACTED]@va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hello – is the attached edit ok with you? It includes more details on the drug, copied from FDA's website.

(b) (5) [REDACTED]

From: Ledesma, Mark P.
Sent: Monday, March 18, 2019 12:30 PM
To: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Greilsamer, Alan <(b6) [REDACTED]@va.gov>; Ledesma, Mark P. <(b6) [REDACTED]@va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hi Monica,

Can 10P please help address OCLA's feedback in the attached release? Thanks.

Regards,
Mark

From: Paige, Paula
Sent: Monday, March 18, 2019 10:06 AM
To: Ledesma, Mark P. <(b6) [REDACTED]@va.gov>
Cc: Carter, Susan <(b6) [REDACTED]@va.gov>; Noller, Randal <(b6) [REDACTED]@va.gov>; Christian, Tatjana <(b6) [REDACTED]@va.gov>; Greilsamer, Alan <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Mark,

Please see feedback from OCLA. OGC had no issues.

Respectfully,
Paula A. Paige
Public Affairs Officer
Office of Media Relations, Office of Public and Intergovernmental Affairs
U.S. Department of Veterans Affairs
810 Vermont Ave. NW, Room 913

Washington, D.C. 20420

(b6) [REDACTED] va.gov

(b6) [REDACTED] (work)

(b6) [REDACTED] (cell)

www.vets.gov

VA on [Facebook](#). [Twitter](#). [YouTube](#). [Flickr](#). [Blog](#)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) [REDACTED] va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) [REDACTED] va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED] va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>
Sent Date:	2019/03/18 13:52:06
Delivered Date:	2019/03/18 13:52:09

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6) [REDACTED] va.gov>
To:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) [REDACTED] va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA
Date:	2019/03/18 13:45:18
Priority:	Normal
Type:	Note

Agree. Thank you!

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) <(b6) [REDACTED] va.gov>
Date: Monday, Mar 18, 2019, 12:30 PM
To: Wiechers, Ilse <(b6) [REDACTED] va.gov>, Llorente, Maria D. <(b6) [REDACTED] va.gov>, Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>, Carroll, David (VACO) <(b6) [REDACTED] va.gov>, Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
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Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

No, we need to continue to include the language on abuse and misuse.

Proposed New: (b) (5)

m

From: Smith, Monica (VACO)

Sent: Monday, March 18, 2019 10:28 AM

To: Llorente, Maria D. <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Carroll, David (VACO) <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Sure will....how's this?

New: (b)(5)

Old:

(b) (5)

From: Llorente, Maria D.

Sent: Monday, March 18, 2019 1:23 PM

To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Smith, Monica (VACO) <(b6)@va.gov>; Carroll, David (VACO) <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>

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Date: Monday, Mar 18, 2019, 12:21 PM

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Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

agree

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Sent: Monday, March 18, 2019 1:15 PM

To: Llorente, Maria D. <(b6) va.gov>; Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

agree

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Sent: Monday, March 18, 2019 10:15 AM

To: Smith, Monica (VACO) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Wiechers, Ilse <(b6) @va.gov>

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Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

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Cc: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>

Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

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Regards,
Mark

From: Paige, Paula

Sent: Monday, March 18, 2019 10:06 AM

To: Ledesma, Mark P. <(b6)@va.gov>

Cc: Carter, Susan <(b6)@va.gov>; Noller, Randal <(b6)@va.gov>; Christian, Tatjana <(b6)@va.gov>; Greilsamer, Alan <(b6)@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Mark,

Please see feedback from OCLA. OGC had no issues.

Respectfully,
Paula A. Paige
Public Affairs Officer
Office of Media Relations, Office of Public and Intergovernmental Affairs
U.S. Department of Veterans Affairs
810 Vermont Ave. NW, Room 913
Washington, D.C. 20420
(b6)@va.gov
(b6) (work)
(b6) (cell)
www.vets.gov
VA on [Facebook](#). [Twitter](#). [YouTube](#). [Flickr](#). [Blog](#)

Sender:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6)@va.gov>
Recipient:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da
<(b6) [REDACTED] va.gov>;
Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino,
<(b6) [REDACTED] va.gov>

Sent Date: 2019/03/18 13:45:16

Delivered Date: 2019/03/18 13:45:18

From:	Ledesma, Mark P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACBC9290CFEC4FFF8651002B5B0330C5-LEDESMA, MA <(b6)@va.gov>
To:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Monica <(b6)@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
CC:	Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, Alan <(b6)@va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, David <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, Ilse <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer, Thomas <(b6)@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Act <VHA10P4Actions@va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Mark <(b6)@va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA
Date:	2019/03/18 13:59:40
Priority:	Normal
Type:	Note

Thanks, Monica.

From: Smith, Monica (VACO)
Sent: Monday, March 18, 2019 1:57 PM
To: Ledesma, Mark P. <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Greilsamer, Alan <(b6)@va.gov>; Carroll, David (VACO) <(b6)@va.gov>;
Wiechers, Ilse <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hi Mark – please see the change below and in the attached.

New: (b) (5)

[REDACTED]

Old:

(b) (5)

From: Smith, Monica (VACO)
Sent: Monday, March 18, 2019 1:17 PM
To: Ledesma, Mark P. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Greilsamer, Alan <(b6) va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Thanks, Mark – I have an email circulating with the mental health team and we will get back to you.

From: Ledesma, Mark P.
Sent: Monday, March 18, 2019 12:45 PM
To: Smith, Monica (VACO) <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Carroll, David (VACO) <(b6) va.gov>
Cc: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Adding Dr. Carroll in case the feedback is for Mental Health.

Regards,
Mark

From: Ledesma, Mark P.
Sent: Monday, March 18, 2019 12:30 PM
To: Smith, Monica (VACO) <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hi Monica,

Can 10P please help address OCLA's feedback in the attached release? Thanks.

Regards,
Mark

From: Paige, Paula
Sent: Monday, March 18, 2019 10:06 AM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: Carter, Susan <(b6) va.gov>; Noller, Randal <(b6) va.gov>; Christian, Tatjana

(b6) [redacted] va.gov>; Greilsamer, Alan <(b6) [redacted] va.gov>; VHA CO 10B2B Media
<VHACO10B2BMedia@va.gov>

Subject: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019
OCLA

Mark,

Please see feedback from OCLA. OGC had no issues.

Respectfully,
Paula A. Paige
Public Affairs Officer
Office of Media Relations, Office of Public and Intergovernmental Affairs
U.S. Department of Veterans Affairs
810 Vermont Ave. NW, Room 913
Washington, D.C. 20420
(b6) [redacted]@va.gov
(b6) [redacted] (work)
(b6) [redacted]
www.vets.gov
VA on [Facebook](#). [Twitter](#). [YouTube](#). [Flickr](#). [Blog](#)

Sender:	Ledesma, Mark P. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ACBC9290CFEC4FFF8651002B5B0330C5-LEDESMA, MA <(b6) [redacted] va.gov>
Recipient:	Smith, Monica (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=511ea9e77a234375a91a7b34ce23719d-Smith, Moni <(b6) [redacted] va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>; Greilsamer, Alan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc02807af08443fbb5c68c590d58fa4b-Greilsamer, <(b6) [redacted] va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) [redacted] va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [redacted] va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [redacted] va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Ledesma, Mark P. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acbc9290cfec4fff8651002b5b0330c5-Ledesma, Ma <(b6) [redacted] va.gov>
Sent Date:	2019/03/18 13:59:39
Delivered Date:	2019/03/18 13:59:40

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) [REDACTED]@va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED]@va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED]@va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA
Date:	2019/03/18 13:09:11
Priority:	Normal
Type:	Note

It's copied and pasted below and in the attachment with a comment added under the name Aja Brooks.

From: Llorente, Maria D.
Sent: Monday, March 18, 2019 12:42 PM
To: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; Carroll, David (VACO) <(b6) [REDACTED]@va.gov>;
Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM)
<(b6) [REDACTED]@va.gov>; Wiechers, Ilse <(b6) [REDACTED]@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant
depression_15MARCH2019 OCLA

What is oCLA feedback? I am not seeing it

Sent with BlackBerry Work
www.blackberry.com

From: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>
Date: Monday, Mar 18, 2019, 11:35 AM
To: Carroll, David (VACO) <(b6) [REDACTED]@va.gov>, Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>, Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>, Wiechers, Ilse <(b6) [REDACTED]@va.gov>, Llorente, Maria D. <(b6) [REDACTED]@va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019
OCLA

Hello – is the attached edit ok with you? It includes more details on the drug, copied from FDA's website.

(b) (5)

From: Ledesma, Mark P.
Sent: Monday, March 18, 2019 12:30 PM
To: Smith, Monica (VACO) <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Greilsamer, Alan <(b6) va.gov>; Ledesma, Mark P. <(b6) va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hi Monica,

Can 10P please help address OCLA's feedback in the attached release? Thanks.

Regards,
Mark

From: Paige, Paula
Sent: Monday, March 18, 2019 10:06 AM
To: Ledesma, Mark P. <(b6) va.gov>
Cc: Carter, Susan <(b6) va.gov>; Noller, Randal <(b6) va.gov>; Christian, Tatjana <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Mark,

Please see feedback from OCLA. OGC had no issues.

Respectfully,
Paula A. Paige
Public Affairs Officer
Office of Media Relations, Office of Public and Intergovernmental Affairs
U.S. Department of Veterans Affairs
810 Vermont Ave. NW, Room 913
Washington, D.C. 20420
(b6) va.gov
(b6) (work)
(b6) (cell)
www.vets.gov
VA on [Facebook](#). [Twitter](#). [YouTube](#). [Flickr](#). [Blog](#)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) [REDACTED] va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED] va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED] va.gov>
Sent Date:	2019/03/18 13:09:10
Delivered Date:	2019/03/18 13:09:11

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA
Date:	2019/03/18 13:50:48
Priority:	Normal
Type:	Note

Maria – do I wait for Dave Carroll's input?

From: Llorente, Maria D.
Sent: Monday, March 18, 2019 1:45 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Agree. Thank you!

Sent with BlackBerry Work
www.blackberry.com

From: Smith, Monica (VACO) <(b6) va.gov>
Date: Monday, Mar 18, 2019, 12:30 PM
To: Wiechers, Ilse (b6) @va.gov>; Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Got it, thanks for that catch, Ilse.

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:29 PM
To: Smith, Monica (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>; Carroll, David (VACO) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

No, we need to continue to include the language on abuse and misuse.

Proposed New: (b) (5)

[REDACTED] d
m [REDACTED].

From: Smith, Monica (VACO)

Sent: Monday, March 18, 2019 10:28 AM

To: Llorente, Maria D. <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>; Wiechers, Ilse (b6) [REDACTED]va.gov>; Carroll, David (VACO) <(b6) [REDACTED]va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Sure will....how's this?

New: (b) (5)

[REDACTED] s.

Old:

(b) (5)

[REDACTED].

From: Llorente, Maria D.

Sent: Monday, March 18, 2019 1:23 PM

To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>; Smith, Monica (VACO) <(b6) [REDACTED]va.gov>; Carroll, David (VACO) <(b6) [REDACTED]va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Monica, will you make the change?

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>

Date: Monday, Mar 18, 2019, 12:21 PM

To: Wiechers, Ilse (b6) [REDACTED]@va.gov>, Llorente, Maria D. <(b6) [REDACTED]va.gov>, Smith, Monica (VACO) <(b6) [REDACTED]va.gov>, Carroll, David (VACO) <(b6) [REDACTED]va.gov>, Valentino, Michael (VACO) <(b6) [REDACTED]va.gov>

Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

agree

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:15 PM
To: Llorente, Maria D. <(b6) [REDACTED] va.gov>; Smith, Monica (VACO) <(b6) [REDACTED] va.gov>; Carroll, David (VACO) <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

agree

From: Llorente, Maria D.
Sent: Monday, March 18, 2019 10:15 AM
To: Smith, Monica (VACO) <(b6) [REDACTED] va.gov>; Carroll, David (VACO) <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>; Wiechers, Ilse <(b6) [REDACTED] @va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

(b) (5)

[REDACTED]

[REDACTED]

Sent with BlackBerry Work
(www.blackberry.com)

From: Smith, Monica (VACO) <(b6) [REDACTED] va.gov>
Date: Monday, Mar 18, 2019, 11:35 AM
To: Carroll, David (VACO) <(b6) [REDACTED] va.gov>, Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>, Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>, Wiechers, Ilse <(b6) [REDACTED] @va.gov>, Llorente, Maria D. <(b6) [REDACTED] va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hello – is the attached edit ok with you? It includes more details on the drug, copied from FDA's website.

(b) (5)

[REDACTED]

From: Ledesma, Mark P.
Sent: Monday, March 18, 2019 12:30 PM

To: Smith, Monica (VACO) <(b6) [REDACTED] va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Greilsamer, Alan <(b6) [REDACTED] va.gov>; Ledesma, Mark P. <(b6) [REDACTED] va.gov>
Subject: FW: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Hi Monica,

Can 10P please help address OCLA's feedback in the attached release? Thanks.

Regards,
Mark

From: Paige, Paula
Sent: Monday, March 18, 2019 10:06 AM
To: Ledesma, Mark P. <(b6) [REDACTED] va.gov>
Cc: Carter, Susan <(b6) [REDACTED] va.gov>; Noller, Randal <(b6) [REDACTED] va.gov>; Christian, Tatjana <(b6) [REDACTED] va.gov>; Greilsamer, Alan <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: VA to make new nasal spray drug available for treatment-resistant depression_15MARCH2019 OCLA

Mark,

Please see feedback from OCLA. OGC had no issues.

Respectfully,
Paula A. Paige
Public Affairs Officer
Office of Media Relations, Office of Public and Intergovernmental Affairs
U.S. Department of Veterans Affairs
810 Vermont Ave. NW, Room 913
Washington, D.C. 20420
(b6) [REDACTED] va.gov
(b6) [REDACTED] (work)
(b6) [REDACTED] (cell)
www.vets.gov
VA on [Facebook](#). [Twitter](#). [YouTube](#). [Flickr](#). [Blog](#)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) [REDACTED] va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED] va.gov>
Sent Date:	2019/03/18 13:50:46
Delivered Date:	2019/03/18 13:50:48

From:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT <(b6)@va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 17:16:55
Priority:	Normal
Type:	Note

(b6) ☺

Joette S. Lowe, PharmD
 VISN 7 Pharmacy Executive (VPE)
 3701 Loop Road East
 Tuscaloosa, AL 35404

(b6)
 Suicide Prevention is Everyone's Business. [#BeThere.](#)



[cid:image009.jpg@01D328A1.8C7B68A0](#)

From: Valentino, Michael (VACO)
Sent: Tuesday, March 19, 2019 4:16 PM
To: Lowe, Joette <(b6)@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression

(b6)

From: Lowe, Joette
Sent: Tuesday, March 19, 2019 5:13 PM
To: Slagle, Mark (V9) <(b6)@va.gov>; VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression

(b6)

Joette S. Lowe, PharmD
 VISN 7 Pharmacy Executive (VPE)
 3701 Loop Road East
 Tuscaloosa, AL 35404

(b6)

Suicide Prevention is Everyone's Business. #BeThere.



cid:image009.jpg@01D328A1.8C7B68A0

From: Slagle, Mark (V9)
Sent: Tuesday, March 19, 2019 3:21 PM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: VA to make new nasal spray drug available for treatment-resistant depression

Well, this is interesting:

VA to make new nasal spray drug available for treatment-resistant depression
<https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5220>

I don't recall voting on this yet! I suppose that technically we make every drug available to Veterans (except hydrocodone SR products). HOW we make them available depends on formulary status and CFU, which we've not discussed yet.

Regards,

Mark A. Slagle, PharmD, BCPS
VISN 9 Pharmacist Executive
1801 West End Ave., Suite 600
Nashville, TN 37203

(b6)

Sender:	Lowe, Joette /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2CDA61A196F849548A246B80455099D9-LOWE, JOETT <(b6)@va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
Sent Date:	2019/03/19 17:16:55
Message Flags:	Unread

From:	Slagle, Mark (V9) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B618B365E2E41509EE26C5586E88679-SLAGLE, MAR (b6) @va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 16:24:08
Priority:	Normal
Type:	Note

I figured as much.

Mark A. Slagle, PharmD, BCPS

VISN 9 Pharmacist Executive
1801 West End Ave., Suite 600
Nashville, TN 37203
(b6)

From: Valentino, Michael (VACO)
Sent: Tuesday, March 19, 2019 3:23 PM
To: Slagle, Mark (V9) (b6) @va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression

This train left the station on March 5th ...we're just trying to catch it at the next stop.

Mike

From: Slagle, Mark (V9)
Sent: Tuesday, March 19, 2019 4:21 PM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: VA to make new nasal spray drug available for treatment-resistant depression

Well, this is interesting:

VA to make new nasal spray drug available for treatment-resistant depression

<https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5220>

I don't recall voting on this yet! I suppose that technically we make every drug available to Veterans (except hydrocodone SR products). HOW we make them available depends on formulary status and CFU, which we've not discussed yet.

Regards,

Mark A. Slagle, PharmD, BCPS

VISN 9 Pharmacist Executive
1801 West End Ave., Suite 600
Nashville, TN 37203

(b6)

Sender:	Slagle, Mark (V9) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B618B365E2E41509EE26C5586E88679-SLAGLE, MAR (b6)@va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>
Sent Date:	2019/03/19 16:24:07
Delivered Date:	2019/03/19 16:24:08
Message Flags:	Unread

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett <(b6)@va.gov>
Subject:	RE: VA to make new nasal spray drug available for treatment-resistant depression
Date:	2019/03/19 17:16:00
Priority:	Normal
Type:	Note

(b6)

From: Lowe, Joette
Sent: Tuesday, March 19, 2019 5:13 PM
To: Slagle, Mark (V9) (b6)@va.gov; VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: RE: VA to make new nasal spray drug available for treatment-resistant depression

Somebody should check all the COIs of who is pushing this.

Joette S. Lowe, PharmD
 VISN 7 Pharmacy Executive (VPE)
 3701 Loop Road East
 Tuscaloosa, AL 35404

(b6)

Suicide Prevention is Everyone's Business. **#BeThere.**



[cid:image009.jpg@01D328A1.8C7B68A0](#)

From: Slagle, Mark (V9)
Sent: Tuesday, March 19, 2019 3:21 PM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: VA to make new nasal spray drug available for treatment-resistant depression

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<https://www.va.gov/opa/pressrel/pressrelease.cfm?id=5220>

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Regards,

Mark A. Slagle, PharmD, BCPS

VISN 9 Pharmacist Executive

1801 West End Ave., Suite 600

Nashville, TN 37203

(b6)

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Lowe, Joette /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2cda61a196f849548a246b80455099d9-Lowe, Joett <(b6) va.gov>
Sent Date:	2019/03/19 17:16:19
Delivered Date:	2019/03/19 17:16:00

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Kelley, Catherine /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62ef810523394d98ae3b91a6ef2623bc-Kelley, Cat (b6)@va.gov>
Subject:	RE: VA Insider: Secretary on FY2020 Budget Request, Nasal Spray for Depression, 3D Printing Saves Veteran's Leg, Tele-ICU Partnership, Female WWII Veteran Honored in Puerto Rico, and more
Date:	2019/03/22 08:07:00
Priority:	Normal
Type:	Note

Hi Cathy,

I missed seeing you at the F2F meeting. I hope all is well with you and your family. I did not present esketamine yet. It is currently slated for May/June. You haven't missed anything besides all the emails about this agent 😊
It will be interesting to see where this goes...

Matthew

From: Kelley, Catherine
Sent: Thursday, March 21, 2019 5:05 PM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>
Subject: FW: VA Insider: Secretary on FY2020 Budget Request, Nasal Spray for Depression, 3D Printing Saves Veteran's Leg, Tele-ICU Partnership, Female WWII Veteran Honored in Puerto Rico, and more

Hi Matthew, Did you recently present Esketamine for treatment resistant depression? I was curious to see this on the VA Insider and didn't recall you presenting it yet but it may have been at the face to face meeting that I was unable to attend. Hope all is well, Cathy

From: US Department of Veterans Affairs
Sent: Thursday, March 21, 2019 1:20 PM
To: VAAIEXOMailboxes <VAAIEXOMailboxes@va.gov>
Subject: VA Insider: Secretary on FY2020 Budget Request, Nasal Spray for Depression, 3D Printing Saves Veteran's Leg, Tele-ICU Partnership, Female WWII Veteran Honored in Puerto Rico, and more



**A MESSAGE FROM
OFFICE OF PUBLIC AND INTERGOVERNMENTAL AFFAIRS (OPIA)
Office of Internal Communications**

Have you seen the latest [VA Insider](#)? It's full of news and resources for VA employees. Articles this week include:

- [Message from the Secretary: Fiscal Year 2020 budget request](#)
- [VA to make new nasal spray drug available for treatment-resistant depression](#)
- [San Francisco: 3D printing saves Veteran's leg, reduces treatment costs](#)
- [VA on path to cure 100,000 Veterans of hepatitis C](#)
- [Loss of Veteran brothers to suicide inspires VA employee to raise awareness with film](#)
- [VA releases inspection reports, staffing data for its nursing home system](#)
- [Nevada VA launches Tele-ICU partnership](#)
- [VA celebrates extraordinary firsts, quiet courage of women Veterans](#)
- [In Puerto Rico: Female WWII Veteran, 96, honored by San Juan Regional Office](#)
- [Podcast: Queens, New York, submariner to North Carolina farmer](#)

Please go to the [VA Insider](#) to find these articles and more. To [submit](#) an article, [click here](#).

We're looking for your inspiring stories!

If you have a best practice you'd like to share, or if you have a story about your colleagues going the extra mile to help Veterans or our VA coworkers, [email us](#) a short (about two paragraphs) summary of the story. Every week, we'll select a story to feature. Here's this week's story:

VBA employee in Buffalo awarded VHA's 'High-Five' award

William "Chad" Stowe, a Veteran Service Representative and Homeless Veteran Coordinator at the Buffalo Regional Office in New York, received VHA's "High-Five" award from Buffalo's VA Medical Center. The recognition is given to VHA staff who go above and beyond normal duties in service of a Veteran under care in a VAMC. Stowe is not a VHA employee, but his actions and collaborative efforts to research a patient's Veteran status and eligibility for VA services earned him the accolade.

In July, an older man was admitted to the Buffalo VAMC's emergency department for cardiac concerns and dementia. It was determined he lacked the capacity to make medical decisions for himself and believed he was ineligible for VA services. This meant the medical center would have to provide care for an ineligible patient who was unable to participate in planning of his care or discharge.

The VAMC's Health Care for Homeless Veterans program manager contacted Stowe to discover the patient's Veteran status. Stowe called the appropriate agencies and asked staff to search boxes for copies of the patient's military service records and past service connection disability claims. The Veteran's DD-214 was located, and he now resides in a comfortable long-term care facility. Originally published on [HEY VBA](#), by Ronald Piaseczny, public affairs officer, Buffalo RO

There are great things happening at VA every day that make a real difference for Veterans and the people who serve them.

**PLEASE PRODUCE LOCALLY FOR ALL THOSE WHO DO NOT ROUTINELY ACCESS
EMAIL DUE TO THEIR SPECIALTIES.**

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Kelley, Catherine /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62ef810523394d98ae3b91a6ef2623bc-Kelley, Cat (b6)@va.gov>
Sent Date:	2019/03/22 08:07:38
Delivered Date:	2019/03/22 08:07:00

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
Subject:	RE: VA Formulary Briefing
Date:	2019/06/27 10:13:00
Priority:	Normal
Type:	Note

Thank you!

From: Brooks, Aja
Sent: Thursday, June 27, 2019 10:12 AM
To: Llorente, Maria D. <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Subject: RE: VA Formulary Briefing

We meet under the blue awning.

From: Llorente, Maria D.
Sent: Thursday, June 27, 2019 10:04 AM
To: Brooks, Aja <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Subject: RE: VA Formulary Briefing

Thank you. Are we to meet in the lobby?

-----Original Appointment-----

From: Brooks, Aja
Sent: Thursday, June 27, 2019 9:39 AM
To: Valentino, Michael (VACO); Emmendorfer, Thomas (PBM); Llorente, Maria D.
Subject: VA Formulary Briefing
When: Monday, July 1, 2019 1:30 PM-2:15 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 3400 O'Neill HOB

Depart VACO 1pm

Meeting scheduled for 1:30PM

>-----Original Message-----

>From: (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>

>Sent: Friday, June 21, 2019 8:41 AM

>To: Brooks, Aja (l(b6) va.gov>

>Cc: (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>; (b6)

(b6) @vetaff.senate.gov>; (b6)

dl@vetaff.senate.gov>; (b6) @mail.house.gov;

(b6) @mail.house.gov

>Subject: [EXTERNAL] Briefing on formulary process

>

>Hi AJ -

>

>We'd appreciate a briefing on VA's process to consider, deliberate and add drugs to its formulary. In particular, we'd like an overview of the drug Spravato - we understand it's under consideration. Sometime in the next two weeks would be great.

>

>Thanks,

(b6)

>

>Sent from my iPhone

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja (l(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/06/27 10:13:53
Delivered Date:	2019/06/27 10:13:00

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Sales, Marie /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0903dec780a4a718d49602777fa5643-Sales, Mari (b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6)@va.gov>
CC:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, (b6)@va.gov>
Subject:	RE: Updated FAQ
Date:	2019/03/15 17:14:04
Priority:	Normal
Type:	Note

Thank you Marie!

Sent with BlackBerry Work
(www.blackberry.com)

From: Sales, Marie (b6)@va.gov>
Date: Friday, Mar 15, 2019, 4:47 PM
To: Wiechers, Ilse <(b6)@va.gov>, Emmendorfer, Thomas (PBM) (b6)@va.gov>
Cc: Cunningham, Fran <(b6)@va.gov>
Subject: RE: Updated FAQ

Hi Isle,

Sending an updated PDF of the FAQ sheet per Tom that corrects the following recently identified typos in case the 10N memo has not gone out yet:

(b) (5) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Thanks,
Marie

From: Sales, Marie
Sent: Friday, March 15, 2019 12:26 PM
To: Wiechers, Ilse (b6) [REDACTED]@va.gov; Emmendorfer, Thomas (PBM) [REDACTED]@va.gov
Cc: Cunningham, Fran (b6) [REDACTED]@va.gov
Subject: RE: Updated FAQ

Hi Ilse,

Please see attached.

Thanks,
Marie

From: Wiechers, Ilse
Sent: Friday, March 15, 2019 12:25 PM
To: Emmendorfer, Thomas (PBM) [REDACTED]@va.gov; Sales, Marie (b6) [REDACTED]@va.gov
Cc: Cunningham, Fran (b6) [REDACTED]@va.gov
Subject: RE: Updated FAQ

Thanks, Tom!

Marie – as soon I have the updated FAQ we will submit our 10N memo for clearance and distribution to the field. So if you could send over as soon as possible, it would be much appreciated. Thanks!

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 10:11 AM
To: Sales, Marie (b6) [REDACTED]@va.gov; Wiechers, Ilse (b6) [REDACTED]@va.gov
Cc: Cunningham, Fran (b6) [REDACTED]@va.gov
Subject: Updated FAQ

Hi Marie,

I know Fran caught a minor typo. Could you send the updated FAQ to Ilse? The FAQ is going to go out thru 10N distribution as well.

Thank you!

Tom

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Sales, Marie /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0903dec780a4a718d49602777fa5643-Sales, Mari (b6) [REDACTED]@va.gov; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I
<(b6) [REDACTED] va.gov>;
Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbb-Cunningham,
<(b6) [REDACTED] va.gov>

Sent Date: 2019/03/15 17:14:03

Delivered Date: 2019/03/15 17:14:04

From:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI (b6)@va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
CC:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6)@va.gov>
Subject:	RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 16:39:32
Priority:	Normal
Type:	Note

Hi Tom,

Attached are updated documents as requested.

I re-reviewed and picked up a couple of very minor typos that are corrected in the revised attachments

- (b) (5)

[REDACTED]

[REDACTED]

I will also forward the updated PDF to Isle.

Thanks,
Marie

From: Sales, Marie
Sent: Friday, March 15, 2019 3:04 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Cc: Cunningham, Fran <(b6)@va.gov>
Subject: RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Will do!

Thanks,
Marie

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 15, 2019 2:59 PM
To: Sales, Marie (b6) <(b6)@va.gov>
Cc: Cunningham, Fran <(b6)@va.gov>
Subject: RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Hi Marie,

Could you fix the one typo and send the word document and pdf to me?

No worries. We are going to have to update some of the responses next week anyway.

Could you send the updated pdf to Isle in case the 10N memo has not gone out yet and let her know what the typo was?

Could you give Pete my cell (b6)? I am driving home but can give him the update.

Sent with BlackBerry Work
(www.blackberry.com)

From: Sales, Marie (b6) <(b6)@va.gov>
Date: Friday, Mar 15, 2019, 3:31 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Cc: Cunningham, Fran <(b6)@va.gov>
Subject: FW: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Hi Tom,

We received 2 comments back regarding the document.

First is a misspelling in item #1 = "eskatamine" should be "esketamine". Sorry that Fran and I did not catch that earlier.

Second is a concern for potential confusion from Pete (please see below wording in red). If additional information is needed to clarify this point, perhaps an addendum could address both this item as well as the misspelling? Thoughts?

Thanks,
Marie

From: Glassman, Peter A.
Sent: Friday, March 15, 2019 2:07 PM
To: Sales, Marie <(b6)@va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Um....(b) (5)

p

ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

From: Sales, Marie

Sent: Friday, March 15, 2019 12:01 PM

To: VHAPBM MAP Committee <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs <PharmacyChiefs@va.gov>; VHAPBM PMO <PMO@va.gov>

Subject: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Importance: High

UPDATED MESSAGE:

Attached is the **Frequently Asked Questions (FAQ)** sheet addressing the newly FDA-approved **esketamine (Spravato®)** nasal spray for treatment-resistant depression published by the VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention. This FAQ sheet will also be available online at the following link <https://vaww.cmopnational.va.gov/cmop/pbm/default.aspx> (pending posting).

The purpose of this FAQ sheet is to:

- Disseminate new drug information to the provider-level regarding esketamine (Spravato®)
- Provide answers on availability and accessibility of esketamine (Spravato®) within VA

Sender:	Sales, Marie /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0903DEC780A4A718D49602777FA5643-SALES, MARI (b6)@va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6)@va.gov>; exchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) [REDACTED] va.gov>
Sent Date:	2019/03/15 16:39:30
Delivered Date:	2019/03/15 16:39:32

Spravato® (Esketamine) Nasal Spray

Frequently Asked Questions

March 14, 2019

VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention

1. Spravato® (esketamine) nasal spray was approved by the Food and Drug Administration (FDA) on March 5, 2019, to be used in conjunction with an oral antidepressant for the treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them. Is Spravato® commercially available for healthcare systems to purchase?

ANSWER: No. Spravato® is not commercially available for healthcare systems to purchase at this time. The manufacturer estimates Spravato® will be available for healthcare systems to purchase in mid to late March 2019.

2. Since Spravato® is a nasal spray, will VA providers be able to prescribe outpatient prescriptions for VA pharmacies to dispense to the Veterans?

ANSWER: No. Because of the risk of serious adverse outcomes resulting from possible sedation and/or dissociation caused by Spravato® administration, and the potential for abuse and misuse of the drug, it is only available through a restricted distribution system, under an FDA approved Risk Evaluation and Mitigation Strategy (REMS).

3. What are the requirements for the Spravato® FDA approved REMS?

ANSWER:

- Spravato® is available only through a limited distribution program that is part of the Spravato® REMS.
- All healthcare settings and pharmacies are required to enroll in the Spravato® REMS via a designated authorized representative before they can purchase product from a distributor, dispense, or supervise administration of Spravato®.
- All patients must be enrolled in the Spravato® REMS before they can receive Spravato®.

The Spravato® REMS Fact Sheet developed by the manufacturer is available at:

[https://www.spravatorems.com/pdfs/SPRAVATO\(TM\)_REMS_Fact_Sheet.pdf](https://www.spravatorems.com/pdfs/SPRAVATO(TM)_REMS_Fact_Sheet.pdf)

4. Will Spravato® be available for VA providers to prescribe in accordance with the FDA approved REMS program when it is commercially available?

ANSWER: Yes.

5. Has Spravato® been added to VA's National Formulary?

ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

6. Is Spravato® a controlled substance?

ANSWER: Yes. It is a Schedule III Controlled Substance.

7. Does my VA medical facility need to take any actions to enroll into the FDA approved REMS program at this time?

ANSWER: No. Not at this time. VA Pharmacy Benefits Management (PBM) Services is working closely with the manufacturer of Spravato®. Once the manufacturer operationalizes the REMS requirements for Spravato®, PBM will collaborate with the Office of Mental Health and Suicide Prevention (OMHSP) to disseminate the information to VA medical facilities. PBM and OMHSP will provide a status update by March 18, 2019.

8. After Spravato® is administered to the patient in a medically supervised healthcare setting, what does the patient need to be monitored for?

ANSWER: At a minimum, patients will need to be monitored with the elements of the Spravato® REMS Patient Monitoring form that is available at www.SPRAVATOREMS.com. Spravato® chemical name is esketamine which is an S (+) enantiomer of ketamine and provides similar therapeutic effects to ketamine. VA PBM developed a national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation which was published in December 2017. ([Ketamine Infusion for Treatment Resistant Depression](#)). The national protocol for intravenous ketamine is consistent with the VA PBM Guidance on Off Label Prescribing of drugs that was published in August 2013 and can be accessed at: ([Guidance on Off Label Prescribing](#)).

9. What actions can VA medical facilities take now to prepare to become a certified healthcare setting?

ANSWER: OMHSP and PBM recommend VA medical facilities review the Spravato® REMS forms available at www.SPRAVATOREMS.com and the VA PBM national protocol for the use of intravenous ketamine in treatment resistant depression and severe suicidal ideation ([Ketamine Infusion for Treatment Resistant Depression](#)) to ensure each VA medical facility has the necessary space and equipment to monitor after the Spravato® dose is administered to the Veterans.

10. Do providers need to have special privileging to prescribe Spravato®?

ANSWER: No

11. Does Spravato® require a signed informed consent?

ANSWER: Yes. An update will be provided by OMHSP by March 18, 2019.

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P <(b6)@va.gov>; Sales, Marie /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0903dec780a4a718d49602777fa5643-Sales, Mari <(b6)@va.gov>
CC:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6)@va.gov>
Subject:	RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Date:	2019/03/15 16:25:08
Priority:	Normal
Type:	Note

Hi Pete,
Sorry. I am off the phone if you want to call me back. I called the number in my phone and it went to Hospital main line

Sent with BlackBerry Work
(www.blackberry.com)

From: Glassman, Peter A. <(b6)@va.gov>
Date: Friday, Mar 15, 2019, 4:15 PM
To: Sales, Marie <(b6)@va.gov>
Cc: Cunningham, Fran <(b6)@va.gov>, Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Subject: RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Just tired calling but went to VM—left a message. I do understand that there is going to be a letter from 10N but my concern is that that sentence is going to create some confusion for the field in understanding when and how this drug can be prescribed.

From: Sales, Marie
Sent: Friday, March 15, 2019 1:08 PM
To: Glassman, Peter A. <(b6)@va.gov>
Cc: Cunningham, Fran <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Subject: RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

Thanks Pete! Forwarded your comment and concern to Tom E. He asked that I give you his cell # (b6) (b6) to discuss as he has left the office and is driving but can provide an update.

Thanks,
Marie

From: Glassman, Peter A.
Sent: Friday, March 15, 2019 2:07 PM
To: Sales, Marie (b6) [REDACTED]@va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]va.gov>
Subject: RE: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

p

ANSWER: The Spravato® formulary review will be on the May 2019 National Formulary Committee agenda. Prior to the National Formulary Committee review, VA providers will be able to prescribe Spravato® based on their clinical assessment and the individual medical needs of the Veteran.

From: Sales, Marie
Sent: Friday, March 15, 2019 12:01 PM
To: VHAPBM MAP Committee <pbm.map@med.va.gov>; VHAPBM VISN Pharmacist Executives <VISNPharmacyExecs@va.gov>; VHAPBM Pharmacy Chiefs <PharmacyChiefs@va.gov>; VHAPBM PMO <PMO@va.gov>
Subject: UPDATE: Frequently Asked Questions (FAQ): Esketamine (Spravato®)
Importance: High

UPDATED MESSAGE:

Attached is the **Frequently Asked Questions (FAQ)** sheet addressing the newly FDA-approved **esketamine (Spravato®)** nasal spray for treatment-resistant depression published by the VA Pharmacy Benefits Management Services and Office of Mental Health and Suicide Prevention. This FAQ sheet will also be available online at the following link <https://vaww.cmopnational.va.gov/cmop/pbm/default.aspx> (pending posting).

The purpose of this FAQ sheet is to:

- Disseminate new drug information to the provider-level regarding esketamine (Spravato®)
- Provide answers on availability and accessibility of esketamine (Spravato®) within VA

Sender: Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Glassman, Peter A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90608d43ef14423db308fb6c71ed750b-Glassman, P <(b6) va.gov>; Sales, Marie /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0903dec780a4a718d49602777fa5643-Sales, Mari (b6)@va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>
Sent Date:	2019/03/15 16:25:07
Delivered Date:	2019/03/15 16:25:08

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbb-Cunningham, <(b6) va.gov>
Subject:	RE: update on TriWest Contract mod for esketamine
Date:	2019/08/14 14:46:28
Priority:	Normal
Type:	Note

Thanks for the update! We will keep our eyes open for the message from David!
JZ

From: Wiechers, Ilse
Sent: Wednesday, August 14, 2019 12:31 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Cunningham, Fran <(b6) va.gov>
Subject: update on TriWest Contract mod for esketamine

Hi Tom & Jenn -

I just wrapped up a lengthy call with the TriWest contract mod team, and I think we have bullets on a draft mod, which should land in your inbox from (b6) later today. (b6) is going to actually take that and turn it into real contract language sometime by late next week.

I think (*fingers crossed*) that we are (b6) included in the language. But it is sticky/confusing them, so we will have some more work to do around that.

Ilse

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
National Lead, Esketamine Clinical Implementation
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6) va.gov | (b6) yale.edu

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbc-Cunningham, <(b6) va.gov>
Sent Date:	2019/08/14 14:46:27
Delivered Date:	2019/08/14 14:46:28

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
CC:	Cunningham, Fran /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=613f0d8e535d46af95fed310f100dcbb-Cunningham, <(b6)@va.gov>
Subject:	RE: update on TriWest Contract mod for esketamine
Date:	2019/08/15 08:24:00
Priority:	Normal
Type:	Note

Sounds like promising news!

From: Wiechers, Ilse
Sent: Wednesday, August 14, 2019 1:31 PM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Cc: Cunningham, Fran <(b6)@va.gov>
Subject: update on TriWest Contract mod for esketamine

Hi Tom & Jenn -

I just wrapped up a lengthy call with the TriWest contract mod team, and I think we have bullets on a draft mod, which should land in your inbox from (b6) later today. (b6) is going to actually take that and turn it into real contract language sometime by late next week.

I think (*fingers crossed*) that we are getting requirements around MUE reporting included in the language. But it is sticky/confusing them, so we will have some more work to do around that.

Ilse

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
National Lead, Esketamine Clinical Implementation
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6)@va.gov | (b6)@yale.edu

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
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Sent Date:	2019/08/15 08:24:03
Delivered Date:	2019/08/15 08:24:00

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6) [REDACTED] va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED] va.gov>
Subject:	RE: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA
Date:	2019/06/13 19:35:16
Priority:	Normal
Type:	Note

(b6)

(b6) 15 minute presentation, tops.....

p

From: Glassman, Peter A.
Sent: Thursday, June 13, 2019 9:11 AM
To: Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>
Subject: RE: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA

I leave my computer for just a little while and now I read this.....

(b6)

p

From: Valentino, Michael (VACO)
Sent: Thursday, June 13, 2019 8:33 AM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>; Glassman, Peter A. <(b6) [REDACTED] va.gov>
Subject: RE: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA

(b6)

(b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Date: Thursday, Jun 13, 2019, 11:15 AM
To: Valentino, Michael (VACO) <(b6)@va.gov>, Glassman, Peter A. <(b6)@va.gov>
Subject: RE: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA

(b6) !

From: Valentino, Michael (VACO)
Sent: Thursday, June 13, 2019 10:14 AM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Glassman, Peter A. <(b6)@va.gov>
Subject: FW: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA

Interesting. (b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Cavanagh, Paul <(b6)@va.gov>
Date: Thursday, Jun 13, 2019, 8:33 AM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>, Valentino, Michael (VACO) <(b6)@va.gov>
Cc: Stoesen, Carolyn <(b6)@va.gov>
Subject: Trump Offers to Negotiate Price of J&J Anti-Depressant for VA

Hi Mike & Jen,

I hope you're doing well. Apparently, POTUS has offered to assist the Department in negotiating the price of a new Johnson & Johnson anti-depressant drug for VA. I am not sure that this will go anywhere and perhaps you're already aware, but I just wanted to bring the story to your attention. Please let me know if OPP can assist in any way. Thanks.

Link: <https://www.bloomberg.com/news/articles/2019-06-12/trump-offers-to-negotiate-price-of-j-j-anti-depressant-for-va>

Best,

Paul L. Cavanagh
Program Analyst
Department of Veterans Affairs
Veterans Health Administration
Office of Policy & Planning
810 Vermont Ave NW

8th Floor, 845A
Washington, DC 20420
Email: (b6) (b6)@va.gov
Office: (b6) (b6)
Mobile: (b6) (b6)

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6)@va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Sent Date:	2019/06/13 19:35:15
Delivered Date:	2019/06/13 19:35:16

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6) va.gov>; Popish, Sarah J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242afb789db04c4a90ec3da8943800f3-Popish, Sar <(b6) va.gov>
Subject:	RE: TRD Provider Guide - FOR YOUR REVIEW
Date:	2019/08/27 16:17:00
Priority:	Normal
Type:	Note

Hi Daina and Sarah,

Please find attached my comments/track changes to the TRD guide. Thanks.

Matthew

From: Wiechers, Ilse

Sent: Friday, August 23, 2019 12:16 PM

To: Oslin, Dave (Philadelphia VAMC) <(b6) va.gov>; Thase, Michael E. <(b6) va.gov>; Fuller, Matthew A. (PBM) <(b6) va.gov>; Madore, Michelle R. <(b6) va.gov>; Capehart, Bruce P. DURVAMC <(b6) va.gov>; Dunn, Walter <(b6) va.gov>; Gilmer, William S. (HIN) <(b6) va.gov>; George, Mark S. <(b6) va.gov>; Maramba, Gloria G <(b6) va.gov>; Mells, Lillie M <(b6) va.gov>

Cc: Wells, Daina L. <(b6) va.gov>; Popish, Sarah J. <(b6) va.gov>; Christopher, Melissa L (VHASDC) <(b6) va.gov>

Subject: TRD Provider Guide - FOR YOUR REVIEW

Importance: High

Hello everyone –

Thanks again for your willingness to help us update the Academic Detailing Provider Guide for Treatment Resistant Depression. Attached you will find the draft version for your review. ***Please return your comments and edits to Daina Wells ((b6) va.gov) and Sarah Popish ((b6) va.gov) by Friday, September 6.***

You can return comments and edits by using track changes on the Word document or by sending a list of line item edits via email. Please DO NOT send back an edited Word document that did not track changes!

Please note that the references are still a work in progress, which is to say all references are cited and listed at the end of the document, but the formatting is inconsistent. We will be cleaning up the formatting before the final version, so please disregard this as you are reviewing the document.

We are also working on Pocket Cards. Some of the information that the you have provided has been moved to that section. The Pocket Cards will include specific actionable information (e.g., drug dosing, drug interactions, rTMS and medications to avoid). More to come on the Pocket Cards in the near future.

If you have any questions, please let me know. Thanks again!

Best,
Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

National Lead, Esketamine Clinical Implementation

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)

email (b6) va.gov | (b6) yale.edu

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Recipient:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6) va.gov>; Popish, Sarah J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242afb789db04c4a90ec3da8943800f3-Popish, Sar <(b6) va.gov>
Sent Date:	2019/08/27 16:17:28
Delivered Date:	2019/08/27 16:17:00

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From:	Thase, Michael E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CAEF785151044128B74D28545152DD08-THASE, MICH <(b6)@va.gov>
To:	Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6)@va.gov>; Madore, Michelle R. /c=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73daaca95f32485194225da4ac2693a-Madore, Mic <(b6)@va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6)@va.gov>; Dunn, Walter /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd06b6b345fe4e25871d6ff0e6b94471-Dunn, Walte <(b6)@va.gov>; Gilmer, William S. (HIN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21a9ad29cb0c4f44a66033c8db916bf1-Gilmer, Wil <(b6)@va.gov>; George, Mark S. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45af546041f14066bed10aa50d4debca-George, Mar <(b6)@va.gov>; Maramba, Gloria G /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8152a557167e4d64bdc79e46a98e6063-Maramba, Gl <(b6)@va.gov>; Mells, Lillie M /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c433ebdf137044d98b16c52fddc10e49-Mells, Lill <(b6)@va.gov>
CC:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6)@va.gov>; Popish, Sarah J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242afb789db04c4a90ec3da8943800f3-Popish, Sar <(b6)@va.gov>; Christopher, Melissa L (VHASDC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a542daad1277489fb77c0b3d08454521-Christopher <(b6)@va.gov>
Subject:	RE: TRD Provider Guide - FOR YOUR REVIEW
Date:	2019/08/26 09:28:00
Priority:	Normal
Type:	Note

Great comments, Dave! I will have mine back to you by Friday at the latest.
Michael

From: Oslin, Dave (Philadelphia VAMC)
Sent: Monday, August 26, 2019 8:53 AM
To: Wiechers, Ilse <(b6)@va.gov>; Thase, Michael E. <(b6)@va.gov>; Fuller, Matthew A. (PBM) <(b6)@va.gov>; Madore, Michelle R. <(b6)@va.gov>; Capehart, Bruce P. DURVAMC <(b6)@va.gov>; Dunn, Walter <(b6)@va.gov>; Gilmer, William S. (HIN) <(b6)@va.gov>; George, Mark S. <(b6)@va.gov>; Maramba, Gloria G

<(b6) [REDACTED] va.gov>; Mells, Lillie M <(b6) [REDACTED] va.gov>

Cc: Wells, Daina L. <(b6) va.gov>; Popish, Sarah J. <(b6) va.gov>; Christopher, Melissa L (VHASDC) <(b6) va.gov>

Subject: RE: TRD Provider Guide - FOR YOUR REVIEW

This is very comprehensive and well done,

(b) (5)

Here are specific comments.

I'll add comments here as I couldn't figure out how to add to the boxes (sorry).

(b) (5)

(b) (5)

From: Wiechers, Ilse

Sent: Friday, August 23, 2019 12:16 PM

To: Oslin, Dave (Philadelphia VAMC) <(b6)@va.gov>; Thase, Michael E. <(b6)@va.gov>; Fuller, Matthew A. (PBM) <(b6)@va.gov>; Madore, Michelle R. <(b6)@va.gov>; Capehart, Bruce P. DURVAMC <(b6)@va.gov>; Dunn, Walter <(b6)@va.gov>; Gilmer, William S. (HIN) <(b6)@va.gov>; George, Mark S. <(b6)@va.gov>; Maramba, Gloria G <(b6)@va.gov>; Mells, Lillie M <(b6)@va.gov>

Cc: Wells, Daina L. <(b6)@va.gov>; Popish, Sarah J. <(b6)@va.gov>; Christopher, Melissa L (VHASDC) <(b6)@va.gov>

Subject: TRD Provider Guide - FOR YOUR REVIEW

Importance: High

Hello everyone –

Thanks again for your willingness to help us update the Academic Detailing Provider Guide for Treatment Resistant Depression. Attached you will find the draft version for your review. ***Please return your comments and edits to Daina Wells ((b6)@va.gov) and Sarah Popish ((b6)@va.gov) by Friday, September 6.***

You can return comments and edits by using track changes on the Word document or by sending a list of line item edits via email. Please DO NOT send back an edited Word document that did not track changes!

Please note that the references are still a work in progress, which is to say all references are cited and listed at the end of the document, but the formatting is inconsistent. We will be cleaning up the formatting before the final version, so please disregard this as you are reviewing the document.

We are also working on Pocket Cards. Some of the information that the you have provided has been moved to that section. The Pocket Cards will include specific actionable information (e.g., drug dosing, drug interactions, rTMS and medications to avoid). More to come on the Pocket Cards in the near future.

If you have any questions, please let me know. Thanks again!

Best,
Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

National Lead, Esketamine Clinical Implementation

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)

(b6)@va.gov | (b6)@yale.edu

Sender:	Thase, Michael E. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CAEF785151044128B74D28545152DD08-THASE, MICH <(b6)@va.gov>
Recipient:	Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6)@va.gov>; Madore, Michelle R. /c=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73daaca95f32485194225da4acb2693a-Madore, Mic <(b6)@va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6)@va.gov>; Dunn, Walter /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd06b6b345fe4e25871d6ff0e6b94471-Dunn, Walte <(b6)@va.gov>; Gilmer, William S. (HIN) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21a9ad29cb0c4f44a66033c8db916bf1-Gilmer, Wil <(b6)@va.gov>; George, Mark S. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45af546041f14066bed10aa50d4debca-George, Mar <(b6)@va.gov>; Maramba, Gloria G /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8152a557167e4d64bdc79e46a98e6063-Maramba, Gl <(b6)@va.gov>; Mells, Lillie M /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c433ebdf137044d98b16c52fddc10e49-Mells, Lill <(b6)@va.gov>; Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6)@va.gov>; Popish, Sarah J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242afb789db04c4a90ec3da8943800f3-Popish, Sar <(b6)@va.gov>; Christopher, Melissa L (VHASDC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a542daad1277489fb77c0b3d08454521-Christopher <(b6)@va.gov>
Sent Date:	2019/08/26 09:27:59
Delivered Date:	2019/08/26 09:28:00
Message Flags:	Unread

From:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6) [REDACTED] va.gov>
To:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6) [REDACTED] va.gov>
CC:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) [REDACTED] va.gov>
Subject:	RE: TRD handout update
Date:	2019/06/28 17:01:15
Priority:	Normal
Type:	Note

Daina,

I'll sign up to write and review pharmacotherapy with Matthew Fuller. He and I can figure out how to divide and conquer specific areas.

Regards,

Bruce

From: Wells, Daina L.

Sent: Monday, June 24, 2019 1:40 PM

To: Capehart, Bruce P. DURVAMC <(b6) [REDACTED] va.gov>; Gilmer, William S. (HIN) <(b6) [REDACTED] va.gov>; George, Mark S. <(b6) [REDACTED] va.gov>

Subject: TRD handout update

Importance: High

Hello,

Several of us were able to meet today to discuss next steps regarding the TRD handout. The goal of this group is to update this handout with accurate, up-to-date, and balanced evidence-based information. The handout will serve as a discussion aid and will be a summary for providers, not an all inclusive guideline. The goal is to have pharmacist academic detailers take this handout with them when they go to meet with providers one-on-one or in small groups to discuss this topic. This handout should display the information in a way that makes it quick and easy for providers to see the key evidence in this area as well as the take-away messages for identification, management, and monitoring of TRD.

Here is a [link](#) to a recent example of an academic detailing discussion handout for a different clinical topic so you can see the look and feel for what we are hoping to do with the updated TRD handout. If you have questions about the intended use of this handout, please let me know.

Today on the call I asked each subject matter expert to indicate 1. whether they could serve as a writer, reviewer, or both and 2. if there was a particular section or area within TRD they wanted to focus on or if they would be willing to help with the entire document. We still need a lead writer for the ECT section

so if you have expertise in that area and the bandwidth to help write content, it would be much appreciated.

Please fill in the table with what you are able/willing to do:

SMEs	Role
Ilse Wiechers	Reviewer - all content
Dave Oslin	Reviewer – all content
Michael Thase	Writer – will review older document and determine what he can update
Matthew Fuller	Writer - pharmacotherapy
Michelle Madore	Writer and reviewer - rTMS section
Bruce Capehart	
William Gilmer	
Mark George	
Walter Dunn	Reviewer - rTMS, esketamine, ketamine

If you are a **writer**, please review the older attached TRD handout and begin reviewing the literature to determine what needs to be updated/added. I will be emailing the writers to set up a call in the next couple of weeks.

If you are a **reviewer only**, the writers will begin working on their sections and I will send out an email to all reviewers once we have a better idea of timeline for review.

Please let me know if you have any questions!

Thank you.

Daina

Daina L. Wells, PharmD, MBA, BCPS, BCPP

National Clinical Program Manager

VA Academic Detailing Service, VACO PBM

[ADS SharePoint](#)

[ADS Inquiry and Request Portal](#)

Suicide Prevention is Everyone's Business.

#BeThere

Veterans in crisis, or their friends or family, can call the Veterans Crisis Line for confidential support 24 hours a day, seven days a week, 365 days a year at 1-800-273-8255 **and Press 1**, chat online at VeteransCrisisLine.net/Chat, or text to **838255**.

Sender:	Capehart, Bruce P. DURVAMC /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6866EFF4E9DF4A48846D056A02044C38-CAPEHART, B <(b6)>@va.gov>
Recipient:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain

<(b6) [REDACTED] va.gov>;
Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat
<(b6) [REDACTED] va.gov>

Sent Date: 2019/06/28 17:01:14

Delivered Date: 2019/06/28 17:01:15

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>
Subject:	RE: touching base on esketamine
Date:	2019/03/21 12:25:00
Priority:	Normal
Type:	Note

Sorry. I got my time zones confused. Can we do 11 AM pacific/ 2 PM ET?

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 12:23 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: touching base on esketamine

Double checking on the time – 12 noon pacific is 3 pm ET. Does that work?

From: Fuller, Matthew A. (PBM)
Sent: Thursday, March 21, 2019 9:16 AM
To: Wiechers, Ilse <(b6)@va.gov>
Subject: RE: touching base on esketamine

Sure. 9 AM EST/Noon Pacific works for me. Would you like me to call your cell listed in your contact info?

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 11:26 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Subject: RE: touching base on esketamine

Let's try to connect tomorrow – I'm free 11- 1:30 Pacific. Let me know what works for you.

Ilse

From: Fuller, Matthew A. (PBM)
Sent: Thursday, March 21, 2019 6:59 AM
To: Wiechers, Ilse <(b6)@va.gov>
Subject: RE: touching base on esketamine

Hi Ilse,

You are correct. I will be reviewing esketamine for PBM and have given it top priority. I am happy to speak with you. I have some time Friday or Monday if either day works for you. Please let me know. Thanks.

Matthew

From: Wiechers, Ilse
Sent: Wednesday, March 20, 2019 4:52 PM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>
Subject: touching base on esketamine

Hi Matthew –

I heard via Melissa Christopher that you are working on the monograph for esketamine. I am leading the efforts for OMHSP to get facilities prepared for certifying with REMS and clinical use of the medication. I would love if we could touch base to talk and get your input and ideas as we start to develop the guidance on clinical processes and procedures.

Let me know when might be a good time to talk more.

Best,
Ilse

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Co-Director, Care for Patients with Complex Problems (CP)²
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email (b6)@va.gov | (b6)@yale.edu

Connect to:
[PDSI Home](#)
[PDSI Management System](#)
[FAQs](#)

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>
Sent Date:	2019/03/21 12:25:30
Delivered Date:	2019/03/21 12:25:00

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6) va.gov>
CC:	Popish, Sarah J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242afb789db04c4a90ec3da8943800f3-Popish, Sar <(b6) va.gov>
Subject:	RE: to do for TRD
Date:	2019/08/16 15:11:00
Priority:	Normal
Type:	Note

Hi Daina,

Hope you have a great time off!

I reviewed the esketamine material and edited it as well as responded to your questions. It looks like you already added author information. However, as I noted in the document, TRANSFORM 1 and 3 have not been published yet, not sure they will given negative outcome. (b) (5)

The document looks good as it is coming together.
Thanks.

Matthew

From: Wells, Daina L.
Sent: Friday, August 16, 2019 12:16 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Cc: Popish, Sarah J. <(b6) va.gov>
Subject: to do for TRD
Importance: High

Hi Matthew,
Sarah and I have been working on the TRD guide and have a couple of questions for you.

- (b) (5)

- (b) (5)

If you could make these edits/updates or get back to us with your comments by the 22nd that would be GREAT. I'm hoping Sarah can clean up the draft and send it out for workgroup review on the 26th. I'm OOO for the next 2 weeks so please cc Sarah on any emails you send to me.

Thanks again for all your help!
Daina

Daina L. Wells, PharmD, MBA, BCPS, BCPP
National Clinical Program Manager
VA Academic Detailing Service, VACO PBM
[ADS SharePoint](#)
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Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b) (5)@va.gov>; Popish, Sarah J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=242afb789db04c4a90ec3da8943800f3-Popish, Sar <(b) (5)@va.gov>
Sent Date:	2019/08/16 15:11:54
Delivered Date:	2019/08/16 15:11:00

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From:	Evaluation Only. Created with Aspose.HTML. Copyright 2013-2020 Aspose Pty Ltd.)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL <(b6)@va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
CC:	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr <(b6)@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 15:09:26
Priority:	Normal
Type:	Note

Final statement from OPIA attached and copied below for easy access

Thanks,
Jill

###

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

###

From: Llorente, Maria D.
Sent: Friday, June 21, 2019 3:03 PM
To: Law, Cassandra M. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Snyder, Jill <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Agree with Cassie. Response addresses both inquiries.

From: Law, Cassandra M.
Sent: Friday, June 21, 2019 2:59 PM
To: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Snyder, Jill <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

Adding Jill Snyder for assistance.

Chris – I have included Dr. Llorente and Jill Snyder from VHA communications as Curt Cashour is working another related issue (the response you have attached). With Jill's assistance, VHA 10B cleared, but his last message noted to hold momentarily.

I want to be sure all are aware of this request also so we are consistent and transparent. Jill, can you check and let us know?

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 2:51 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

10P4-I believe what we cleared earlier to Curt covers this, do you agree?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM

To: VHA 10P Actions <VHA10PAActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) ((b6) [REDACTED] va.gov) <(b6) [REDACTED] va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: (b6) (b6) (Veterans Affairs) ((b6) [REDACTED] @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) <(b6) [REDACTED] va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

(b6) [REDACTED]

[REDACTED]
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b6) [REDACTED]

Sender:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL <(b6)@va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr <(b6)@va.gov>
Sent Date:	2019/06/21 15:09:25
Delivered Date:	2019/06/21 15:09:26
From:	Cashour, Curtis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DBA510634BAA46A085E28C62C254093F-CASHOUR, CU <(b6)@va.gov>
To:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jil <(b6)@va.gov>
CC:	Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr <(b6)@va.gov>; Sandifer, Estella (Maria) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a38d9112ad904c5a84ffc6c931693af7-Sandifer, E <(b6)@va.gov>
Subject:	RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision
Date:	2019/06/21 15:06:07
Priority:	Normal
Type:	Note

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to “prior authorization” formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

From: Snyder, Jill
Sent: Friday, June 21, 2019 2:57 PM
To: Cashour, Curtis <(b6) va.gov>
Cc: Graham, Christopher L. <(b6) va.gov>; Sandifer, Estella (Maria) <(b6) va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt – can you please send me a copy of the final statement? We are also getting congressional inquiries and would like to use the same verbiage, but want to make sure we have the final □

Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 2:14 PM
To: Snyder, Jill <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) @va.gov>; Greilsamer, Alan <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Hastings, Patricia R. <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hold please.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Snyder, Jill
Sent: Friday, June 21, 2019 2:13 PM
To: Cashour, Curtis <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>
Cc: Outlaw, William N. <(b6) va.gov>; Valentino, Michael (VACO)

<(b6) [REDACTED] va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>; Greilsamer, Alan
<(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>; Hastings, Patricia R.
<(b6) [REDACTED] va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

Sorry for the delay – VHA clears the statement. Also adding Ndidi since she has queries on this as well.

Statement

###

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to “prior authorization” formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA’s commitment to seek new ways to provide the best health care available for our nation’s Veterans.

###

Thanks,
Jill

From: Cashour, Curtis

Sent: Friday, June 21, 2019 1:55 PM

To: Snyder, Jill <(b6) [REDACTED] va.gov>; Law, Cassandra M. <(b6) [REDACTED] va.gov>; Llorente, Maria D. <(b6) [REDACTED] va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) [REDACTED] va.gov>

Cc: Outlaw, William N. <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>; Greilsamer, Alan <(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>; Hastings, Patricia R. <(b6) [REDACTED] va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>

Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Any update?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Snyder, Jill
Sent: Friday, June 21, 2019 1:07 PM
To: Cashour, Curtis <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) @va.gov>; Greilsamer, Alan <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Hastings, Patricia R. <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt – can you please hold while I get 10B to sign off? I am walking up right now.

Thanks,
Jill

From: Cashour, Curtis
Sent: Friday, June 21, 2019 1:07 PM
To: Law, Cassandra M. <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; VHA 10P Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6) va.gov>
Cc: Outlaw, William N. <(b6) @va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Wiechers, Ilse <(b6) @va.gov>; Snyder, Jill <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Hastings, Patricia R. <(b6) va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

So I can release it to the media now?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Law, Cassandra M.
Sent: Friday, June 21, 2019 1:06 PM
To: Cashour, Curtis <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>; VHA 10P

Actions <VHA10PActions@va.gov>; Beck, Lucille B. <(b6)@va.gov>
Cc: Outlaw, William N. <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Snyder, Jill <(b6)@va.gov>; Greilsamer, Alan <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Hastings, Patricia R. <(b6)@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt – this is cleared for 10P. Thank you, Cassie

From: Cashour, Curtis
Sent: Friday, June 21, 2019 1:05 PM
To: Llorente, Maria D. <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Outlaw, William N. <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Snyder, Jill <(b6)@va.gov>; Greilsamer, Alan <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Law, Cassandra M. <(b6)@va.gov>; Hastings, Patricia R. <(b6)@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA - What is the ETA for final approval on this?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6)@va.gov
@curtcashour

From: Llorente, Maria D.
Sent: Friday, June 21, 2019 12:37 PM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: Outlaw, William N. <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Snyder, Jill <(b6)@va.gov>; Greilsamer, Alan <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Cashour, Curtis <(b6)@va.gov>; Law, Cassandra M. <(b6)@va.gov>; Hastings, Patricia R. <(b6)@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

This is cleared by 10P4. There is short time frame. Jill Snyder is the POC for VHA Comms. Now for 10P review/concurrence.

From: Outlaw, William N.
Sent: Friday, June 21, 2019 12:30 PM
To: Cashour, Curtis <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Snyder, Jill <(b6)@va.gov>
Cc: Greilsamer, Alan <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>;

Llorente, Maria D. <(b6) va.gov>

Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Per Mike Valentino, Pharmacy Benefits is good with the statement but will send up through clearance channels.

From: Cashour, Curtis

Sent: Friday, June 21, 2019 12:24 PM

To: Valentino, Michael (VACO) <(b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; Snyder, Jill <(b6) va.gov>

Cc: Outlaw, William N. <(b6) va.gov>; Greilsamer, Alan <(b6) va.gov>;

Zacher, Jennifer L. (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>

Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks. Does VHA concur with the following?

###

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

###

Curt Cashour

Press Secretary

Department of Veterans Affairs

(b6)

(b6) va.gov

@curtcashour

From: Valentino, Michael (VACO)

Sent: Friday, June 21, 2019 12:17 PM

To: Wiechers, Ilse (b6) @va.gov>; Snyder, Jill <(b6) va.gov>; Cashour, Curtis

<(b6) [REDACTED]@va.gov>

Cc: Outlaw, William N. (b6) [REDACTED]@va.gov>; Greilsamer, Alan <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Dr. Llorente and I drafted a statement for the NYT inquiry and I believe it will be coming forward soon.

Here it is but please consider it DRAFT:

From: Wiechers, Ilse

Sent: Friday, June 21, 2019 12:07 PM

To: Snyder, Jill <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Cashour, Curtis <(b6) [REDACTED]@va.gov>

Cc: Outlaw, William N. <(b6) [REDACTED]@va.gov>; Greilsamer, Alan <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>

Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Adding Jen Zacher for coordination purposes.

From: Snyder, Jill

Sent: Friday, June 21, 2019 9:02 AM

To: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>; Cashour, Curtis <(b6) [REDACTED]@va.gov>

Cc: Outlaw, William N. (b6) [REDACTED]@va.gov>; Greilsamer, Alan <(b6) [REDACTED]@va.gov>; Snyder, Jill <(b6) [REDACTED]@va.gov>

Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Good afternoon Mike and Ilse,

I know you all are working on media responses regarding Ketamine, however we just received an email from the Boston Globe that the decision was made NOT to include it in the formulary. Please see email below and I am including Curt Cashour, VA Press Secretary, on this message to streamline responses.

Thank you,
Jill

From: Silverman, Ed (b6) [REDACTED]@statnews.com>

Sent: Friday, June 21, 2019 11:24 AM

To: VA Public Affairs <VAPublicAffairs@va.gov>

Subject: [EXTERNAL] question from a journalist

Hi ,

My name is Ed Silverman and I work for The Boston Globe's STAT News health site, where I track the pharmaceutical industry.

I understand a VA committee voted not to include a new Johnson&Johnson antidepressant spray drug called Spravato on its pharmacy list.

Can you please confirm and explain why the committee voted not to include it?

Thanks

ed silverman

(b6)

www.statnews.com/pharmalot/

From: Snyder, Jill

Sent: Friday, June 21, 2019 9:59 AM

To: Cashour, Curtis <(b6) [REDACTED] va.gov>; Greilsamer, Alan <(b6) [REDACTED] va.gov>

Cc: Eason, William J. <(b6) [REDACTED] va.gov>; Screen, Gina <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Hi Curt –

I am following this in Alan's absence, program office is still working on the response, I will continue to follow up.

Thanks,
Jill

From: Cashour, Curtis

Sent: Friday, June 21, 2019 9:57 AM

To: Greilsamer, Alan <(b6) [REDACTED] va.gov>; Snyder, Jill <(b6) [REDACTED] va.gov>

Cc: Eason, William J. <(b6) [REDACTED] va.gov>; Screen, Gina <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Just following up here. Thanks.

From: Greilsamer, Alan

Sent: Thursday, June 20, 2019 3:34 PM

To: Cashour, Curtis <(b6) [REDACTED] va.gov>

Cc: Eason, William J. <(b6) [REDACTED] va.gov>; Screen, Gina <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

We will try to pin them down on a timeframe.

—
Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b6)
E: (b6)@va.gov

From: Cashour, Curtis <(b6)@va.gov>
Date: Thursday, Jun 20, 2019, 3:18 PM
To: Greilsamer, Alan <(b6)@va.gov>
Cc: Eason, William J. <(b6)@va.gov>, Screen, Gina <(b6)@va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Is there an update here?

The original question was when will VA make a decision about putting spravato on the formulary.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
Curt.Cashour@va.gov
[@curtcashour](https://twitter.com/curtcashour)

From: Greilsamer, Alan
Sent: Wednesday, June 19, 2019 9:05 AM
To: Cashour, Curtis <(b6)@va.gov>
Cc: Eason, William J. <(b6)@va.gov>; Screen, Gina <(b6)@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

VHA clears

(b) (5)
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

Additional information

(b) (5)

Ongoing next steps include:

(b) (5)

From: Cashour, Curtis

Sent: Tuesday, June 18, 2019 12:38 PM

To: Greilsamer, Alan <(b6) va.gov>; Screen, Gina <(b6) va.gov>

Cc: Eason, William J. <(b6) va.gov>

Subject: FW: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Please let me know your recommended response to the below.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs

(b6)

(b6) va.gov

@curtcashour

From: Ben Carey (b6) [REDACTED]@nytimes.com>
Sent: Tuesday, June 18, 2019 12:35 PM
To: Cashour, Curtis <(b6) [REDACTED]va.gov>
Subject: Re: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Thanks Curt, please do. Main question for now is when is decision expected..? (i.e. how much time I got?)

Ben

Sent from my iPhone

On Jun 18, 2019, at 12:22 PM, Cashour, Curtis <(b6) [REDACTED]va.gov> wrote:

Will keep you posted. Thanks, Ben.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6) [REDACTED]
(b6) [REDACTED]va.gov
@curtcashour

From: Carey, Ben (b6) [REDACTED]@nytimes.com>
Sent: Tuesday, June 18, 2019 11:36 AM
To: Cashour, Curtis <(b6) [REDACTED]va.gov>
Subject: [EXTERNAL] NY TIMES QUERY/ Ketamine decision

Curt Cashour-

Hello from New York. It's Ben Carey emailing. I am a reporter in science at the NY Times, I cover psych topics. I have your email from Jennifer Steinhauer, NYT reporter in DC.

I would love to hear what/ when on the VA's expected decision this week whether to put Spravato on its formulary. Keep me in the loop on this, kindly, would be good to know when decision will be made, with some notice, and anything else VA puts out on this.

We'll likely cover decision either way.

Sincerely,

Ben Carey

Sender:	Cashour, Curtis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DBA510634BAA46A085E28C62C254093F-CASHOUR, CU <(b6) [REDACTED]va.gov>
Recipient:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jill <(b6) [REDACTED]va.gov>; Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr
<(b6) [REDACTED] va.gov>;
Sandifer, Estella (Maria) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a38d9112ad904c5a84ffc6c931693af7-Sandifer, E
<(b6) [REDACTED] va.gov>

Sent Date: 2019/06/21 15:06:05

Delivered Date: 2019/06/21 15:06:07

From:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA (b6) va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 14:44:54
Priority:	Normal
Type:	Note

Thanks. (b6) Blair called 2x and someone notified her, that this was rejected. I have no idea where she's getting her information from.

v/r
AJ

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 2:21 PM
To: Brooks, Aja <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

It wasn't rejected AJ....it is available on a case-by-case basis.

We've drafted a response for media inquiries that could probably be used to answer this.

Could you please send this to 10P4 Actions for a response?

Mike

From: Brooks, Aja
Sent: Friday, June 21, 2019 1:55 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

What's going on

From: (b6) (b6) Veterans Affairs) (b6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:57 PM
To: Wilson, Joe (VHA) (b6) va.gov>; Brooks, Aja (b6) va.gov>
Subject: [EXTERNAL] RE: SVAC-Majority Inquiry for Info re: Esketamine

Thank you, Joe.

Hi Aja—any info you could share on this today would be greatly appreciated!

Thanks all,

(b6)

From: Wilson, Joe (VHA) (b6) va.gov>
Sent: Friday, June 21, 2019 12:53 PM
To: (b6) (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>; Brooks, Aja (b6) va.gov>
Cc: Wilson, Joe (VHA) (b6) va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Hi (b6)

Adding Aja Brooks as I was covering for her during her absence.

Regards,

Joe Wilson

From: (b6) (b6) (Veterans Affairs) (b6) @vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) (b6) va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

(b6)

Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510

(b6)

Sender:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA (b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>
Sent Date:	2019/06/21 14:44:54

From:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA <(b6) [REDACTED]@va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 14:22:02
Priority:	Normal
Type:	Note

I can.

From: Valentino, Michael (VACO)
Sent: Friday, June 21, 2019 2:21 PM
To: Brooks, Aja <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

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Sent: Friday, June 21, 2019 12:57 PM
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Cc: Wilson, Joe (VHA) <(b6) va.gov>
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(b6)

(b6)
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b6)

Sender: Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/06/21 14:22:01
Delivered Date:	2019/06/21 14:22:02

From:	Graham, Christopher L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4FF0FE692B31483E909235222067A767-GRAHAM, CHR <(b6) [REDACTED]@va.gov>
To:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 15:32:59
Priority:	Normal
Type:	Note

Please ignore the below, Jill clarified with me.

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 3:12 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Actually, this is not the same. Says the oversight committee rejected the drug today?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b6) [REDACTED]

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 2:51 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

10P4-I believe what we cleared earlier to Curt covers this, do you agree?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs

Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) ((b6) va.gov) <(b6) va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: (b6) (b6) (Veterans Affairs) <(b6) (b6)@vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) <(b6) va.gov>
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I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

(b6)

(b6)

Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510

(b6)

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Recipient:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>
Sent Date:	2019/06/21 15:32:57
Delivered Date:	2019/06/21 15:32:59
Message Flags:	Unread

From:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6)@va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 15:15:58
Due Date:	2019/06/20 20:00:00
Priority:	Normal
Type:	Note

Yes.

Cassandra M. Law

From: Valentino, Michael (VACO) <(b6)@va.gov>
Date: Friday, Jun 21, 2019, 3:14 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Can we tell 10P4 to state VA did not reject it and then follow with the media response?

As in:

VA did not reject the use of esketamine. After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Mike

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Sent: Friday, June 21, 2019 3:12 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b6)@va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

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Office of the Deputy Under Secretary for Health for Policy and Services (10P)
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To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b6)@va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

10P4-I believe what we cleared earlier to Curt covers this, do you agree?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM
To: VHA 10P Actions <VHA10PAActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM

To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) ((b6) [REDACTED] va.gov) <(b6) [REDACTED] va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

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Sent: Friday, June 21, 2019 12:50 PM
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Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

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Thank you!

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(b6)
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
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Washington, DC 20510
(b6)

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6) [REDACTED] va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>

Sent Date:	2019/06/21 15:15:56
Delivered Date:	2019/06/21 15:15:58

From:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA <(b6)@va.gov>
To:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>; Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr <(b6)@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 15:39:40
Priority:	Normal
Type:	Note

Roger

Sent with BlackBerry Work
(www.blackberry.com)

From: Law, Cassandra M. <(b6)@va.gov>
Date: Friday, Jun 21, 2019, 3:21 PM
To: Graham, Christopher L. <(b6)@va.gov>, Brooks, Aja <(b6)@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PAActions@va.gov>, Llorente, Maria D. <(b6)@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Thank you all. Aja - you can add one line at the beginning to address the specific language of your request, but the rest should remain the same as just cleared. Below is how it should read.

This has been closely worked at both VHA and Department levels. Many thanks, Cassie

VA did not reject the use of esketamine. After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

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From: Graham, Christopher L. <(b6) va.gov>
Date: Friday, Jun 21, 2019, 3:15 PM
To: Brooks, Aja <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P Actions <VHA10PAActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Aja,

please see the attached cleared earlier today, will this work?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM
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Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

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Cc: Michael Valentino (VACO) ((b6) va.gov) <(b6) va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
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AJ

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(b6)
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b6)

Sender:	Brooks, Aja /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5C59E6730234420DA11251416B699F1C-BROOKS, AJA <(b6)@va.gov>
Recipient:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>; Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr <(b6)@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>
Sent Date:	2019/06/21 15:39:39
Delivered Date:	2019/06/21 15:39:40

From:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6)@va.gov>
To:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jill <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
CC:	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr <(b6)@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 15:11:43
Priority:	Normal
Type:	Note

Thank you very much. We will submit this to OCLA for the related request.
Cassie

From: Snyder, Jill <(b6)@va.gov>
Date: Friday, Jun 21, 2019, 3:09 PM
To: Llorente, Maria D. <(b6)@va.gov>, Law, Cassandra M. <(b6)@va.gov>, Valentino, Michael (VACO) <(b6)@va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>, VHA 10P4 Actions <VHA10P4Actions@va.gov>, Graham, Christopher L. <(b6)@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Final statement from OPIA attached and copied below for easy access

Thanks,
Jill

###

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for

esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

###

From: Llorente, Maria D.
Sent: Friday, June 21, 2019 3:03 PM
To: Law, Cassandra M. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Snyder, Jill <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

Agree with Cassie. Response addresses both inquiries.

From: Law, Cassandra M.
Sent: Friday, June 21, 2019 2:59 PM
To: Llorente, Maria D. <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>; Snyder, Jill <(b6) va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

Adding Jill Snyder for assistance.

Chris – I have included Dr. Llorente and Jill Snyder from VHA communications as Curt Cashour is working another related issue (the response you have attached). With Jill's assistance, VHA 10B cleared, but his last message noted to hold momentarily.

I want to be sure all are aware of this request also so we are consistent and transparent. Jill, can you check and let us know?

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 2:51 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

10P4-I believe what we cleared earlier to Curt covers this, do you agree?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) ((b6) va.gov) <(b6) va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: (b6) (b6) (Veterans Affairs) <(b6) (b6)@vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) <(b6) va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

(b6)

(b6)

Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510

(b6)

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6)@va.gov>
Recipient:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jill <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e90923522067a767-Graham, Chr <(b6)@va.gov>
Sent Date:	2019/06/21 15:11:42
Delivered Date:	2019/06/21 15:11:43

From:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL <(b6)@va.gov>
To:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
CC:	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 15:01:26
Priority:	Normal
Type:	Note

I just sent a note to Curt and added Chris Graham and Maria Sandifer asking for him to send the final VA cleared response, noting we wanted to use it for congressional inquiry.

Thanks!
Jill

From: Law, Cassandra M.
Sent: Friday, June 21, 2019 2:59 PM
To: Llorente, Maria D. <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Snyder, Jill <(b6)@va.gov>
Cc: VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

Adding Jill Snyder for assistance.

Chris – I have included Dr. Llorente and Jill Snyder from VHA communications as Curt Cashour is working another related issue (the response you have attached). With Jill's assistance, VHA 10B cleared, but his last message noted to hold momentarily.

I want to be sure all are aware of this request also so we are consistent and transparent. Jill, can you check and let us know?

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 2:51 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Cc: Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

10P4-I believe what we cleared earlier to Curt covers this, do you agree?

Thanks,

Chris Graham, MHA

Health Systems Specialist

Department of Veterans Affairs

Office of the Deputy Under Secretary for Health for Policy and Services (10P)

Office: (b6) [REDACTED]

From: Brooks, Aja

Sent: Friday, June 21, 2019 2:44 PM

To: VHA 10P Actions <VHA10PActions@va.gov>

Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

Importance: High

Adding 10P

From: Brooks, Aja

Sent: Friday, June 21, 2019 2:41 PM

To: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Cc: Michael Valentino (VACO) ((b6) [REDACTED] va.gov) <(b6) [REDACTED] va.gov>

Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r

AJ

From: (b6) [REDACTED] (Veterans Affairs) <(b6) [REDACTED] vetaff.senate.gov>

Sent: Friday, June 21, 2019 12:50 PM

To: Wilson, Joe (VHA) <(b6) [REDACTED] va.gov>

Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

(b6)

(b6)

Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510

(b6)

Sender:	Snyder, Jill /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6E91EF72EE4A05ACC63873C64570E1-SNYDER, JIL <(b6)@va.gov>
Recipient:	Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/21 15:01:25
Delivered Date:	2019/06/21 15:01:26

From:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6)@va.gov>
To:	Kraemer, John E /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2a0091f85ff4e6e8042219f6027a842-Kraemer, Jo (b6)@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: SVAC-Majority Inquiry for Info re: Esketamine
Date:	2019/06/21 14:57:51
Priority:	Normal
Type:	Note

Hold please...too many related messages.

From: Kraemer, John E
Sent: Friday, June 21, 2019 2:57 PM
To: VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine

10P4P, please see the question below from 10P. You have already submitted a response.

From: Graham, Christopher L.
Sent: Friday, June 21, 2019 2:51 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Valentino, Michael (VACO) <(b6)@va.gov>; VHA 10P Actions
<VHA10PAActions@va.gov>
Subject: RE: SVAC-Majority Inquiry for Info re: Esketamine

10P4-I believe what we cleared earlier to Curt covers this, do you agree?

Thanks,
Chris Graham, MHA
Health Systems Specialist
Department of Veterans Affairs
Office of the Deputy Under Secretary for Health for Policy and Services (10P)
Office: (b6)

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:44 PM
To: VHA 10P Actions <VHA10PAActions@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

Adding 10P

From: Brooks, Aja
Sent: Friday, June 21, 2019 2:41 PM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Michael Valentino (VACO) ((b6) [REDACTED] va.gov) <(b6) [REDACTED] va.gov>
Subject: FW: SVAC-Majority Inquiry for Info re: Esketamine
Importance: High

VHA 10P4 –

OCLA request a response on the inquiry regarding Spravato. Do we have any information we can share with the committee regarding this drug. Committee staff are under the assumption that this drug was rejected. Any previously cleared language would be much appreciated. We'd like to share something with them today, if possible.

v/r
AJ

From: (b6) (b6) (Veterans Affairs) <(b6) (b6)@vetaff.senate.gov>
Sent: Friday, June 21, 2019 12:50 PM
To: Wilson, Joe (VHA) <(b6) [REDACTED] va.gov>
Subject: [EXTERNAL] SVAC-Majority Inquiry for Info re: Esketamine

Hi Joe,

I'm just reaching out to request info on the VA health oversight committee's rejection of Spravato/Esketamine, the ketamine-based drug used to treat treatment-resistant depression. I know the decision by the oversight committee was just made today, but any quick info you can provide on this today would be great.

Thank you!

(b6)

(b6)
Professional Staff Member
U.S. Senate Committee on Veterans' Affairs
412 Russell Senate Office Building
Washington, DC 20510
(b6)

Sender:	Law, Cassandra M. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F888D507D6C54EB5A92FC44199EB5838-LAW, CASSAN <(b6)@va.gov>
Recipient:	Kraemer, John E /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2a0091f85ff4e6e8042219f6027a842-Kraemer, Jo (b6)@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/21 14:57:50
Delivered Date:	2019/06/21 14:57:51

From:	Lieberman, Steven </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25138F5D2E734AFA81397F0B357CBCC1-LIEBERMAN,>
To:	Powers, Pamela /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6021d9c02594b52bc57194848ca7ef6-Powers, Pam (b6) va.gov>
Subject:	RE: Successful first dose of esketamine in VHA
Date:	2019/06/18 14:01:03
Priority:	Normal
Type:	Note

Will do. We keep close eyes on any of our patients whenever we start a new drug or drug indication to ensure the patient stays safe and determine if the drug is efficacious.

Sent with BlackBerry Work
(www.blackberry.com)

From: Powers, Pamela <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 1:48 PM
To: Lieberman, Steven <(b6) va.gov>
Subject: RE: Successful first dose of esketamine in VHA

Thank you. Please keep up informed on the status of the veteran. There (b6)

From: Lieberman, Steven
Sent: Tuesday, June 18, 2019 12:18 PM
To: RLW (b6)@va.gov>
Cc: Powers, Pamela <(b6) va.gov>
Subject: FW: Successful first dose of esketamine in VHA

Sir,

Dr. Stone requested I notify you of the first administration intranasal ketamine for treatment-resistant depression administered at VA Boston Healthcare System this morning as was requested by President Trump.

From: Wiechers, Ilse (b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 11:47 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Boyd, Teresa D. <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>
Cc: Dantzer, Anne (b6) va.gov>, Todd, Catherine A. (b6) va.gov>, Bradley, John (b6) va.gov>, Festin, Fe Erlita (b6) va.gov>, Wiechers, Ilse (b6)@va.gov>

Houranieh, Antoun <(b6) [REDACTED]@va.gov>, Salow, Marci VHABHS (b6) [REDACTED]@va.gov>, Charness, Michael (b6) [REDACTED]@va.gov>

Subject: Successful first dose of esketamine in VHA

Hello everyone –

This morning the team at VA Boston (cc'd) successfully provided the first VHA treatment with esketamine to one of their Veterans with treatment-resistant depression at the JP VA Medical Center. The Veteran tolerated the treatment well and was discharged home with close outpatient follow up plans.

Congratulations to the team for all of their hard work in making this happen! Your leadership on this important work is greatly appreciated. We look forward to learning from VA Boston as we move forward with other Early Adopter sites to bring this treatment to Veterans across VHA.

Best,
Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6) [REDACTED]

email: (b6) [REDACTED]@va.gov | (b6) [REDACTED]@yale.edu

Sender:	Lieberman, Steven </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25138F5D2E734AFA81397F0B357CBCC1-LIEBERMAN,>
Recipient:	Powers, Pamela /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6021d9c02594b52bc57194848ca7ef6-Powers, Pam <(b6) [REDACTED]@va.gov>
Sent Date:	2019/06/18 14:01:03

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6) va.gov>
To:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6) va.gov>; Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich <(b6) va.gov>; Oshinski, Renee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56925a4f59df47d19fcceb5e7c270bc0-Oshinski, R <(b6) va.gov>
CC:	Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La <(b6) va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>
Subject:	RE: Successful first dose of esketamine in VHA
Date:	2019/06/18 12:08:07
Priority:	Normal
Type:	Note

Thanks!
I have notified Deborah.
T

Sent with BlackBerry Work
(www.blackberry.com)

From: Lieberman, Steven <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 11:54 AM
To: Boyd, Teresa D. <(b6) va.gov>, Stone, Richard A., MD <(b6) va.gov>, Oshinski, Renee <(b6) va.gov>
Cc: Connell, Lawrence B. <(b6) va.gov>, Jensen, Jon M. <(b6) va.gov>
Subject: RE: Successful first dose of esketamine in VHA

Fantastic news. Thanks for sharing
You can certainly let her know. Much thanks for your role with this!

Sent with BlackBerry Work
(www.blackberry.com)

From: Boyd, Teresa D. <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 11:52 AM
To: Stone, Richard A., MD <(b6) va.gov>, Lieberman, Steven <(b6) va.gov>, Oshinski, Renee <(b6) va.gov>
Cc: Connell, Lawrence B. <(b6) va.gov>, Jensen, Jon M. <(b6) va.gov>
Subject: FW: Successful first dose of esketamine in VHA

As promised - first administration intranasal ketamine!
Steve - would you like me to let Deborah Scher know or do you want the honors? Thx!
Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Boyd, Teresa D. <(b6) va.gov>
Date: Tuesday, Jun 18, 2019, 11:49 AM
To: Wiechers, Ilse <(b6) va.gov>, VHA 10NC5 Action <VHA10NC5Action@va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>, Llorente, Maria D. <(b6) va.gov>
Cc: Dantzler, Anne <(b6) va.gov>, Todd, Catherine A. <(b6) va.gov>, Bradley, John <(b6) va.gov>, Festin, Fe Erlita <(b6) va.gov>, Wiechers, Ilse <(b6)@va.gov>, Houranich, Antoun <(b6) va.gov>, Salow, Marci VHABHS <(b6) va.gov>, Charness, Michael <(b6) va.gov>
Subject: RE: Successful first dose of esketamine in VHA

Congratulations! And our journey begins - intentional and mindful. Really appreciate your leadership!
Teresa

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Best,
Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)

email (b6)@va.gov | (b6)yale.edu

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6)@va.gov>
Recipient:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6)@va.gov>; Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich <(b6)@va.gov>; Oshinski, Renee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56925a4f59df47d19fcceb5e7c270bc0-Oshinski, R <(b6)@va.gov>; Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e7233376344045980ad214122389f4-Connell, La <(b6)@va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6)@va.gov>
Sent Date:	2019/06/18 12:08:06
Delivered Date:	2019/06/18 12:08:07

From:	Lieberman, Steven /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=25138F5D2E734AFA81397F0B357CBCC1-LIEBERMAN, <(b6) [REDACTED] va.gov>
To:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich <(b6) [REDACTED] va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6) [REDACTED] va.gov>; Oshinski, Renee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56925a4f59df47d19fcceb5e7c270bc0-Oshinski, R <(b6) [REDACTED] va.gov>
CC:	Connell, Lawrence B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3e723376344045980ad214122389f4-Connell, La <(b6) [REDACTED] va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) [REDACTED] va.gov>
Subject:	RE: Successful first dose of esketamine in VHA
Date:	2019/06/18 11:54:39
Priority:	Normal
Type:	Note

Will do

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From: Stone, Richard A., MD <(b6) [REDACTED] va.gov>
Date: Tuesday, Jun 18, 2019, 11:53 AM
To: Boyd, Teresa D. <(b6) [REDACTED] va.gov>, Lieberman, Steven <(b6) [REDACTED] va.gov>, Oshinski, Renee <(b6) [REDACTED] va.gov>
Cc: Connell, Lawrence B. <(b6) [REDACTED] va.gov>, Jensen, Jon M. <(b6) [REDACTED] va.gov>
Subject: RE: Successful first dose of esketamine in VHA

Well done! Please ensure the Secretary is aware.

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From: Boyd, Teresa D. <(b6) [REDACTED] va.gov>
Date: Tuesday, Jun 18, 2019, 11:52 AM
To: Stone, Richard A., MD <(b6) [REDACTED] va.gov>, Lieberman, Steven <(b6) [REDACTED] va.gov>, Oshinski, Renee <(b6) [REDACTED] va.gov>
Cc: Connell, Lawrence B. <(b6) [REDACTED] va.gov>, Jensen, Jon M. <(b6) [REDACTED] va.gov>
Subject: FW: Successful first dose of esketamine in VHA

As promised - first administration intranasal ketamine!

Steve - would you like me to let Deborah Scher know or do you want the honors? Thx!
Teresa

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Sent Date:	2019/06/18 11:54:38
Delivered Date:	2019/06/18 11:54:39

From:	Llorente, Maria D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M <(b6)@va.gov>
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Subject:	RE: Successful first dose of esketamine in VHA
Date:	2019/06/18 11:58:22
Priority:	Normal
Type:	Note

Thank you for the update and we look forward to the follow up and hopefully a therapeutic outcome.

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cell (b6) [REDACTED]
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Sent Date:	2019/06/18 11:58:21
Delivered Date:	2019/06/18 11:58:22

From:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P <(b6) [REDACTED]@va.gov>
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Subject:	RE: Successful first dose of esketamine in VHA
Date:	2019/06/18 12:10:10
Priority:	Normal
Type:	Note

Ma'am,

I removed identifiers and forwarded.

[[This morning VHA provided the first treatment with esketamine. The Veteran tolerated the treatment well and was discharged home with close outpatient follow up plans.]]
pat

From: Llorente, Maria D.

Sent: Tuesday, June 18, 2019 12:01 PM

To: Hastings, Patricia R. <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>

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email (b6) va.gov | (b6) yale.edu

Sender:	Hastings, Patricia R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A504FBFE766048A5A65461C45F28E9DE-HASTINGS, P <(b6) va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/06/18 12:10:08
Delivered Date:	2019/06/18 12:10:10

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: STFAC call tomorrow
Date:	2019/03/07 15:58:00
Priority:	Normal
Type:	Note

I am happy to call/email. Please let me know your availability. Thanks.

Matthew

From: McGuire, Marsden H.
Sent: Wednesday, March 06, 2019 10:03 PM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: STFAC call tomorrow

Matt,

Thanks for letting me know. Unfortunately Ilesha was out so the information that you wouldn't be on didn't get to us. And yesterday was a huge day for ketamine/esketamine nationwide. Let's be in touch in the next day or two.

M

Sent with BlackBerry Work
www.blackberry.com

From: Fuller, Matthew A. (PBM) <(b6) va.gov>
Date: Wednesday, Mar 06, 2019, 9:58 PM
To: McGuire, Marsden H. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: STFAC call tomorrow

Hi Dr McGuire,

I am sorry that I missed the call. I am traveling and was unable to join the call yesterday. I responded to Isha's calendar invite before I left. I agree that the second survey will offer some guidance. In addition, PBM has been working to construct a MUET for ketamine use in pain and depression. I am interested to learn your thoughts about ways to provide direction to the field. Thanks.

Matthew

Matthew A. Fuller, BS, Pharm.D., FASHP, BCPP
National PBM Clinical Pharmacy Program Manager – Psychiatry and Geriatrics
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue – 1 Block North of Cermak (Bldg 37)
Hines, IL 60141
(b6)

From: McGuire, Marsden H.
Sent: Monday, March 04, 2019 1:01 PM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>
Cc: Valentino, Michael (VACO) <(b6)@va.gov>
Subject: STFAC call tomorrow

Hi Matt,

One of our agenda items for tomorrow's call at 12 noon (EDT) is PBM's perspective on current status of ketamine usage in VA and whether we should be providing specific direction to the field at this time. The answer to this may hinge on the results of the second survey we are sending to the field re: ECT, rTMS and ketamine use. However, there may be ways in which we should move before those results come in. Please let me your preliminary thoughts about this today if you can.

Thx.

MM

+++++

Marsden H. McGuire, M.D., M.B.A. (SES-EQV)
Acting Assistant Deputy Under Secretary for Health for Patient Care Services
Office of Patient Care Services (10P4)
VA Central Office
810 Vermont Avenue NW
Washington, DC 20420
Tel: (b6)
Cell: (b6)
Fax: (b6)
e-mail: (b6)@va.gov

Sender: Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/07 15:58:04
Delivered Date:	2019/03/07 15:58:00

From:	Sharpe, Virginia A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=082E348B444D4565AA069F3C7B50A090-SHARPE, VIR <(b6)@va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>
CC:	Tompkins, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54deee370ede4ccebf82d26d8f7f62ed-Tompkins, P <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>
Subject:	RE: starting process of possible iMed Consent for intranasal esketamine
Date:	2019/03/08 14:48:19
Priority:	Normal
Type:	Note

Hi Ilse – Coincidentally, I just emailed about this to Dr. Llorente! Please see the attached for information on next steps regarding consent form development. I'm not sure what the potential is for abuse and misuse of Spravato if it will only be available in a medically supervised healthcare setting that provides patient monitoring, but we'd welcome the opportunity to ensure that VA develops patient education that focuses on safe use. We have a model for this in our [education about long-term opioids for pain](#). From an ethics perspective, we strongly discourage the use of patient contracts (which are unenforceable and adversarial) in favor of a therapeutic approach in line with consent for other high risk treatments. We're happy to assist. I'm including Paul Tompkins in my office for awareness. He is the national program manager for iMedConsent.

Ashby

+++++

Virginia Ashby Sharpe, Ph.D.
Acting Executive Director
National Center for Ethics in Health Care
Veterans Health Administration 10E1E
810 Vermont Ave. NW, Washington, DC 20420 (mail)
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fax: 202-632-8456
(b6)@va.gov
intranet: <http://vaww.ethics.va.gov/>
internet: <http://www.ethics.va.gov/>

From: Wiechers, Ilse
Sent: Friday, March 08, 2019 1:52 PM
To: Sharpe, Virginia A. <(b6)@va.gov>
Subject: starting process of possible iMed Consent for intranasal esketamine

Hello Dr. Sharpe -

I am working as lead for the Office of Mental Health and Suicide Prevention (10NC5) in collaboration with PBM to prepare for use in VHA of the newly FDA-approved intranasal esketamine (Spravato). As part of FDA approval, there will be a Spravato REMS program, to mitigate risks associated with serious adverse outcomes resulting from sedation and sedation caused by Spravato, and abuse and misuse of Spravato.

I am hoping you can direct me to the person(s) within the National Center for Ethics in Health Care who could best assist me in determining if an iMed consent will be needed for this new medication, and who can help assist me in drafting necessary documents for that informed consent.

Thanks for your assistance.

Best,
Ilse

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Co-Director, Care for Patients with Complex Problems (CP)²
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6)
email: (b6)@va.gov | (b6)@yale.edu

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Sender:	Sharpe, Virginia A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=082E348B444D4565AA069F3C7B50A090-SHARPE, VIR <(b6)@va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Tompkins, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54deee370ede4ccebf82d26d8f7f62ed-Tompkins, P <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>

Sent Date:	2019/03/08 14:48:17
Delivered Date:	2019/03/08 14:48:19
Message Flags:	Unread
From:	Sharpe, Virginia A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=082E348B444D4565AA069F3C7B50A090-SHARPE, VIR <(b6)@va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Tompkins, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54deee370ede4ccebfb82d26d8f7f62ed-Tompkins, P <(b6)@va.gov>
Subject:	RE: iMedConsent - intranasal esketamine
Date:	2019/03/08 14:27:00
Priority:	Normal
Type:	Note

Thank you, I've received the email from Ilse and will cc you on the reply.
Ashby

From: Llorente, Maria D.
Sent: Friday, March 08, 2019 2:26 PM
To: Sharpe, Virginia A. <(b6)@va.gov>; Tompkins, Paul A. <(b6)@va.gov>
Subject: RE: iMedConsent - intranasal esketamine

Thank you very much. Tom Emmendorfer reached out to mental health program office re the ketamine informed consent and Ilse Wiechers was going to be reaching out to you. I will forward this to the group to assure communication. Thank you again for raising this question this morning.
Maria Llorente

From: Sharpe, Virginia A.
Sent: Friday, March 8, 2019 2:17 PM
To: Llorente, Maria D. <(b6)@va.gov>; Tompkins, Paul A. <(b6)@va.gov>
Subject: iMedConsent - intranasal esketamine

Hi Maria – Great to meet you this morning. I wanted you to have my contact info and also provide you with information about the process to develop a consent form for intranasal esketamine. I'm adding Paul Tompkins from my office in case he has more to add.

Paul Dr. Llorente is here on detail to PCS from the DCVA.
Ashby

Here's the information about the risk threshold for treatments and procedures requiring signature informed consent:

VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009 (Revised May 22, 2017).

(2) Treatments and Procedures That Require Signature Consent. Prior to undertaking certain treatments and procedures, the practitioner must document the informed consent process in detail (as specified in subpars. 13c(2)(a) and 13c(2)(b)) and obtain the patient's signature on a VA authorized consent form.

(a) The patient's signature consent must be obtained for treatments and procedures that:

1. Can be reasonably expected to produce significant pain or discomfort to the patient;
2. Can be reasonably expected to produce pain or discomfort to the patient that is substantial enough to require sedation, anesthesia, or narcotic analgesia;
3. Can be reasonably considered to have a significant risk of complication or morbidity;
4. Require injections of any substance into a joint space or body cavity (excluding the intravascular space); or
5. Are listed in Appendix A.

Here's the info. about the process for consent form development. 10NC and PCS have process in place to manage SME input.

VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014.

10. CONTACTS:

b. Clinical Content Concerns and Requests.

(1) Concerns related to the clinical content in the iMedConsent™ program and requests for new content need to be reviewed and approved by the relevant Specialty Chief and submitted to the vendor using email (content@dialogmedical.com). Submission must include the name of the document (or proposed name if new content is being requested), the specialty (or proposed specialty), and a description of the concern or new content request.

(2) The vendor, Dialog Medical, evaluates content requests on a 90-day timeframe (estimated) to determine whether content modification or new content is needed. Dialog Medical provides a summary of actions taken in response to any field request to Patient Care Services for review.

(3) Patient Care Services, in conjunction with designated operational policy offices under the Deputy Under Secretary for Health for Operations and Management, is responsible for ensuring that consent form content is consistent with VHA policy and practice.

+++++

Virginia Ashby Sharpe, Ph.D.

Acting Executive Director

National Center for Ethics in Health Care

Veterans Health Administration 10E1E

810 Vermont Ave. NW, Washington, DC 20420 (mail)

811 Vermont Ave. NW, Washington, DC 20420 #624 (physical)

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fax: 202-632-8456

(b6)@va.gov

intranet: <http://vaww.ethics.va.gov/>

internet: <http://www.ethics.va.gov/>

Sender:	Sharpe, Virginia A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=082E348B444D4565AA069F3C7B50A090-SHARPE, VIR <(b6) [REDACTED]@va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED]@va.gov>; Tompkins, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54deee370ede4cceb82d26d8f7f62ed-Tompkins, P <(b6) [REDACTED]@va.gov>
Sent Date:	2019/03/08 14:27:30
Delivered Date:	2019/03/08 14:27:00

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Sharpe, Virginia A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=082e348b444d4565aa069f3c7b50a090-Sharpe, Vir <(b6) va.gov>
CC:	Tompkins, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54deee370ede4ccebf82d26d8f7f62ed-Tompkins, P <(b6) va.gov>
Subject:	RE: starting process of possible iMed Consent for intranasal esketamine
Date:	2019/03/08 17:01:00
Priority:	Normal
Type:	Note

I would agree with Ilse's comments. Per the ketamine protocol, patients also cant drive themselves home (similar to other procedures with anesthesia). Would the same requirement apply to this formulation? I think it would, and that is an additional reason for a consent form.

From: Wiechers, Ilse
Sent: Friday, March 8, 2019 3:49 PM
To: Sharpe, Virginia A. <(b6) va.gov>
Cc: Tompkins, Paul A. <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: RE: starting process of possible iMed Consent for intranasal esketamine

Thanks so much. I'll start working on this in collaboration with Maria and others in OMHSP and PBM. I need to think a bit more myself (and with input from others) about whether Spravato meets the standards you sent for requiring signature on consent. My initial thoughts are yes, given FDA felt the risk of adverse events were significant enough to warrant a REMS process.

Best,
Ilse

From: Sharpe, Virginia A.
Sent: Friday, March 08, 2019 11:48 AM
To: Wiechers, Ilse <Ilse.Wiechers@va.gov>
Cc: Tompkins, Paul A. <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: RE: starting process of possible iMed Consent for intranasal esketamine

Hi Ilse – Coincidentally, I just emailed about this to Dr. Llorente! Please see the attached for information on next steps regarding consent form development. I'm not sure what the potential is for abuse and misuse of Spravato if it will only be available in a medically supervised healthcare setting that provides patient monitoring, but we'd welcome the opportunity to ensure that VA develops patient education that focuses on safe use. We have a model for this in our [education about long-term opioids for pain](#). From an ethics perspective, we strongly discourage the use of patient contracts (which

are unenforceable and adversarial) in favor of a therapeutic approach in line with consent for other high risk treatments. We're happy to assist.
I'm including Paul Tompkins in my office for awareness. He is the national program manager for iMedConsent.
Ashby

+++++

Virginia Ashby Sharpe, Ph.D.
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fax: 202-632-8456
(b6)@va.gov
intranet: <http://vaww.ethics.va.gov/>
internet: <http://www.ethics.va.gov/>

From: Wiechers, Ilse
Sent: Friday, March 08, 2019 1:52 PM
To: Sharpe, Virginia A. <(b6)@va.gov>
Subject: starting process of possible iMed Consent for intranasal esketamine

Hello Dr. Sharpe -

I am working as lead for the Office of Mental Health and Suicide Prevention (10NC5) in collaboration with PBM to prepare for use in VHA of the newly FDA-approved intranasal esketamine (Spravato). As part of FDA approval, there will be a Spravato REMS program, to mitigate risks associated with serious adverse outcomes resulting from sedation and sedation caused by Spravato, and abuse and misuse of Spravato.

I am hoping you can direct me to the person(s) within the National Center for Ethics in Health Care who could best assist me in determining if an iMed consent will be needed for this new medication, and who can help assist me in drafting necessary documents for that informed consent.

Thanks for your assistance.

Best,
Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)
Co-Director, Care for Patients with Complex Problems (CP)²
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6) [REDACTED]
email: (b6) [REDACTED]@va.gov | (b6) [REDACTED]@yale.edu

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[FAQs](#)

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED]@va.gov>; Sharpe, Virginia A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=082e348b444d4565aa069f3c7b50a090-Sharpe, Vir <(b6) [REDACTED]@va.gov>; Tompkins, Paul A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54deee370ede4ccebf82d26d8f7f62ed-Tompkins, P <(b6) [REDACTED]@va.gov>
Sent Date:	2019/03/08 17:01:53
Delivered Date:	2019/03/08 17:01:00

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) va.gov>
Subject:	RE: Sprvato update....
Date:	2019/03/14 14:24:00
Priority:	Normal
Type:	Note

Hi Jenn,

Could you please review the Draft 10N memo Ise put together? I made suggested edits.

Thank you,

Tom

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 2:09 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Streit, Phillip P <(b6) va.gov>
Subject: RE: Sprvato update....

Lynn is working today—Would she be able to answer the question about (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] and I agree with you Jenn on pulling in Rob.

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, March 14, 2019 2:03 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Streit, Phillip P <(b6) va.gov>
Subject: RE: Sprvato update....

In talking with Mike, we need to work out the (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]s....we may need to pull in Rob on that piece once he's back from travel Monday.

Thoughts?

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 12:58 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>; Streit, Phillip P <(b6) [REDACTED] va.gov>
Subject: FW: Sprvato update....

Here is what Ilse sent this morning for her draft 10N memo.

I am good with the ordering document as it is written....

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, March 14, 2019 1:23 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Cc: Streit, Phillip P <(b6) [REDACTED] va.gov>
Subject: FW: Sprvato update....

Hi Tom,
Please see draft that Phillip and I have collectively worked on. Let us know if you have any suggestions or edits.
Thanks,
JZ

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96B44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED] va.gov>; Streit, Phillip P /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=acfac72743604e3b8e80a555ebba45df-Streit, Phi <(b6) [REDACTED] va.gov>
Sent Date:	2019/03/14 14:24:13
Delivered Date:	2019/03/14 14:24:00
Message Flags:	Unsent

(b5)

(b5)

(b5)

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/24 13:35:00
Priority:	Normal
Type:	Note

Hi Ilse,

My apologies for not including you on my draft response (I thought you might be on your way back east... (b6))

I'm happy to modify it to include your statement.....just let me know...

Mike

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b) (5)

[REDACTED]

[REDACTED]

2. How will the VA monitor its use nationwide?

(b) (5)

[REDACTED]

From: Wiechers, Ilse

Sent: Monday, June 24, 2019 1:23 PM

To: Valentino, Michael (VACO) <(b6) va.gov>; Snyder, Jill <(b6) va.gov>; Sandifer, Estella (Maria) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

Here is draft language for #2, for PBM consideration and edits.

Ilse

(b) (5)

From: Valentino, Michael (VACO)

Sent: Monday, June 24, 2019 7:54 AM

To: Snyder, Jill <(b6) va.gov>; Sandifer, Estella (Maria) <(b6) @va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Wiechers, Ilse <(b6) @va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

Adding Jenn for cost info

Sent with BlackBerry Work

(www.blackberry.com)

From: Snyder, Jill <(b6) va.gov>

Date: Monday, Jun 24, 2019, 10:52 AM

To: Sandifer, Estella (Maria) <(b6) va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Wiechers, Ilse <(b6) @va.gov>, VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

We have a call into the reporter to check on extension, but we did send her the statement so hopefully that gets us the extra time!

Thanks,

Jill

From: Sandifer, Estella (Maria)

Sent: Monday, June 24, 2019 10:45 AM

To: Snyder, Jill <(b6) va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Valentino, Michael (VACO)

<(b6) [REDACTED]@va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>; VHA 10P Actions
<VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

Good morning Jill,

Please note that PBM leadership is in a meeting now and will be tied up until 11:30. Please advise if we are able to get an extension to 2 p.m.

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6) [REDACTED]

Cell: (b6) [REDACTED]

Email: (b6) [REDACTED]@va.gov

From: Snyder, Jill

Sent: Monday, June 24, 2019 10:29 AM

To: VHA 10P Actions <VHA10PActions@va.gov>; Valentino, Michael (VACO)

<(b6) [REDACTED]@va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: Spravato/esketamine approval

Good morning,

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Thanks,
Jill

From: (b6) (b6) @connectingvets.com
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

|

2. How will the VA monitor its use nationwide?

(b6)
Reporter
Connecting Vets
C (b6)
(b6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +1 (b6)
entercom.com

Sender: Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Sent Date:	2019/06/24 13:35:14
Delivered Date:	2019/06/24 13:35:00
From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RF: Spravato/esketamine approval
Date:	2019/06/24 12:09:00
Priority:	Normal
Type:	Note

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b) (5)

[REDACTED]

2. How will the VA monitor its use nationwide?

(b) (5)

[REDACTED]

(b) (5)

[REDACTED]

Mike

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:35 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PAActions@va.gov>
Subject: FW: Spravato/esketamine approval

10P4,

Please see the entire email and provide a response no later than 11:30 a.m., today.

Request:

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6)

Cell: (b6)

Email: (b6)@va.gov

From: Snyder, Jill

Sent: Monday, June 24, 2019 10:29 AM

To: VHA 10P Actions <VHA10PACTIONS@va.gov>; Valentino, Michael (VACO)
<Michael.Valentino@va.gov>; Wiechers, Ilse (b6)@va.gov

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: Spravato/esketamine approval

Good morning,

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Thanks,
Jill

From: (b6) <[REDACTED]@connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

2. How will the VA monitor its use nationwide?

(b6)
Reporter
Connecting Vets
C (b6)
(b6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: (b6)(b6)
entercom.com

Sender: Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>

Recipient:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/24 12:09:20
Delivered Date:	2019/06/24 12:09:00

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Sandifer, Estella (Maria) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a38d9112ad904c5a84ffc6c931693af7-Sandifer, E <(b6)@va.gov>; Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jill <(b6)@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>
CC:	VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/24 14:44:00
Priority:	Normal
Type:	Note

It is accurate but in my opinion (b6)

(b) (5)

See attached.

Mike

From: Wiechers, Ilse
Sent: Monday, June 24, 2019 2:40 PM
To: Sandifer, Estella (Maria) (b6)@va.gov; Snyder, Jill (b6)@va.gov; Valentino, Michael (VACO) (b6)@va.gov; VHA 10P Actions <VHA10PAActions@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: Spravato/esketamine approval

The below statements are accurate per my review.
Ilse

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 11:36 AM
To: Snyder, Jill (b6)@va.gov; Valentino, Michael (VACO) (b6)@va.gov;

Wiechers, Ilse (b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions
<VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: Spravato/esketamine approval

Adding 10P4

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6) [REDACTED]

Cell: (b6) [REDACTED]

Email: (b6) [REDACTED]@va.gov

From: Snyder, Jill

Sent: Monday, June 24, 2019 2:33 PM

To: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>;
VHA 10P Actions <VHA10PActions@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: Spravato/esketamine approval

Good afternoon –

Can you confirm the below is accurate?

Thanks,
Jill

From: Cashour, Curtis

Sent: Monday, June 24, 2019 2:25 PM

To: Snyder, Jill <(b6) [REDACTED]@va.gov>; Mojay, Ndidi <(b6) [REDACTED]@va.gov>; Carter, Susan
<(b6) [REDACTED]@va.gov>

Cc: Noller, Randal <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: Spravato/esketamine approval

So is this accurate?

Q: What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

A: (b) (5)
[REDACTED]

Q: How will the VA monitor its use nationwide?

A: (b) (5)

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Snyder, Jill
Sent: Monday, June 24, 2019 2:21 PM
To: Cashour, Curtis <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: Spravato/esketamine approval

Per the below it says (b) (5)

From: Cashour, Curtis
Sent: Monday, June 24, 2019 2:19 PM
To: Mojay, Ndidi <(b6) va.gov>; Snyder, Jill <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: Spravato/esketamine approval

How many packages does a veteran need for treatment?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 2:02 PM
To: Snyder, Jill <(b6) va.gov>; Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>

Cc: Noller, Randal <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: Spravato/esketamine approval

Curt are you ok with VHA's concurrence below?

In the interest of time, I've shared last week's statement.

VA still owes her the answers to these questions.

Ndidi

From: Snyder, Jill

Sent: Monday, June 24, 2019 12:40 PM

To: Mojay, Ndidi <(b6) [REDACTED] va.gov>; Cashour, Curtis <(b6) [REDACTED] va.gov>; Carter, Susan <(b6) [REDACTED] va.gov>

Cc: Noller, Randal <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: Spravato/esketamine approval

Hi Ndidi –

VHA response to the two questions below:

Response:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b) (5) [REDACTED]

[REDACTED]

[REDACTED]

2. How will the VA monitor its use nationwide?

(b) (5) [REDACTED]

[REDACTED]

Thanks,
Jill

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 10:58 AM
To: Snyder, Jill <(b6) va.gov>; Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Jill,

I tried to call the reporter's cell phone, but to no avail. I sent her the statement for now.

Please let us know when you get those responses from the program area.

Ndidi

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 10:46 AM
To: Snyder, Jill <(b6) va.gov>; Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

I will ask her

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:46 AM
To: Cashour, Curtis <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Will do – just heard back from program office and they are in a meeting until noon – can we have extension on the two questions until 3pm?

From: Cashour, Curtis
Sent: Monday, June 24, 2019 10:44 AM
To: Snyder, Jill <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Please have them answer those questions as well.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)

(b6) [REDACTED] va.gov
@curtcashour

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:44 AM
To: Cashour, Curtis <(b6) [REDACTED] va.gov>; Mojay, Ndidi <(b6) [REDACTED] va.gov>; Carter, Susan <(b6) [REDACTED] va.gov>
Cc: Noller, Randal <(b6) [REDACTED] va.gov>
Subject: RE: Spravato/esketamine approval

I will have the program office stand down on responding to the two additional questions. Thanks!

From: Cashour, Curtis
Sent: Monday, June 24, 2019 10:43 AM
To: Mojay, Ndidi <(b6) [REDACTED] va.gov>; Snyder, Jill <(b6) [REDACTED] va.gov>; Carter, Susan <(b6) [REDACTED] va.gov>
Cc: Noller, Randal <(b6) [REDACTED] va.gov>
Subject: RE: Spravato/esketamine approval

Just send her the approved statement.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6) [REDACTED]
(b6) [REDACTED] va.gov
@curtcashour

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 10:32 AM
To: Snyder, Jill <(b6) [REDACTED] va.gov>; Cashour, Curtis <(b6) [REDACTED] va.gov>; Carter, Susan <(b6) [REDACTED] va.gov>
Cc: Noller, Randal <(b6) [REDACTED] va.gov>
Subject: RE: Spravato/esketamine approval

Curt, I looked thru my queries last week and I didn't send her the statement last week.

Is Jill's approach below sufficient with you for response to her inquiry?

Ndidi

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:26 AM
To: Mojay, Ndidi <(b6) [REDACTED] va.gov>; Cashour, Curtis <(b6) [REDACTED] va.gov>; Carter, Susan <(b6) [REDACTED] va.gov>
Cc: Noller, Randal <(b6) [REDACTED] va.gov>
Subject: RE: Spravato/esketamine approval

I will request noon – I assume we will use the statement that was cleared last week, and I will follow-up on the two questions.

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 10:25 AM
To: Snyder, Jill <(b6) va.gov>; Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

She said ASAP below. Can we try for Noon?

Ndidi

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:24 AM
To: Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Thanks, I have this for VHA. Do we have a deadline?

Thanks,
Jill

From: Cashour, Curtis
Sent: Monday, June 24, 2019 10:23 AM
To: Carter, Susan <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Snyder, Jill <Jill.Snyder@va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

That's fine. Just run the answers by me prior to release.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Carter, Susan
Sent: Monday, June 24, 2019 10:22 AM

To: Cashour, Curtis <(b6) [REDACTED] va.gov>; Mojay, Ndidi <(b6) [REDACTED] va.gov>; Snyder, Jill
(b6) [REDACTED] va.gov>
Cc: Noller, Randal <(b6) [REDACTED] va.gov>
Subject: FW: Spravato/esketamine approval

Curt – I have asked Ndidi to follow up with VHA to answer the two questions. Are you fine with that?

Regards,

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b6) [REDACTED] va.gov
Desk: (b6) [REDACTED]
Cell: (b6) [REDACTED]



cid:image002.jpg@01D3D61E.49531160

From: (b6) [REDACTED] @connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?
2. How will the VA monitor its use nationwide?

(b6) [REDACTED]
Reporter
Connecting Vets
C (b6) [REDACTED]
(b6) [REDACTED]

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +(b)(6)
entercom.com

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b)(6)@va.gov>; Sandifer, Estella (Maria) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a38d9112ad904c5a84ffc6c931693af7-Sandifer, E <(b)(6)@va.gov>; Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jill <(b)(6)@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/06/24 14:44:25
Delivered Date:	2019/06/24 14:44:00
From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/24 12:09:00
Priority:	Normal
Type:	Note

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b) (5)

2. How will the VA monitor its use nationwide?

(b) (5)

Mike

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:35 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PAActions@va.gov>
Subject: FW: Spravato/esketamine approval

10P4,

Please see the entire email and provide a response no later than 11:30 a.m., today.

Request:

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6)

Cell: (b6)

Email: (b6)@va.gov

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:29 AM
To: VHA 10P Actions <VHA10PAActions@va.gov>; Valentino, Michael (VACO) (b6)@va.gov>; Wiechers, Ilse (b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: Spravato/esketamine approval

Good morning,

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Thanks,
Jill

From: (b6) [REDACTED]@connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

2. How will the VA monitor its use nationwide?

(b6)
Reporter
Connecting Vets
C (b6)
(b6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +1 (b6)
entercom.com

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/24 12:09:20
Delivered Date:	2019/06/24 12:09:00

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/25 10:25:00
Priority:	Normal
Type:	Note

Nope.....we're good.

Cheryl sent it to me.

(b6)

From: Zacher, Jennifer L. (PBM)
Sent: Tuesday, June 25, 2019 10:21 AM
To: Valentino, Michael (VACO) <(b6)@va.gov>
Subject: RE: Spravato/esketamine approval

Sorry – I was out yesterday, and I have been having IT issues all morning.....does this still need a respond, or did someone from my office assist?

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 9:54 AM
To: Snyder, Jill <(b6)@va.gov>; Sandifer, Estella (Maria) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Wiechers, Ilse <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: Spravato/esketamine approval

Adding Jenn for cost info

Sent with BlackBerry Work
www.blackberry.com

From: Snyder, Jill <(b6)@va.gov>
Date: Monday, Jun 24, 2019, 10:52 AM
To: Sandifer, Estella (Maria) <(b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>, Valentino, Michael (VACO) <(b6)@va.gov>, Wiechers, Ilse <(b6)@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

We have a call into the reporter to check on extension, but we did send her the statement so hopefully that gets us the extra time!

Thanks,
Jill

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:45 AM
To: Snyder, Jill <(b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: Spravato/esketamine approval

Good morning Jill,

Please note that PBM leadership is in a meeting now and will be tied up until 11:30. Please advise if we are able to get an extension to 2 p.m.

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b6)
Cell: (b6)
Email: (b6)@va.gov

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:29 AM
To: VHA 10P Actions <VHA10PActions@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: Spravato/esketamine approval

Good morning,

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

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VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Thanks,
Jill

From: (b6) <(b6)@connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

|

2. How will the VA monitor its use nationwide?

(b6)

Reporter
Connecting Vets
C (b6)
(b6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +1 (b6)
entercom.com

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Sent Date:	2019/06/25 10:25:41
Delivered Date:	2019/06/25 10:25:00

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6)@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/24 13:38:12
Priority:	Normal
Type:	Note

No need to incorporate mine, yours says the same thing to my read.

(b6)

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 10:35 AM
To: Wiechers, Ilse (b6)@va.gov>; Zacher, Jennifer L. (PBM) (b6)@va.gov>
Subject: RE: Spravato/esketamine approval

Hi Ilse,

My apologies for not including you on my draft response (I thought you might be on your way back east. (b6))

I'm happy to modify it to include your statement.....just let me know...

Mike

I. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b) (5)

2. How will the VA monitor its use nationwide?

(b) (5)

From: Wiechers, Ilse

Sent: Monday, June 24, 2019 1:23 PM

To: Valentino, Michael (VACO) <(b6)@va.gov>; Snyder, Jill <(b6)@va.gov>; Sandifer, Estella (Maria) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

Here is draft language for #2, for PBM consideration and edits.

Ilse

(b) (5)

From: Valentino, Michael (VACO)

Sent: Monday, June 24, 2019 7:54 AM

To: Snyder, Jill <(b6)@va.gov>; Sandifer, Estella (Maria) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Wiechers, Ilse <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

Adding Jenn for cost info

Sent with BlackBerry Work

(www.blackberry.com)

From: Snyder, Jill <(b6)@va.gov>

Date: Monday, Jun 24, 2019, 10:52 AM

To: Sandifer, Estella (Maria) <(b6)@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>, Valentino, Michael (VACO) <(b6)@va.gov>, Wiechers, Ilse <(b6)@va.gov>, VHA 10P Actions <VHA10PActions@va.gov>

Subject: RE: Spravato/esketamine approval

We have a call into the reporter to check on extension, but we did send her the statement so hopefully that gets us the extra time!

Thanks,
Jill

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:45 AM
To: Snyder, Jill <(b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: RE: Spravato/esketamine approval

Good morning Jill,

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V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b6)
Cell: (b6)
Email: (b6)@va.gov

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:29 AM
To: VHA 10P Actions <VHA10PActions@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: Spravato/esketamine approval

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Thanks,
Jill

From: (b6) (b6) @connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

|

2. How will the VA monitor its use nationwide?

(b6)
Reporter
Connecting Vets

C (b6)
(b6)

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1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +1 (b6)
entercom.com

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/06/24 13:38:11
Delivered Date:	2019/06/24 13:38:12

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jill <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Sandifer, Estella (Maria) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a38d9112ad904c5a84ffc6c931693af7-Sandifer, E <(b6)@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>
CC:	VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/24 14:54:00
Priority:	Normal
Type:	Note

Makes no difference to me.....I am OK either way...I just wanted folks to be aware we provided a more detailed response.

Mike

From: Snyder, Jill
Sent: Monday, June 24, 2019 2:47 PM
To: Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse (b6)@va.gov>; Sandifer, Estella (Maria) (b6)@va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: Spravato/esketamine approval

I submitted the response with the costs included, OPIA removed the actual costs. I am happy to push back if you like.

From: Valentino, Michael (VACO)
Sent: Monday, June 24, 2019 2:44 PM
To: Wiechers, Ilse (b6)@va.gov>; Sandifer, Estella (Maria) (b6)@va.gov>; Snyder, Jill (b6)@va.gov>; VHA 10P Actions <VHA10PAActions@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions

<VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>

Subject: RE: Spravato/esketamine approval

It is accurate but in my opinion, incomplete.

The cost of the product which I submitted was omitted from the response.

See attached.

Mike

From: Wiechers, Ilse

Sent: Monday, June 24, 2019 2:40 PM

To: Sandifer, Estella (Maria) <(b6)@va.gov>; Snyder, Jill <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>

Subject: RE: Spravato/esketamine approval

The below statements are accurate per my review.

Ilse

From: Sandifer, Estella (Maria)

Sent: Monday, June 24, 2019 11:36 AM

To: Snyder, Jill <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>

Subject: RE: Spravato/esketamine approval

Adding 10P4

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6)

Cell: (b6)

Email: (b6)@va.gov

From: Snyder, Jill

Sent: Monday, June 24, 2019 2:33 PM

To: Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: Spravato/esketamine approval

Good afternoon –

Can you confirm the below is accurate?

Thanks,
Jill

From: Cashour, Curtis

Sent: Monday, June 24, 2019 2:25 PM

To: Snyder, Jill <(b6)@va.gov>; Mojay, Ndidi <(b6)@va.gov>; Carter, Susan

<(b6)@va.gov>

Cc: Noller, Randal <(b6)@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: Spravato/esketamine approval

So is this accurate?

Q: What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

A: (b) (5)

Q: How will the VA monitor its use nationwide?

A: (b) (5)

Curt Cashour
Press Secretary
Department of Veterans Affairs

(b6)
(b6)@va.gov
@curtcashour

From: Snyder, Jill

Sent: Monday, June 24, 2019 2:21 PM

To: Cashour, Curtis <(b6)@va.gov>; Mojay, Ndidi <(b6)@va.gov>; Carter, Susan

<(b6)@va.gov>

Cc: Noller, Randal <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: Spravato/esketamine approval

Per the below it says (b) (5)

From: Cashour, Curtis
Sent: Monday, June 24, 2019 2:19 PM
To: Mojay, Ndidi <(b6) [REDACTED]@va.gov>; Snyder, Jill <(b6) [REDACTED]@va.gov>; Carter, Susan <(b6) [REDACTED]@va.gov>
Cc: Noller, Randal <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: Spravato/esketamine approval

How many packages does a veteran need for treatment?

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6) [REDACTED]
(b6) [REDACTED]@va.gov
@curtcashour

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 2:02 PM
To: Snyder, Jill <(b6) [REDACTED]@va.gov>; Cashour, Curtis <(b6) [REDACTED]@va.gov>; Carter, Susan <(b6) [REDACTED]@va.gov>
Cc: Noller, Randal <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: Spravato/esketamine approval

Curt are you ok with VHA's concurrence below?

In the interest of time, I've shared last week's statement.

VA still owes her the answers to these questions.

Ndidi

From: Snyder, Jill
Sent: Monday, June 24, 2019 12:40 PM
To: Mojay, Ndidi <(b6) [REDACTED]@va.gov>; Cashour, Curtis <(b6) [REDACTED]@va.gov>; Carter, Susan <(b6) [REDACTED]@va.gov>
Cc: Noller, Randal <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: Spravato/esketamine approval

Hi Ndidi –

VHA response to the two questions below:

Response:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b) (5)

[REDACTED]

[REDACTED]

2. How will the VA monitor its use nationwide?

(b) (5)

[REDACTED]

[REDACTED]

Thanks,
Jill

From: Mojay, Ndidi

Sent: Monday, June 24, 2019 10:58 AM

To: Snyder, Jill <(b6) [REDACTED]@va.gov>; Cashour, Curtis <(b6) [REDACTED]@va.gov>; Carter, Susan <(b6) [REDACTED]@va.gov>

Cc: Noller, Randal <(b6) [REDACTED]@va.gov>

Subject: RE: Spravato/esketamine approval

Jill,

I tried to call the reporter's cell phone, but to no avail. I sent her the statement for now.

Please let us know when you get those responses from the program area.

Ndidi

From: Mojay, Ndidi

Sent: Monday, June 24, 2019 10:46 AM

To: Snyder, Jill <(b6) [REDACTED]@va.gov>; Cashour, Curtis <(b6) [REDACTED]@va.gov>; Carter, Susan <(b6) [REDACTED]@va.gov>

Cc: Noller, Randal <(b6) [REDACTED]@va.gov>

Subject: RE: Spravato/esketamine approval

I will ask her

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:46 AM
To: Cashour, Curtis <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Will do – just heard back from program office and they are in a meeting until noon – can we have extension on the two questions until 3pm?

From: Cashour, Curtis
Sent: Monday, June 24, 2019 10:44 AM
To: Snyder, Jill <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Please have them answer those questions as well.

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:44 AM
To: Cashour, Curtis <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

I will have the program office stand down on responding to the two additional questions. Thanks!

From: Cashour, Curtis
Sent: Monday, June 24, 2019 10:43 AM
To: Mojay, Ndidi <(b6) va.gov>; Snyder, Jill <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Just send her the approved statement.

Curt Cashour

Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 10:32 AM
To: Snyder, Jill <(b6) va.gov>; Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Curt, I looked thru my queries last week and I didn't send her the statement last week.

Is Jill's approach below sufficient with you for response to her inquiry?

Ndidi

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:26 AM
To: Mojay, Ndidi <(b6) va.gov>; Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

I will request noon – I assume we will use the statement that was cleared last week, and I will follow-up on the two questions.

From: Mojay, Ndidi
Sent: Monday, June 24, 2019 10:25 AM
To: Snyder, Jill <(b6) va.gov>; Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

She said ASAP below. Can we try for Noon?

Ndidi

From: Snyder, Jill
Sent: Monday, June 24, 2019 10:24 AM
To: Cashour, Curtis <(b6) va.gov>; Carter, Susan <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

Thanks, I have this for VHA. Do we have a deadline?

Thanks,
Jill

From: Cashour, Curtis
Sent: Monday, June 24, 2019 10:23 AM
To: Carter, Susan <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Snyder, Jill <(b6) @va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: RE: Spravato/esketamine approval

That's fine. Just run the answers by me prior to release.

Thanks,

Curt Cashour
Press Secretary
Department of Veterans Affairs
(b6)
(b6) va.gov
@curtcashour

From: Carter, Susan
Sent: Monday, June 24, 2019 10:22 AM
To: Cashour, Curtis <(b6) va.gov>; Mojay, Ndidi <(b6) va.gov>; Snyder, Jill <(b6) @va.gov>
Cc: Noller, Randal <(b6) va.gov>
Subject: FW: Spravato/esketamine approval

Curt – I have asked Ndidi to follow up with VHA to answer the two questions. Are you fine with that?

Regards,

Susan Carter
Director, Office of Media Relations
U.S. Department of Veterans Affairs
(b6) va.gov
Desk: (b6) (b6)
Cell: (b6)



cid:image002.jpg@01D3D61E.49531160

From: (b6) (b6) @connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM

To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?
2. How will the VA monitor its use nationwide?

(b6)
Reporter
Connecting Vets
C (b6)
(b6)

Entercom | Washington D.C.
1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +1 (b6)
entercom.com

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Snyder, Jill /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6e91ef72ee4a05acc63873c64570e1-Snyder, Jill <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Sandifer, Estella (Maria) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a38d9112ad904c5a84ffc6c931693af7-Sandifer, E <(b6)@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>;

	VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/06/24 14:54:41
Delivered Date:	2019/06/24 14:54:00

To:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Subject:	RE: Spravato/esketamine approval
Date:	2019/06/24 12:05:20
Priority:	Normal
Type:	Note

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

(b) (5)

[REDACTED]

2. How will the VA monitor its use nationwide?

(b) (5)

[REDACTED]

From: Sandifer, Estella (Maria)
Sent: Monday, June 24, 2019 10:35 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PAActions@va.gov>
Subject: FW: Spravato/esketamine approval

10P4,

Please see the entire email and provide a response no later than 11:30 a.m., today.

Request:

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6)

Cell: (b6)

Email: (b6)@va.gov

From: Snyder, Jill

Sent: Monday, June 24, 2019 10:29 AM

To: VHA 10P Actions <VHA10PActions@va.gov>; Valentino, Michael (VACO)
<(b6)@va.gov>; Wiechers, Ilse (b6)@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: Spravato/esketamine approval

Good morning,

We have received additional questions on Spravato/esketamine. Is it possible to receive responses by noon?

There are two new questions highlighted below. For everyone awareness I am copying the statement that was cleared last week.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to "prior authorization" formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA's commitment to seek new ways to provide the best health care available for our nation's Veterans.

Thanks,
Jill

From: (b6) (b6) @connectingvets.com>
Sent: Monday, June 24, 2019 9:09 AM
To: VA Public Affairs <VAPublicAffairs@va.gov>
Subject: [EXTERNAL] Spravato/esketamine approval

Could I please get a statement ASAP on the VA's decision to approve Spravato/esketamine for use in VA medical centers ASAP?

I would also like the following information:

1. What is the estimated cost to the VA for Spravato/esketamine prescription per veteran?

|

2. How will the VA monitor its use nationwide?

(b6)
Reporter
Connecting Vets
C (b6)
(b6)

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1015 Half Street, S.E., Suite 200
Washington, D.C. 20003
M: +1 (b6)
entercom.com

Recipient:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/06/24 11:44:44
Delivered Date:	2019/06/24 12:05:20
Message Flags:	Unread Unsent

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) [REDACTED] va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>
Subject:	RE: Spravato Updates
Date:	2019/03/08 15:50:08
Priority:	Normal
Type:	Note

(b) (5)

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 2:18 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
Subject: Re: Spravato Updates

Very Awesome!

(b) (5)

From: Jennifer Zacher <(b6) [REDACTED] va.gov>
Date: Friday, March 8, 2019 at 3:14 PM
To: Michael Valentino <(b6) [REDACTED] va.gov>, Thomas Emmendorfer <(b6) [REDACTED] va.gov>
Subject: RE: Spravato Updates

Product has been added to FSS with effective date of tomorrow.

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:32 AM
To: Valentino, Michael (VACO) (SES EQV) <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Subject: Spravato Updates

Hi,
I am making good progress....

1. • Got provisional FCP approved and entered. (b) (5)
2. • J&J will provide all educational materials to me by no later than next Friday so that they can be reviewed prior to launch.
3. • PBM is working on getting guidelines for enrolling in the REMS program. The REMS site doesn't even open until Tuesday, but the company will get back to me today on when they will be open to accepted enrollment of healthcare centers and pharmacies through the REMS.
4. • (b) (5)
5. • I will do my best to get the review completed in May....June at the latest.

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6) @va.gov

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6)@va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
Sent Date:	2019/03/08 15:50:07
Delivered Date:	2019/03/08 15:50:08
Message Flags:	Unread

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED] va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>
Subject:	Re: Spravato Updates
Date:	2019/03/08 12:48:40
Priority:	Normal
Type:	Note

Jenn-

The below update is amazing work!

Here is my first draft of the internal communication. At morning report, I heard they thought a FAQ style document would be appropriate (assuming for the internal communication).

Could you take next crack at this and then send this over to Isle on the other e-mail string for her review and edits? Also, could you ask Isle to add questions related to imed consent and privileging—maybe insert a place holder in the document for her....

External Customer Communication Draft--

Could you ask Matt to take a first crack at the document to send to us for review? The info we prepared for Dr. Stone may be helpful along with that is already on VA contract (for when the drug is actually commercially available ☺)

Thank you!

Tom

From: Jennifer Zacher <(b6) [REDACTED] va.gov>
Date: Friday, March 8, 2019 at 12:32 PM
To: Michael Valentino <(b6) [REDACTED] va.gov>, Thomas Emmendorfer <(b6) [REDACTED] va.gov>
Subject: Spravato Updates

Hi,
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Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6) @va.gov

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6)@va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
Sent Date:	2019/03/08 12:48:39
Delivered Date:	2019/03/08 12:48:40

(b) (5)

(b) (5)

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED]@va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED]@va.gov>
CC:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>
Subject:	RE: Spravato Updates
Date:	2019/03/08 17:16:31
Priority:	Normal
Type:	Note

Will do

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Date: Friday, Mar 08, 2019, 4:53 PM
To: Llorente, Maria D. <(b6) [REDACTED]@va.gov>, Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Updates

Great work Jenn.....thanks much!
Tom, on Monday would you ask Kristy to set up a meeting with Dr. Stone on the date he mentioned this AM?
Thanks
Mike

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) [REDACTED]@va.gov>
Date: Friday, Mar 08, 2019, 1:18 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>, Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Updates

Outstanding!!!

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 8, 2019 1:07 PM
To: Llorente, Maria D. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: Spravato Updates

Excellent work Jenn!

From: Jennifer Zacher <(b6) va.gov>
Date: Friday, March 8, 2019 at 12:32 PM
To: Michael Valentino <(b6) va.gov>, Thomas Emmendorfer <(b6) va.gov>
Subject: Spravato Updates

Hi,
I am making good progress....

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5. • I will do my best to get the review completed in May....June at the latest.

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b6)
(b6) va.gov

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
Recipient:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen

<(b6) [REDACTED] va.gov>

Sent Date: 2019/03/08 17:16:31

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED] va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED] va.gov>
Subject:	Re: Spravato Updates
Date:	2019/03/08 15:06:51
Priority:	Normal
Type:	Note

Thank you Jenn! Just met with Dr. Boyd. Next e-mail coming shortly...

From: Jennifer Zacher <(b6) [REDACTED] va.gov>
Date: Friday, March 8, 2019 at 2:35 PM
To: Thomas Emmendorfer <(b6) [REDACTED] va.gov>, Michael Valentino <(b6) [REDACTED] va.gov>
Subject: RE: Spravato Updates

This looks great to me! I actually don't have any edits.
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 1:03 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
Subject: Re: Spravato Updates

Hi Jenn,

Attached is my first crack at an "External Communication" for Spravato for your review. I used a Hep C press release as a template.

After PBM and OMHO get a draft we concur on, I will ask Bill Outlaw to get this one moving thru the Communications pathway.....

Tom

From: Jennifer Zacher <(b6) [REDACTED] va.gov>
Date: Friday, March 8, 2019 at 12:32 PM
To: Michael Valentino <(b6) [REDACTED] va.gov>, Thomas Emmendorfer <(b6) [REDACTED] va.gov>
Subject: Spravato Updates

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[REDACTED]
[REDACTED]
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4. • (b) (5)
[REDACTED]
[REDACTED]
5. • I will do my best to get the review completed in May....June at the latest.

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6) [REDACTED]@va.gov

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED]@va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>
Sent Date:	2019/03/08 15:06:51

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) [REDACTED]@va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>
Subject:	RE: Spravato Update
Date:	2019/03/20 09:01:26
Priority:	Normal
Type:	Note

McKesson does have the drug in stock.

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 20, 2019 8:01 AM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>;
Subject: RE: Spravato Update

Thank you Jenn for the update! I will work on updating the slides today for the April 1, 2019 briefing to Dr. Stone and send to you guys as I am going to be OOF starting next Monday for 2 weeks.

Let me know if McKesson has received the drug from J&J so it is in the supply chain for VA medical facilities to order. My guess, is probably not…but that will be one of the items I will list on the slide…

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 8:56 AM
To: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>;
Subject: Spravato Update

Good Morning,

I had a call with J&J yesterday. Here are the updates that I got:

1. • REMS program: Only the Health Care facility can be enrolled on-line through the REMS portal. The pharmacies and the patients can only be enrolled via faxing the applicable forms to the REMS. They don't anticipate that this part of the web portal will be functional for at least several months.
2. • On that “Know Your Customer” form that Mark Slagle sent…they claim that this is something required by the DEA and that generally distributors and wholesalers send the form to the facilities after they are certified in order to meet DEA regulations. (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

3. • The said that the plan is to send daily updates of newly certified facilities to McKesson, (b) (5) [REDACTED]. Because this is a REMS product, it isn't visible in the McKesson Connect catalog until a site has been certified. We will need to state this in our guidance too;
4. • Donation request; if you recall, we asked them to consider donating some product. (b6) [REDACTED], but they did pitch something along the lines (b) (5) [REDACTED]
5. • I did give them PBM approval for their initial marketing piece. They claim that they have a “veteran” centric piece that has been “in development” for over a year… (b6) [REDACTED] I told them that whenever they completed it, I would have it reviewed.

JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6) [REDACTED]

(b6) [REDACTED]@va.gov

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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>
Sent Date:	2019/03/20 09:01:25
Delivered Date:	2019/03/20 09:01:26

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED] va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED] va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED] va.gov>
Subject:	RE: Spravato update
Date:	2019/03/14 15:25:23
Priority:	Normal
Type:	Note

Hi Ilse,

A few edits for your consideration.

Tom

From: Wiechers, Ilse
Sent: Thursday, March 14, 2019 10:25 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>; Llorente, Maria D. <(b6) [REDACTED] va.gov>
Subject: RE: Spravato update

Good morning!

Here is the draft memo for Spravato. Please take a look and let me know what you think. The main
 (b) (5) [REDACTED]

Working on the informed consent language today.

Ilse

From: Wiechers, Ilse
Sent: Wednesday, March 13, 2019 12:32 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>; Llorente, Maria D. <(b6) [REDACTED] va.gov>
Subject: Spravato update

Tom & Maria –

I just sent the draft 10N memo to 10NC5 Action and to our SMEs for review and input. I've asked for feedback by tomorrow 10 AM, so I should have you a document to review by midday ET.

As a heads up, the pieces are coming together in my head right now as I've laid out in the notes below. I think this will be memo #1 of 2, with a second memo and further instruction to follow in ~ 2 weeks time. I'm awaiting input from OMHSP leadership to see what they think about how I've outlined things below (and in the memo draft), but wanted to keep you in the loop on my thought process.

Turning to informed consent this afternoon, more on that to follow.

Ilse

I see this as a 2 part plan: 1) communication with the field and 2) establishing OMHSP monitoring/oversight of the field.

Re communication with the field, I think we need to do the following:

1. (b) (5) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

So at the end of the day, I think this memo will be memo #1 focused on information and certification with REMS, and going out first of next week. I anticipate memo #2 re training and clinical processes, aiming to go out ~ 2 weeks from now if all goes well.

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)

email (b6) va.gov | (b6) yale.edu

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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) va.gov>
Sent Date:	2019/03/14 15:25:21
Delivered Date:	2019/03/14 15:25:23

(b) (5)

(b) (5)

(b) (5)

From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: Spravato update
Date:	2019/03/13 17:05:00
Priority:	Normal
Type:	Note

Thank you very much for the quick processing of this.

From: Wiechers, Ilse
Sent: Wednesday, March 13, 2019 3:32 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Subject: Spravato update

Tom & Maria –

I just sent the draft 10N memo to 10NC5 Action and to our SMEs for review and input. I've asked for feedback by tomorrow 10 AM, so I should have you a document to review by midday ET.

As a heads up, the pieces are coming together in my head right now as I've laid out in the notes below. I think this will be memo #1 of 2, with a second memo and further instruction to follow in ~ 2 weeks time. I'm awaiting input from OMHSP leadership to see what they think about how I've outlined things below (and in the memo draft), but wanted to keep you in the loop on my thought process.

Turning to informed consent this afternoon, more on that to follow.

Ilse

I see this as a 2 part plan: 1) communication with the field and 2) establishing OMHSP monitoring/oversight of the field.

Re communication with the field, I think we need to do the following:

1. • Provide general information about Spravato and the Spravato REMS
2. • Instruct facilities to become certified Healthcare Settings and certified Pharmacies with REMS
3. • Provide guidance on clinical process and procedures for actually using Spravato (includes informed consent)
4. • Provide guidance on training for staff

The internal FAQ addresses #1. My draft memo addresses #1 & 2, and hints at 3 & 4.

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)
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Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
Sent Date:	2019/03/13 17:05:30
Delivered Date:	2019/03/13 17:05:00
Message Flags:	Unsent

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Spravato Update
Date:	2019/03/20 18:03:25
Priority:	Normal
Type:	Note

Thank you Jenn!

Sent with BlackBerry Work
(www.blackberry.com)

From: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Date: Wednesday, Mar 20, 2019, 5:41 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Spravato Update

This version has the dates updated
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 20, 2019 3:55 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Spravato Update

I updated the CMO slide set with actions completed and items still pending.

Jenn,

(b) (5)

(b) (5)

I can send this slide deck over to Isle to add to after we are done.

Tom

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 9:25 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Update

Yesterday

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 20, 2019 8:21 AM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Update

Thank you Jenn. (b) (5) [REDACTED].

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 9:01 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Update

(b) (5) [REDACTED]

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 20, 2019 8:01 AM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Update

Thank you Jenn for the update! I will work on updating the slides today for the April 1, 2019 briefing to Dr. Stone and send to you guys as I am going to be OOF starting next Monday for 2 weeks.

(b) (5) [REDACTED]
[REDACTED] ...

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 8:56 AM
To: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: Spravato Update

Good Morning,
I had a call with J&J yesterday. Here are the updates that I got:

(b) (5) [REDACTED]

Device Type	Percentage of Respondents
Smartphone	100%
Tablet	98%
Laptop	95%
Desktop Computer	92%
Smartwatch	88%
Smart TV	85%
Smart Speaker	82%
Smart Car	78%
Smart Home System	75%
Smart Lock	72%

[illegible]

_____.

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6) [REDACTED] va.gov

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED] va.gov>
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Sent Date:	2019/03/20 18:03:25

Message Flags: Unread

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To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: Spravato update
Date:	2019/03/14 11:33:45
Priority:	Normal
Type:	Note

Wow! That was an awesome question by Anthony 😊

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 11:27 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Spravato update

Wrong time on calendar...I don't know if the updated...but it was a weird start time 10:45 am eastern...(b6)

From: Valentino, Michael (VACO)
Sent: Thursday, March 14, 2019 11:26 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: Spravato update

(b6)

Did this start early or did I have the wrong time on my calendar?

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www.blackberry.com

From: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Date: Thursday, Mar 14, 2019, 10:24 AM
To: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Spravato update

I am on the call. Do you want me to go to the room?

(b6)

From: Valentino, Michael (VACO)
Sent: Thursday, March 14, 2019 11:05 AM

To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Subject: RE: Spravato update

(b6) [REDACTED]are you in the room? Did it start early? It was on my calendar for 11am. EST

Sent with BlackBerry Work
(www.blackberry.com)

From: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Date: Thursday, Mar 14, 2019, 9:50 AM
To: Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
Subject: RE: Spravato update

No problem.

From: Valentino, Michael (VACO)
Sent: Thursday, March 14, 2019 10:50 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Subject: RE: Spravato update

I'm not going to be able to review Tom

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From: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Date: Thursday, Mar 14, 2019, 9:27 AM
To: Wiechers, Ilse (b6) [REDACTED] @va.gov>, Llorente, Maria D. <(b6) [REDACTED] va.gov>, Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
Subject: RE: Spravato update

Thank you Ilse!

I have added Mike V. for his review as well.

Tom

From: Wiechers, Ilse
Sent: Thursday, March 14, 2019 10:25 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>; Llorente, Maria D. <(b6) [REDACTED] va.gov>
Subject: RE: Spravato update

Good morning!

?

Ilse

Tom & Maria –

As a heads up, the pieces are coming together in my head right now as I've laid out in the notes below. I think this will be memo #1 of 2, with a second memo and further instruction to follow in ~ 2 weeks time. I'm awaiting input from OMHSP leadership to see what they think about how I've outlined things below (and in the memo draft), but wanted to keep you in the loop on my thought process.

(b) (5) [REDACTED]

(b) (5) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6) [REDACTED]

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Delivered Date:	2019/03/14 11:33:45

From:	Scher, Deborah L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FEE3389DFA024F25B96B6D75AC2E7B9F-SCHER, DEBO (b6)@va.gov>
To:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres (b6)@va.gov>
CC:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b6)@va.gov>
Subject:	RE: Spravato timeline?
Date:	2019/06/18 07:54:04
Priority:	Normal
Type:	Note

Of course Teresa. Good luck today!
Best,

Deborah
Deborah Lafer Scher
Executive Advisor to the Secretary
Secretary's Center for Strategic Partnerships
U.S. Department of Veterans Affairs
www.va.gov/scsp

From: Boyd, Teresa D. <(b6)@va.gov>
Date: Tuesday, Jun 18, 2019, 6:00 AM
To: Scher, Deborah L. (b6)@va.gov>
Cc: Lieberman, Steven <(b6)@va.gov>
Subject: RE: Spravato timeline?

Thanks, Deborah - a great team effort!
Yes - as discussed last month - fingers crossed - today will be the first patient in Boston. As soon as I hear, will let everyone know. Appreciate holding close until then.
Thanks!
Teresa

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(www.blackberry.com)

From: Scher, Deborah L. <(b6)@va.gov>
Date: Monday, Jun 17, 2019, 4:37 PM
To: Boyd, Teresa D. <(b6)@va.gov>
Cc: Boyd, Teresa D. <(b6)@va.gov>
Subject: RE: Spravato timeline?

Hi Teresa:

I hope you had a wonderful weekend.

Congratulations on the effective implementation of Mission! What a terrific accomplishment. Just circling back on this as today would be the 90 day milestone. Is Boston still the target site of first patient use? If so, is there a scheduled date?

Thank you very much,

Deborah

Deborah Lafer Scher

Executive Advisor to the Secretary

Secretary's Center for Strategic Partnerships

U.S. Department of Veterans Affairs

www.va.gov/scsp

From: Boyd, Teresa D. <(b6)@va.gov>

Date: Tuesday, Jun 04, 2019, 3:57 PM

To: Scher, Deborah L. <(b6)@va.gov>

Cc: Boyd, Teresa D. <(b6)@va.gov>

Subject: RE: Spravato timeline?

Looking positive for Boston for early to mid-June. More specifics to come but seems on track!
Teresa

Sent with BlackBerry Work
(www.blackberry.com)

From: Scher, Deborah L. (b6)@va.gov>

Date: Tuesday, Jun 04, 2019, 2:55 PM

To: Boyd, Teresa D. <(b6)@va.gov>

Subject: Spravato timeline?

H Teresa:

Hope all is well. I know you are probably swamped preparing for the launch of Mission on Thursday. Just wanted to touch base on the time line to see if we are on track to meet the 90 day target. Please let me know if our office can provide support in any way that would be helpful.

Thank you,

Deborah

Deborah Lafer Scher

Executive Advisor to the Secretary

Secretary's Center for Strategic Partnerships

US Department of Veterans Affairs

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Sender:	Scher, Deborah L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FEE3389DFA024F25B96B6D75AC2E7B9F-SCHER, DEBO (b6) @va.gov>
Recipient:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres (b6) va.gov>; Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, (b6) va.gov>
Sent Date:	2019/06/18 07:54:02
Delivered Date:	2019/06/18 07:54:04
Message Flags:	Unread

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED]@va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED]@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>
Subject:	RE: Spravato Slide Deck with completed/pending actions
Date:	2019/03/21 12:05:18
Priority:	Normal
Type:	Note

This is perfect Ilse! We are going to have to modify the first few slides for Dr. Stone's briefing. I just wanted to have the actions completed/pending slides done.

Thank you!

Tom

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 11:23 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Slide Deck with completed/pending actions

Updated with:

- • (b) (5) [REDACTED]

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 21, 2019 4:52 AM
To: Wiechers, Ilse <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: Spravato Slide Deck with completed/pending actions

Good Morning Ilse,

I am using the slide deck we used for the CMO call to keep track of the Completed and Pending Actions on Spravato® that we will be able to use for the April 1, 2019 briefing to update Dr. Stone on progress.

Could you continue the Completed Action and In Progress slide with the actions you have been working on (distribution of 10N memo, iMed consent, ect...)?

Thank you!

Tom

Sender:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER <(b6) va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/21 12:05:17
Delivered Date:	2019/03/21 12:05:18
Message Flags:	Unread

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6)@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>
Subject:	RE: Spravato Slide Deck with completed/pending actions
Date:	2019/03/21 10:34:13
Priority:	Normal
Type:	Note

Thanks – very helpful to know healthcare facilities side of the REMS is online and operational.

Please keep me in the loop on when the pharmacy REMS guidance goes out. I have been asked to speak with VISN Chief MH Officers Call on Monday to address questions and concerns.

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, March 21, 2019 7:18 AM
To: Wiechers, Ilse <Ilse.Wiechers@va.gov>; Emmendorfer, Thomas (PBM) (b6)@va.gov>
Cc: Valentino, Michael (VACO) (b6)@va.gov>
Subject: RE: Spravato Slide Deck with completed/pending actions

Hi Ilse,

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

We will be sending out the pharmacy guidance in the next few days. I am just waiting for one piece of information to be resolved on that.

Let me know if questions.

JZ

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 9:16 AM
To: Emmendorfer, Thomas (PBM) (b6)@va.gov>
Cc: Valentino, Michael (VACO) (b6)@va.gov>; Zacher, Jennifer L. (PBM)

<(b6) [REDACTED]@va.gov>

Subject: RE: Spravato Slide Deck with completed/pending actions

Will do.

(b) (5)

Thanks,
Ilse

From: Emmendorfer, Thomas (PBM)

Sent: Thursday, March 21, 2019 4:52 AM

To: Wiechers, Ilse (b6) [REDACTED]@va.gov>

Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM)

<(b6) [REDACTED]@va.gov>

Subject: Spravato Slide Deck with completed/pending actions

Good Morning Ilse,

I am using the slide deck we used for the CMO call to keep track of the Completed and Pending Actions on Spravato® that we will be able to use for the April 1, 2019 briefing to update Dr. Stone on progress.

Could you continue the Completed Action and In Progress slide with the actions you have been working on (distribution of 10N memo, iMed consent, ect...)?

Thank you!

Tom

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) [REDACTED]@va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>
Sent Date:	2019/03/21 10:34:12
Delivered Date:	2019/03/21 10:34:13
Message Flags:	Unread

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6)@va.gov>
Subject:	RE: Spravato planning follow up
Date:	2019/03/13 15:34:27
Priority:	Normal
Type:	Note

Got it , thanks!

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 13, 2019 11:50 AM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Wiechers, Ilse (b6)@va.gov>
Subject: RE: Spravato planning follow up

The answer is no. We will be purchasing through our wholesaler as we do with every other drug, not a specialty distributor.
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Wednesday, March 13, 2019 1:24 PM
To: Wiechers, Ilse (b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: RE: Spravato planning follow up

Hi Ilse,

Good catch.

Jenn,

Did you know or did J&J tell you how they want VA medical facilities to answer?

Tom

From: Wiechers, Ilse
Sent: Wednesday, March 13, 2019 2:13 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: RE: Spravato planning follow up

Quick question re something on the Healthcare Facility enrollment form:

Does your healthcare setting intend to purchase SPRAVATO™ from a specialty distributor (i.e., buy and bill)?*

(b) (5)

Thanks,
Ilse

From: Wiechers, Ilse

Sent: Wednesday, March 13, 2019 9:06 AM

To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Llorente, Maria D. <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Subject: RE: Spravato planning follow up

Perfect. I will simply allude to this occurring then in my 10N memo. More to come later today & tomorrow (*hopefully*).

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Sent: Wednesday, March 13, 2019 9:02 AM

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Subject: RE: Spravato planning follow up

Hi Ilse,

Our messaging will align. We do not need to through 10N with an official memo. Jenn Z.'s team has a whole process to communicate REMS Pharmacy requirements to VA Pharmacy.

I think Jenn is still waiting to hear back from J&J one additional question about the Pharmacy enrollment. Once we have the guidance document finalized, we can definitely share with you.

Tom

From: Wiechers, Ilse

Sent: Wednesday, March 13, 2019 11:56 AM

To: Llorente, Maria D. <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Subject: RE: Spravato planning follow up

Tom –

As I'm working on efforts through OMHSP to get all VAMC facilities registered in REMS, I'm also realizing pharmacies will – separately, I believe – need to register. Is PBM issuing guidance on that to the field? I want to make sure our language/messaging on that aligns.

Thanks,
Ilse

From: Llorente, Maria D.
Sent: Tuesday, March 12, 2019 2:19 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Wiechers, Ilse <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato planning follow up

Thank you everyone!

From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, March 12, 2019 4:52 PM
To: Wiechers, Ilse <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato planning follow up

Thank you Ilse! Adding Mike and Jenn for awareness. I will update the slide set with info below

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse <(b6) [REDACTED]@va.gov>
Date: Tuesday, Mar 12, 2019, 4:45 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato planning follow up

Sorry – I neglected to add a timeline. Adding that in below in red.

From: Wiechers, Ilse
Sent: Tuesday, March 12, 2019 1:21 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>
Subject: Spravato planning follow up

Tom & Maria –

Below are the summary points from our conversation. Take a look and make sure you agree and I've captured things accurately.

Thanks,
Ilse

- • (b) (5)

FAQs

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Sent Date:	2019/03/13 15:34:27

To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Subject:	RE: Spravato planning follow up
Date:	2019/03/13 15:01:39
Priority:	Normal
Type:	Note

In this case, is McKesson technical considered a Specialty Distributor?

I am good with the answer as being "no"

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 13, 2019 2:50 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>
Subject: RE: Spravato planning follow up

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JZ

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Subject: RE: Spravato planning follow up

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(b) (5)

r.

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Subject: RE: Spravato planning follow up

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Subject: RE: Spravato planning follow up

Thank you everyone!

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Sent: Tuesday, March 12, 2019 4:52 PM
To: Wiechers, Ilse <(b6)@va.gov>; Llorente, Maria D. <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
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(www.blackberry.com)

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Date: Tuesday, Mar 12, 2019, 4:45 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Llorente, Maria D. <(b6)@va.gov>
Subject: RE: Spravato planning follow up

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Sent: Tuesday, March 12, 2019 1:21 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Llorente, Maria D. <(b6)@va.gov>
Subject: Spravato planning follow up

Tom & Maria –

Below are the summary points from our conversation. Take a look and make sure you agree and I've captured things accurately.

Also, just as a heads up - I will be on AL on Monday, Mar. 18th and unavailable all day. Hope to have most of this moving forward by end of the week, but just letting you know in advance.

Thanks,

.....

(4) (5)

- [illegible]



National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)

email: (b6) [REDACTED] va.gov | (b6) [REDACTED] yale.edu

Connect to:

[PDSI Home](#)

PDSI Management System

FAQs

Recipient: Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)>@va.gov>

Sent Date:	2019/03/13 15:01:47
Delivered Date:	2019/03/13 15:01:39
Message Flags:	Unread Unsent

From:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES <(b6)@va.gov>
To:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6)@va.gov>
Subject:	RE: Spravato overview
Date:	2019/06/17 05:37:47
Priority:	Normal
Type:	Note

(b6)

Boston will be first site tomorrow I believe - unless there is an email I missed :).

Sent with BlackBerry Work
(www.blackberry.com)

From: Lieberman, Steven <(b6)@va.gov>
Date: Sunday, Jun 16, 2019, 3:27 PM
To: Boyd, Teresa D. <(b6)@va.gov>
Subject: FW: Spravato overview

Sent the below to Rich. We definitely have to keep our eyes open with this.

From: Lieberman, Steven
Sent: Sunday, June 16, 2019 3:24 PM
To: Stone, Richard A., MD <(b6)@va.gov>
Subject: Spravato overview

1.2 - Kaiser Health News: [FDA Overlooked Red Flags In Drugmaker's Testing of New Depression Medicine](#) (15 June, Emmarie Huettelman, 236k uvm; Washington, DC)

Ketamine is a darling of combat medics and clubgoers, an anesthetic that can quiet your pain without suppressing breathing and a hallucinogenic that can get you high with little risk of a fatal overdose.

For some patients, it also has dwelled in the shadows of conventional medicine as a depression treatment — prescribed by their doctors, but not approved for that purpose by the federal agency responsible for determining which treatments are “safe and effective.”

That effectively changed in March, when the Food and Drug Administration approved a ketamine cousin called esketamine, taken as a nasal spray, for patients with intractable depression. With that, the esketamine nasal spray, under the brand name Spravato, was introduced as a miracle drug — announced in press releases, celebrated on the evening news and embraced by major health care providers like the Department of Veterans Affairs.

The problem, critics say, is that the drug's manufacturer, Janssen, provided the FDA at best modest evidence it worked and then only in limited trials. It presented no information about the safety of Spravato for long-term use beyond 60 weeks. And three patients who received the drug died by suicide during clinical trials, compared with none in the control group, raising red flags Janssen and the FDA dismissed.

The FDA, under political pressure to rapidly greenlight drugs that treat life-threatening conditions, approved it anyway. And, though Spravato's appearance on the market was greeted with public applause, some deep misgivings were expressed at its day-long review meeting and in the agency's own briefing materials, according to public recordings, documents and interviews with participants, KHN found.

Dr. Jess Fiedorowicz, director of the Mood Disorders Center at the University of Iowa and a member of the FDA advisory committee that reviewed the drug, described its benefit as "almost certainly exaggerated" after hearing the evidence.

Fiedorowicz said he expected at least a split decision by the committee. "And then it went strongly in favor, which surprised me," he said in an interview.

Esketamine's trajectory to approval shows — step by step — how drugmakers can take advantage of shortcuts in the FDA process with the agency's blessing and maneuver through safety and efficacy reviews to bring a lucrative drug to market.

Step 1: In late 2013, Janssen got the FDA to designate esketamine a "breakthrough therapy" because it showed the potential to reverse depression rapidly — a holy grail for suicidal patients, such as those in an emergency room. That potential was based on a two-day study during which 30 patients were given esketamine intravenously.

"Breakthrough therapy" status puts drugs on a fast track to approval, with more frequent input from the FDA.

Step 2: But discussions between regulators and drug manufacturers can affect the amount and quality of evidence required by the agency. In the case of Spravato, they involved questions like, how many drugs must fail before a patient's depression is considered intractable or "treatment-resistant"? And how many successful clinical trials are necessary for FDA approval?

Step 3: Any prior agreements can leave the FDA's expert advisory committees hamstrung in reaching a verdict. Fiedorowicz abstained on Spravato because, though he considered Janssen's study design flawed, the FDA had approved it.

The expert panel cleared the drug according to the evidence that the agency and Janssen had determined was sufficient. Dr. Matthew Rudorfer, an associate director at the National Institute of Mental Health, concluded that the "benefits outweighed the risks." Explaining his "yes" vote, he said: "I think we're all agreeing on the very important, and sometimes life-or-death, risk of inadequately treated depression that factored into my equation."

But others who also voted "yes" were more explicit in their qualms. "I don't think that we really understand what happens when you take this week after week for weeks and months and years," said

Steven Meisel, the system director of medication safety for Fairview Health Services based in Minneapolis.

A Nasal Spray Offers A Path To A Patent

Spravato is available only under supervision at a certified facility, like a doctor's office, where patients must be monitored for at least two hours after taking the drug to watch for side effects like dizziness, detachment from reality and increased blood pressure, as well as to reduce the risk of abuse. Patients must take it with an oral antidepressant.

Despite those requirements, Janssen, part of Johnson & Johnson, defended its new offering. "Until the recent FDA approval of Spravato, health care providers haven't had any new medication options," Kristina Chang, a Janssen spokeswoman, wrote in an emailed statement.

Esketamine is the first new type of drug approved to treat severe depression in about three decades.

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What's more, that single positive efficacy trial showed just a 4-point improvement in depression symptoms compared with the placebo treatment on a 60-point scale some clinicians use to measure depression severity. Some committee members noted the trial wasn't really blind since participants could recognize they were getting the drug from side effects like a temporary out-of-body sensation.

Finally, the FDA lowered the bar for "treatment-resistant depression." Initially, for inclusion, trial participants would have had to have failed two classes of oral antidepressants.

Less than two years later, the FDA loosened that definition, saying a patient needed only to have taken two different pills, no matter the class.

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Steven L. Lieberman, MD, MBA, FACHE
Acting Principal Deputy Under Secretary for Health
Veterans Health Administration

Sender:	Boyd, Teresa D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F6886A7D555A43E0BEE23C1E40E1C234-BOYD, TERES<(b6)>va.gov>
Recipient:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman,<(b6)>va.gov>
Sent Date:	2019/06/17 05:37:46
Delivered Date:	2019/06/17 05:37:47

From:	Stone, Richard A., MD </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD16619615D64ADEA22E45E63FF6462A-STONE, RICH>
To:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6) va.gov>
Subject:	RE: Spravato overview
Date:	2019/06/16 16:34:21
Priority:	Normal
Type:	Note

Read it this morning.

Sent with BlackBerry Work
(www.blackberry.com)

From: Lieberman, Steven <(b6) va.gov>
Date: Sunday, Jun 16, 2019, 3:23 PM
To: Stone, Richard A., MD <(b6) va.gov>
Subject: Spravato overview

1.2 - Kaiser Health News: FDA Overlooked Red Flags In Drugmaker's Testing of New Depression Medicine (15 June, Emmarie Huettelman, 236k uvm; Washington, DC)

Ketamine is a darling of combat medics and clubgoers, an anesthetic that can quiet your pain without suppressing breathing and a hallucinogenic that can get you high with little risk of a fatal overdose.

For some patients, it also has dwelled in the shadows of conventional medicine as a depression treatment — prescribed by their doctors, but not approved for that purpose by the federal agency responsible for determining which treatments are “safe and effective.”

That effectively changed in March, when the Food and Drug Administration approved a ketamine cousin called esketamine, taken as a nasal spray, for patients with intractable depression. With that, the esketamine nasal spray, under the brand name Spravato, was introduced as a miracle drug — announced in press releases, celebrated on the evening news and embraced by major health care providers like the Department of Veterans Affairs.

The problem, critics say, is that the drug's manufacturer, Janssen, provided the FDA at best modest evidence it worked and then only in limited trials. It presented no information about the safety of Spravato for long-term use beyond 60 weeks. And three patients who received the drug died by suicide during clinical trials, compared with none in the control group, raising red flags Janssen and the FDA dismissed.

The FDA, under political pressure to rapidly greenlight drugs that treat life-threatening conditions, approved it anyway. And, though Spravato's appearance on the market was greeted with public applause, some deep misgivings were expressed at its day-long review meeting and in the agency's own

briefing materials, according to public recordings, documents and interviews with participants, KHN found.

Dr. Jess Fiedorowicz, director of the Mood Disorders Center at the University of Iowa and a member of the FDA advisory committee that reviewed the drug, described its benefit as “almost certainly exaggerated” after hearing the evidence.

Fiedorowicz said he expected at least a split decision by the committee. “And then it went strongly in favor, which surprised me,” he said in an interview.

Esketamine’s trajectory to approval shows — step by step — how drugmakers can take advantage of shortcuts in the FDA process with the agency’s blessing and maneuver through safety and efficacy reviews to bring a lucrative drug to market.

Step 1: In late 2013, Janssen got the FDA to designate esketamine a “breakthrough therapy” because it showed the potential to reverse depression rapidly — a holy grail for suicidal patients, such as those in an emergency room. That potential was based on a two-day study during which 30 patients were given esketamine intravenously.

“Breakthrough therapy” status puts drugs on a fast track to approval, with more frequent input from the FDA.

Step 2: But discussions between regulators and drug manufacturers can affect the amount and quality of evidence required by the agency. In the case of Spravato, they involved questions like, how many drugs must fail before a patient’s depression is considered intractable or “treatment-resistant”? And how many successful clinical trials are necessary for FDA approval?

Step 3: Any prior agreements can leave the FDA’s expert advisory committees hamstrung in reaching a verdict. Fiedorowicz abstained on Spravato because, though he considered Janssen’s study design flawed, the FDA had approved it.

The expert panel cleared the drug according to the evidence that the agency and Janssen had determined was sufficient. Dr. Matthew Rudorfer, an associate director at the National Institute of Mental Health, concluded that the “benefits outweighed the risks.” Explaining his “yes” vote, he said: “I think we’re all agreeing on the very important, and sometimes life-or-death, risk of inadequately treated depression that factored into my equation.”

But others who also voted “yes” were more explicit in their qualms. “I don’t think that we really understand what happens when you take this week after week for weeks and months and years,” said Steven Meisel, the system director of medication safety for Fairview Health Services based in Minneapolis.

A Nasal Spray Offers A Path To A Patent

Spravato is available only under supervision at a certified facility, like a doctor’s office, where patients must be monitored for at least two hours after taking the drug to watch for side effects like dizziness, detachment from reality and increased blood pressure, as well as to reduce the risk of abuse. Patients must take it with an oral antidepressant.

Despite those requirements, Janssen, part of Johnson & Johnson, defended its new offering. “Until the recent FDA approval of Spravato, health care providers haven’t had any new medication options,” Kristina Chang, a Janssen spokeswoman, wrote in an emailed statement.

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Recipient:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6) va.gov>
Sent Date:	2019/06/16 16:34:20
Delivered Date:	2019/06/16 16:34:21

To:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6) [REDACTED] va.gov>
Subject:	RE: Spravato overview
Date:	2019/06/16 16:34:20
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Read it this morning.

Sent with BlackBerry Work
(www.blackberry.com)

From: Lieberman, Steven <(b6) [REDACTED] va.gov>
Date: Sunday, Jun 16, 2019, 3:23 PM
To: Stone, Richard A., MD <(b6) [REDACTED] va.gov>
Subject: Spravato overview

Recipient:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6) [REDACTED] va.gov>
Sent Date:	2019/06/16 16:34:20
Message Flags:	Unsent

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>
Subject:	RE: Spravato monograph
Date:	2019/03/25 12:20:00
Priority:	Normal
Type:	Note

Matt,

Thanks for your review and comments! I have incorporated your suggested changes into the monograph.

You are correct, (b) (5).

(b) (5)

Also, I reviewed the ICER Draft evidence reports (attached).

"Conclusions

(b) (5)

Thanks,

Matthew

From: Schreiber, Matthew A.
Sent: Monday, March 25, 2019 10:23 AM
To: Fuller, Matthew A. (PBM) <(b6) va.gov>; Capehart, Bruce P. DURVAMC <(b6) va.gov>
Subject: Spravato monograph

Hi Matthew and Bruce,

First of all, kudos for writing this document with such high quality under such time constraints. It's truly excellent, extremely clear and informative. And I agree—this process is a foregone conclusion, so in some ways, we'll just have to wait and see what happens.

My specific comments about the monograph are very minor.

p.5 – (b) (5)

[REDACTED]

p.6 – (b) (5)

[REDACTED"])

p. 8 – (b) (5)

[REDACTED]

p. 14 – (b) (5)

[REDACTED]

Other than that, these are just my personal thoughts to vent – (b6)

[REDACTED]

(b6)

[REDACTED]

[REDACTED]

Sorry this is so wordy, but it's an emotional subject! Thanks for sending this, I enjoyed reading it, please let me know if I can read or review anything else or help in any way. Hope all is well in beautiful Cleveland! Hope you are also doing well Bruce, I am eager to hear your thoughts.
Matt

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>; Capehart, Bruce P. DURVAMC /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6866eff4e9df4a48846d056a02044c38-Capehart, B <(b6) va.gov>
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Delivered Date:	2019/03/25 12:20:00

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From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Nowak, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ca75ef114d34b359144763e297ce0ba-Nowak, John (b6) va.gov>
CC:	Lenz, Sue (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b721e21e31d8492dbe1b48c560531315-Lenz, Sue (b6) va.gov>
Subject:	RE: Spravato Info
Date:	2019/08/23 11:19:00
Priority:	Normal
Type:	Note

Thank you both!

From: Nowak, John
Sent: Friday, August 23, 2019 11:08 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Lenz, Sue (PBM) <(b6) va.gov>
Subject: FW: Spravato Info

Prime vendor data shows 28 units but only up to July 31. The same facilities on the smo list appeared on the PPV data list
I think the SMO is good

From: Lenz, Sue (PBM)
Sent: Friday, August 23, 2019 9:50 AM
To: Nowak, John <(b6) va.gov>
Subject: RE: Spravato Info

This is what I got

From: Nowak, John
Sent: Friday, August 23, 2019 9:45 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Lenz, Sue (PBM) <(b6) va.gov>
Subject: RE: Spravato Info

Sue/Tom

I just submitted to SMO for the last 24 months. I don't know how long the product has been on the market but will check for purchases in the ppv data to validate the SMO and to add if there are purchases going back further

From: Emmendorfer, Thomas (PBM)
Sent: Friday, August 23, 2019 9:11 AM
To: Lenz, Sue (PBM) <(b6) va.gov>; Nowak, John <(b6) va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: Spravato Info

Sue/John,

Could one of you run the request below using the report functions in McKesson Connect so we have the most recent data?

Tom

From: Valentino, Michael (VACO)
Sent: Friday, August 23, 2019 10:07 AM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: FW: Spravato Info

From: Valentino, Michael (VACO)
Sent: Thursday, August 22, 2019 1:32 PM
To: Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: Spravato Info

Hi Jenn,

Can you have someone run our PPV purchases and let me know how much VA facilities have purchased from the time it was available through whatever data we have now.

Should include the site name, how many units ordered and the cost.

Thanks!

Mike

From: Lieberman, Steven
Sent: Thursday, August 22, 2019 1:25 PM
To: Beck, Lucille B. <(b6) va.gov>; Stone, Richard A., MD <(b6) va.gov>; Boyd, Teresa D. <(b6) va.gov>; Oshinski, Renee <(b6) va.gov>; Czarnecki, Tammy <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Cc: Jensen, Jon M. <(b6) va.gov>; Howard, Kristi <(b6) va.gov>; Law, Cassandra M. <(b6) va.gov>
Subject: RE: Spravato Info

Thanks Lu. This is very helpful. Any word on amount purchased? Do we purchase it only when needed or do we have some on stock? Sorry if that is below and I missed it.

From: Beck, Lucille B.

Sent: Thursday, August 22, 2019 10:26 AM

To: Lieberman, Steven <(b6)@va.gov>; Stone, Richard A., MD <(b6)@va.gov>; Boyd, Teresa D. <(b6)@va.gov>; Oshinski, Renee <(b6)@va.gov>; Czarnecki, Tammy <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>

Cc: Jensen, Jon M. <(b6)@va.gov>; Howard, Kristi <(b6)@va.gov>; Law, Cassandra M. <(b6)@va.gov>

Subject: FW: Spravato Info

Importance: High

Update from Pharmacy per our discussion this morning and the clips today.

From: Zacher, Jennifer L. (PBM)

Sent: Thursday, August 22, 2019 9:39 AM

To: Beck, Lucille B. <(b6)@va.gov>

Cc: Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>

Subject: Spravato Info

Importance: High

Hi Lu,

As per call with Mike this morning, here is a brief bullet list of all of the controls we put in place for Spravato:

- • March 5, 2019 – Spravato was approved by FDA
- • March 8, 2019 – Spravato was added to FSS contract for purchase by VA sites
- • March 11-12, 2019 – Product overview presented to internal clinical groups (CMOs, MH leads, VISN Pharmacist Executives)
- • March 15, 2019 – FAQ document distributed to the field
- • March 18, 2019 – Memo issued to field with instructions on how to obtain REMS certification as required by FDA
- • March 19, 2019 – Spravato became available in the U.S. pharmaceutical supply chain
- • May 13-15, 2019 – The Spravato drug monograph, draft criteria for use, and field comments were presented to both the VISN Pharmacist Executive Committee and the Medical Advisory Panel. Draft documents were developed in collaboration with the Office of Mental Health. After discussion, the issue was tabled until the June face to face committee meeting so that feedback from the VPE/MAP committee and field commenters could be incorporated.
- • June 12, 2019 – launched Esketamine Community of Practice monthly teleconference, open to anyone in VHA interested in learning about esketamine
- • June 20, 2019 – based on careful review of available evidence, the MAP/VPE committee voted to:
 - • Designate esketamine as a non-formulary drug which will be made available with an approved prospective review
 - • Approve evidence-based prescribing guidance

- • Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population
- • Provide clear and consistent messaging to VA providers
- • July 1, 2019 – launched Esketamine Community of Practice SharePoint site, which serves as a repository of resources related to clinical use of esketamine within VHA
- • July 15, 2019 –Date that the clinical monitor to assess Spravato's safety and effectiveness (aka MUET) went live

Here is the patient specific data from Ilse:

- • 3 patients to date at 2 sites
- • VA Boston began treatment of Patient #1 on (b6), 2019
- • VA New Mexico began treatment of Patient #2 on (b6) 2019 and Patient #3 on (b6) 2019
- • All three patients are continuing to receive treatments, no significant adverse events reported to date, tolerating treatment well

Please let us know if you need any additional information.

JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6)r@va.gov

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
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Delivered Date:	2019/08/23 11:19:00

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Subject:	Re: Spravato Info
Date:	2019/08/23 11:03:40
Priority:	Normal
Type:	Note

Thank you very much John! The product has only been approved by the FDA since March 2019. It is a REMS drugs, but it can be procured thru McKesson by the sites.

From: John Nowak <(b6) [REDACTED] va.gov>
Date: Friday, August 23, 2019 at 10:45 AM
To: Thomas Emmendorfer <(b6) [REDACTED] va.gov>
Cc: "Lenz, Sue (PBM)" <(b6) [REDACTED] va.gov>
Subject: RE: Spravato Info

Sue/Tom

I just submitted to SMO for the last 24 months. I don't know how long the product has been on the market but will check for purchases in the ppv data to validate the SMO and to add if there are purchases going back further

From: Emmendorfer, Thomas (PBM)
Sent: Friday, August 23, 2019 9:11 AM
To: Lenz, Sue (PBM) <(b6) [REDACTED] va.gov>; Nowak, John <(b6) [REDACTED] va.gov>
Cc: Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>
Subject: FW: Spravato Info

Sue/John,

Could one of you run the request below using the report functions in McKesson Connect so we have the most recent data?

Tom

From: Valentino, Michael (VACO)
Sent: Friday, August 23, 2019 10:07 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>
Subject: FW: Spravato Info

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Sent: Thursday, August 22, 2019 1:32 PM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: FW: Spravato Info

Hi Jenn,

Can you have someone run our PPV purchases and let me know how much VA facilities have purchased from the time it was available through whatever data we have now.

Should include the site name, how many units ordered and the cost.

Thanks!

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From: Lieberman, Steven
Sent: Thursday, August 22, 2019 1:25 PM
To: Beck, Lucille B. <(b6)@va.gov>; Stone, Richard A., MD <(b6)@va.gov>; Boyd, Teresa D. <(b6)@va.gov>; Oshinski, Renee <(b6)@va.gov>; Czarnecki, Tammy <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>
Cc: Jensen, Jon M. <(b6)@va.gov>; Howard, Kristi <(b6)@va.gov>; Law, Cassandra M. <(b6)@va.gov>
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Cc: Jensen, Jon M. <(b6)@va.gov>; Howard, Kristi <(b6)@va.gov>; Law, Cassandra M. <(b6)@va.gov>
Subject: FW: Spravato Info
Importance: High

Update from Pharmacy per our discussion this morning and the clips today.

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Sent: Thursday, August 22, 2019 9:39 AM

To: Beck, Lucille B. <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>
Subject: Spravato Info
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Here is the patient specific data from Ilse:

- • 3 patients to date at 2 sites
- • VA Boston began treatment of Patient #1 on (b6) [REDACTED] 2019
- • VA New Mexico began treatment of Patient #2 on (b6) [REDACTED] 2019 and Patient #3 on (b6) [REDACTED] 5, 2019
- • All three patients are continuing to receive treatments, no significant adverse events reported to date, tolerating treatment well

Please let us know if you need any additional information.

JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6) [\[REDACTED\]@va.gov](mailto:[REDACTED]@va.gov)

Sender:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>
Recipient:	Nowak, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ca75ef114d34b359144763e297ce0ba-Nowak, John <(b6) [REDACTED]@va.gov>; Lenz, Sue (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b721e21e31d8492dbe1b48c560531315-Lenz, Sue <(b6) [REDACTED]@va.gov>
Sent Date:	2019/08/23 11:03:40

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Spravato Info
Date:	2019/08/23 14:45:00
Priority:	Normal
Type:	Note

Yes...sorry Jenn. I just saw they dropped you from the e-mail string. This one is done.

From: Zacher, Jennifer L. (PBM)
Sent: Friday, August 23, 2019 2:35 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: Spravato Info

Did either of them respond to you?

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To: Lenz, Sue (PBM) <(b6) va.gov>; Nowak, John <(b6) va.gov>
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Please let us know if you need any additional information.

JZ

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 Associate Chief Consultant
 VA Pharmacy Benefits Management Services
 (b6)
 (b6)@va.gov

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Sent Date:	2019/08/23 14:45:35
Delivered Date:	2019/08/23 14:45:00

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6)@va.gov>
Subject:	RE: Spravato Info
Date:	2019/08/22 11:12:00
Priority:	Normal
Type:	Note

Jenn is a key part of the PBM succession plan....she is fantastic and I am so pleased we are able to laterally move her into a Deputy position. I greatly appreciate your support for that and for the special pay endorsement.

All the PBM Deputies (Jenn, Tom, Mario, Ron and Ginny) will build on our past successes and serve VA very well into the future.

Mike

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Recipient:	Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6) va.gov>
Sent Date:	2019/08/22 11:12:47
Delivered Date:	2019/08/22 11:12:00

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
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CC:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>
Subject:	RE: Spravato Info
Date:	2019/08/22 11:03:00
Priority:	Normal
Type:	Note

Superb Jenn....thanks much!

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Thank you, exactly what we needed.

Lucille B. Beck, Ph.D.
Deputy Under Secretary for Health
for Policy and Services (10P)
VA Central Office
Phone: (b6)
Cell : (b6)

Sent with BlackBerry Work
(www.blackberry.com).

From: Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Date: Thursday, Aug 22, 2019, 9:38 AM
To: Beck, Lucille B. <(b6)@va.gov>
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Sent Date:	2019/08/22 11:03:45
Delivered Date:	2019/08/22 11:03:00

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6)@va.gov>
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CC:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6)@va.gov>; Howard, Kristi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8d0afc371994181883d8861127791c3-Howard, Kri <(b6)@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>
Subject:	RE: Spravato Info
Date:	2019/08/26 08:22:41
Priority:	Normal
Type:	Note

37 Dose kits purchased at 5 VA medical facilities up thru 8/22/2019.

VA Medical Facilities

- • Nashville =4
- • Lom Linda =4
- • Albuquerque = 21
- • Fayetteville, AR =2
- • Boston = 6

From: Lieberman, Steven

Sent: Thursday, August 22, 2019 10:02 PM

To: Valentino, Michael (VACO) <(b6)@va.gov>; Beck, Lucille B. <(b6)@va.gov>; Stone, Richard A., MD <(b6)@va.gov>; Boyd, Teresa D. <(b6)@va.gov>; Oshinski, Renee <(b6)@va.gov>; Czarnecki, Tammy <(b6)@va.gov>

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<(b6) [REDACTED] va.gov>
Subject: RE: Spravato Info

Thanks. We had a question about purchases at our morning meeting. This is most helpful

From: Valentino, Michael (VACO)
Sent: Thursday, August 22, 2019 1:31 PM
To: Lieberman, Steven <(b6) [REDACTED] va.gov>; Beck, Lucille B. <(b6) [REDACTED] va.gov>; Stone, Richard A., MD <(b6) [REDACTED] va.gov>; Boyd, Teresa D. <(b6) [REDACTED] va.gov>; Oshinski, Renee <(b6) [REDACTED] va.gov>; Czarnecki, Tammy <(b6) [REDACTED] va.gov>
Cc: Jensen, Jon M. <(b6) [REDACTED] va.gov>; Howard, Kristi <(b6) [REDACTED] va.gov>; Law, Cassandra M. <(b6) [REDACTED] va.gov>
Subject: RE: Spravato Info

Hi Steve,

This is readily available from our Pharmaceutical Prime Vendor (PPV). We can order it by a time certain (I think it is 8pm daily) and have it delivered the next business day.

In practice, VA pharmacies would not order the product just in case they might need it. They would only order it when they are notified a patient is scheduled for self-administration.

I'll ask our folks to look at our pharmaceutical purchases and see what we've purchased (NOTE: There is a lag in our PPV data feed.....we likely only have complete data through June 2019.

Mike

From: Lieberman, Steven
Sent: Thursday, August 22, 2019 1:25 PM
To: Beck, Lucille B. <(b6) [REDACTED] va.gov>; Stone, Richard A., MD <(b6) [REDACTED] va.gov>; Boyd, Teresa D. <(b6) [REDACTED] va.gov>; Oshinski, Renee <(b6) [REDACTED] va.gov>; Czarnecki, Tammy <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
Cc: Jensen, Jon M. <(b6) [REDACTED] va.gov>; Howard, Kristi <(b6) [REDACTED] @va.gov>; Law, Cassandra M. <(b6) [REDACTED] va.gov>
Subject: RE: Spravato Info

Thanks Lu. This is very helpful. Any word on amount purchased? Do we purchase it only when needed or do we have some on stock? Sorry if that is below and I missed it.

From: Beck, Lucille B.
Sent: Thursday, August 22, 2019 10:26 AM
To: Lieberman, Steven <(b6) [REDACTED] va.gov>; Stone, Richard A., MD <(b6) [REDACTED] va.gov>; Boyd, Teresa D. <(b6) [REDACTED] va.gov>; Oshinski, Renee <(b6) [REDACTED] va.gov>; Czarnecki, Tammy <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED] va.gov>
Cc: Jensen, Jon M. <(b6) [REDACTED] va.gov>; Howard, Kristi <(b6) [REDACTED] rd@va.gov>; Law, Cassandra M. <(b6) [REDACTED] va.gov>

Subject: FW: Spravato Info
Importance: High

Update from Pharmacy per our discussion this morning and the clips today.

From: Zacher, Jennifer L. (PBM)
Sent: Thursday, August 22, 2019 9:39 AM
To: Beck, Lucille B. <(b6)@va.gov>
Cc: Valentino, Michael (VACO) <(b6)@va.gov>; Wiechers, Ilse (b6)@va.gov
Subject: Spravato Info
Importance: High

Hi Lu,

As per call with Mike this morning, here is a brief bullet list of all of the controls we put in place for Spravato:

- • March 5, 2019 – Spravato was approved by FDA
- • March 8, 2019 – Spravato was added to FSS contract for purchase by VA sites
- • March 11-12, 2019 – Product overview presented to internal clinical groups (CMOs, MH leads, VISN Pharmacist Executives)
- • March 15, 2019 – FAQ document distributed to the field
- • March 18, 2019 – Memo issued to field with instructions on how to obtain REMS certification as required by FDA
- • March 19, 2019 – Spravato became available in the U.S. pharmaceutical supply chain
- • May 13-15, 2019 – The Spravato drug monograph, draft criteria for use, and field comments were presented to both the VISN Pharmacist Executive Committee and the Medical Advisory Panel. Draft documents were developed in collaboration with the Office of Mental Health. After discussion, the issue was tabled until the June face to face committee meeting so that feedback from the VPE/MAP committee and field commenters could be incorporated.
- • June 12, 2019 – launched Esketamine Community of Practice monthly teleconference, open to anyone in VHA interested in learning about esketamine
- • June 20, 2019 – based on careful review of available evidence, the MAP/VPE committee voted to:
 - • Designate esketamine as a non-formulary drug which will be made available with an approved prospective review
 - • Approve evidence-based prescribing guidance
 - • Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population
 - • Provide clear and consistent messaging to VA providers
- • July 1, 2019 – launched Esketamine Community of Practice SharePoint site, which serves as a repository of resources related to clinical use of esketamine within VHA
- • July 15, 2019 – Date that the clinical monitor to assess Spravato's safety and effectiveness (aka MUET) went live

Here is the patient specific data from Ilse:

- 3 patients to date at 2 sites
- VA Boston began treatment of Patient #1 on (b6) 2019
- VA New Mexico began treatment of Patient #2 on (b6), 2019 and Patient #3 on (b6) 2019
- All three patients are continuing to receive treatments, no significant adverse events reported to date, tolerating treatment well

Please let us know if you need any additional information.

JZ

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6)@va.gov

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6)@va.gov>
Recipient:	Lieberman, Steven /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=25138f5d2e734afa81397f0b357cbcc1-Lieberman, <(b6)@va.gov>; Beck, Lucille B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=845480228a8b43e7a5fef5716ded04c2-Beck, Lucil <(b6)@va.gov>; Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich <(b6)@va.gov>; Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres <(b6)@va.gov>; Oshinski, Renee /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56925a4f59df47d19fcceb5e7c270bc0-Oshinski, R <(b6)@va.gov>; Czarnecki, Tammy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f4012e074ac4891979c9cd6bc08dfa9-Czarnecki, <(b6)@va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6)@va.gov>; Howard, Kristi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8d0afc371994181883d8861127791c3-Howard, Kri <(b6)@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>
Sent Date:	2019/08/26 08:22:40
Delivered Date:	2019/08/26 08:22:41
Message Flags:	Unread

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Spravato External Communication Draft
Date:	2019/03/11 10:08:20
Priority:	Normal
Type:	Note

Looks great...a couple of minor edits included for consideration....

Mike

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 6:15 PM
To: Valentino, Michael (VACO) <(b6) va.gov>
Cc: Wiechers, Ilse (b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: FW: Spravato External Communication Draft

Hi Mike,

The external communication document is ready for your review.

Isle,

(b) (5)

Jenn has made it clear to J&J that we need their educational materials as soon as possible.

Jenn,

Can you make sure J&J includes educational materials that are listed in their REMS form below as one of their deliverables to us?

Thank you,

Tom

Sent with BlackBerry Work
www.blackberry.com

To: Wiechers, Ilse (b6) [REDACTED]@va.gov; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]va.gov>
Subject: Re: Spravato External Communication Draft

Hi Ilse,

Here is our first draft on the External Communication for your review. I used one of the Hep C. Communications from a few years ago as an example.

Tom

From: "Wiechers, Ilse" (b6) [REDACTED]@va.gov>
Date: Friday, March 8, 2019 at 3:03 PM
To: Jennifer Zacher <(b6) [REDACTED]va.gov>
Cc: Thomas Emmendorfer <(b6) [REDACTED]va.gov>
Subject: RE: Spravato Internal Communication Draft

Got it – thanks. Keep me posted as more details are made clear in the coming days. I've started reading the documents they have made available on the Spravato REMS webpage to try to familiarize myself as well.

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:44 AM
To: Wiechers, Ilse (b6) [REDACTED]@va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>
Subject: RE: Spravato Internal Communication Draft

Hi,

Based on how this REMS is written, I don't think so. (b) (5) [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]. I will know more in the next day or two though, and I will keep you posted.

JZ

From: Wiechers, Ilse
Sent: Friday, March 08, 2019 1:41 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>
Subject: RE: Spravato Internal Communication Draft

Thanks – will take a look shortly. I still haven't heard back from ethics, the iMed consent issues will likely need some time next week to further sort out.

Also – regarding the (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

Ilse

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:27 AM
To: Wiechers, Ilse (b6) [REDACTED]@va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: Spravato Internal Communication Draft

Hi Ilse,
As per your conversation with Tom earlier, attached is a draft internal communication that we developed related to Spravato. Can you please review, add any edits you might have and then send back to us?
Thanks much!
Jennifer

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services
(b6) [REDACTED]
(b6) [REDACTED]@va.gov

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
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Sent Date:	2019/03/11 10:08:23
Delivered Date:	2019/03/11 10:08:20

(b) (5)

(b) (5)

(b) (5)

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M (b6)@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6)@va.gov>
Subject:	RE: Spravato External Communication Draft
Date:	2019/03/12 10:10:25
Priority:	Normal
Type:	Note

I've got a call with Workforce Management from 12-1:30 PT / 3-4:30 ET, but let me see if I can get someone to cover it for me. I'll confirm availability shortly.

From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, March 12, 2019 7:00 AM
To: Llorente, Maria D. (b6)@va.gov>; Wiechers, Ilse (b6)@va.gov>
Cc: Valentino, Michael (VACO) (b6)@va.gov>; Zacher, Jennifer L. (PBM) (b6)@va.gov>
Subject: Re: Spravato External Communication Draft

Hi Ilse,

I will setup the call for us today. By chance will a call starting at 3pm eastern work for you?

If not, could you send me your availability starting at 3pm eastern?

Thank you,

Tom

From: "Llorente, Maria D." (b6)@va.gov>
Date: Tuesday, March 12, 2019 at 8:20 AM
To: "Wiechers, Ilse" (b6)@va.gov>, Thomas Emmendorfer (b6)@va.gov>
Cc: Michael Valentino (b6)@va.gov>, Jennifer Zacher (b6)@va.gov>
Subject: RE: Spravato External Communication Draft

Ok, we will set up a call. Appreciate all the work you and your team have completed.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 8:42 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Spravato External Communication Draft

Maria -

I think (b) (5) And I'm honestly not sure re sorting out iMed consent by April 1. My understanding from people who've worked on these before is they can take some time, but perhaps with the urgency to implement this as soon as possible we can navigate the process more quickly. I'll make a couple more contacts with people tomorrow and give a more firm time line for this piece by end of day.

Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:28 PM
To: Wiechers, Ilse <(b6) @va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Spravato External Communication Draft

Hi Ilse. We have an update due to Dr. Stone on April 1. Do you think there will be enough time to resolve the imed consent by then?

I agree in principle with your response below. However, would like to discuss how to (b) (5) . Do you think this is something we can do via email, or should we plan to have a call?

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 3:53 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Spravato External Communication Draft

I think it makes sense to list TBD for the imed consent, since it will take a bit to sort out. I think (b) (5)

[REDACTED]
[REDACTED].

Do providers need to have special privileging to prescribe Spravato®?

ANSWER: (b) (5)

[REDACTED]
[REDACTED].

What do you think?

Ilse

From: Emmendorfer, Thomas (PBM)

Sent: Monday, March 11, 2019 12:37 PM

To: Llorente, Maria D. <(b6) [REDACTED]@va.gov>

Cc: Wiechers, Ilse (b6) [REDACTED]@va.gov; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>;

Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>

Subject: Re: Spravato External Communication Draft

Hi Maria,

The internal communication (Frequently Asked Question) document is ready for your review.

Ilse,

Our thought was (b) (5)

[REDACTED]
[REDACTED]).

Does that sound reasonable to you?

Thank you!

Tom

From: Thomas Emmendorfer <(b6) [REDACTED]@va.gov>

Date: Monday, March 11, 2019 at 10:28 AM

To: "Llorente, Maria D." <(b6) [REDACTED]@va.gov>

Cc: "Wiechers, Ilse" (b6) [REDACTED]@va.gov, Michael Valentino <(b6) [REDACTED]@va.gov>, Jennifer Zacher <(b6) [REDACTED]@va.gov>

Subject: FW: Spravato External Communication Draft

Hi Maria,

The external communication is ready for your review.

We are working on finalizing the internal FAQ document.

Tom

From: Thomas Emmendorfer <(b6)@va.gov>
Date: Friday, March 8, 2019 at 6:14 PM
To: Michael Valentino <(b6)@va.gov>
Cc: "Wiechers, Ilse" (b6)@va.gov, Jennifer Zacher <(b6)@va.gov>
Subject: FW: Spravato External Communication Draft

Hi Mike,

The external communication document is ready for your review.

Isle,

We agree with you on the (b) (5).

Jenn has made it clear to J&J that we need their educational materials as soon as possible.

Jenn,

Can you make sure J&J includes educational materials that are listed in their REMS form below as one of their deliverables to us?

Thank you,

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b6)@va.gov
Date: Friday, Mar 08, 2019, 5:35 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>, Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: RE: Spravato External Communication Draft

Hi Tom & Jenn –

Attached are my edits to the external document.

I've also made edits to the internal document as well, but still need some time to further flesh out the privileging and informed consent Q&A. I've attached the draft with edits and placeholders for those two last sections, that I hope we will have further fleshed out on Monday.

Regarding privileging: (b) (5)

More to come on Monday after further discussion with folks in Ethics and OMHSP re informed consent.

Thanks,
Ilse

(b) (5)

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 08, 2019 12:28 PM
To: Wiechers, Ilse (b6) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: Re: Spravato External Communication Draft

Hi Ilse,

Here is our first draft on the External Communication for your review. I used one of the Hep C. Communications from a few years ago as an example.

Tom

From: "Wiechers, Ilse" (b6) <(b6)@va.gov>
Date: Friday, March 8, 2019 at 3:03 PM
To: Jennifer Zacher <(b6)@va.gov>

Cc: Thomas Emmendorfer <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Internal Communication Draft

Got it – thanks. Keep me posted as more details are made clear in the coming days. I've started reading the documents they have made available on the Spravato REMS webpage to try to familiarize myself as well.

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:44 AM
To: Wiechers, Ilse (b6) [REDACTED]@va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Internal Communication Draft

Hi,

Based on (b) (5) [REDACTED]

[REDACTED]

[REDACTED]. I will know more in the next day or two though, and I will keep you posted.

JZ

From: Wiechers, Ilse
Sent: Friday, March 08, 2019 1:41 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato Internal Communication Draft

Thanks – will take a look shortly. I still haven't heard back from ethics, the iMed consent issues will likely need some time next week to further sort out.

Also – regarding the (b) (5) [REDACTED]

[REDACTED]

Ilse

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:27 AM
To: Wiechers, Ilse (b6) [REDACTED]@va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: Spravato Internal Communication Draft

Hi Ilse,

As per your conversation with Tom earlier, attached is a draft internal communication that we developed related to Spravato. Can you please review, add any edits you might have and then send back to us?

Thanks much!

Jennifer

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6)@va.gov

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6)@va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Sent Date:	2019/03/12 10:10:24
Delivered Date:	2019/03/12 10:10:25

To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
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Subject:	RE: Spravato External Communication Draft
Date:	2019/03/11 19:40:10
Priority:	Normal
Type:	Note

Hi Ilse. Thank you and the OMHSP for your thoughtful assistance and rapid responses.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 3:53 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Llorente, Maria D. <(b6)@va.gov>
Cc: Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: RE: Spravato External Communication Draft

I think it makes sense to (b) (5)

[REDACTED]

[REDACTED]

Do providers need to have special privileging to prescribe Spravato®?

ANSWER: (b) (5)

[REDACTED]

[REDACTED]

What do you think?
Ilse

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Sent: Monday, March 11, 2019 12:37 PM
To: Llorente, Maria D. <(b6)@va.gov>
Cc: Wiechers, Ilse <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>
Subject: Re: Spravato External Communication Draft

Hi Maria,

The internal communication (Frequently Asked Question) document is ready for your review.

Ilse,

(b) (5)

Does that sound reasonable to you?

Thank you!

Tom

From: Thomas Emmendorfer <(b6)@va.gov>

Date: Monday, March 11, 2019 at 10:28 AM

To: "Llorente, Maria D." <(b6)@va.gov>

Cc: "Wiechers, Ilse" <(b6)@va.gov>, Michael Valentino <(b6)@va.gov>, Jennifer Zacher <(b6)@va.gov>

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Hi Maria,

The external communication is ready for your review.

We are working on finalizing the internal FAQ document.

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From: Thomas Emmendorfer <(b6)@va.gov>

Date: Friday, March 8, 2019 at 6:14 PM

To: Michael Valentino <(b6)@va.gov>

Cc: "Wiechers, Ilse" <(b6)@va.gov>, Jennifer Zacher <(b6)@va.gov>

Subject: FW: Spravato External Communication Draft

Hi Mike,

The external communication document is ready for your review.

Isle,

(b) (5)

Jenn has made it clear to J&J that we need their educational materials as soon as possible.

Jenn,

Can you make sure J&J includes educational materials that are listed in their REMS form below as one of their deliverables to us?

Thank you,

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Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b6) [REDACTED]@va.gov>

Date: Friday, Mar 08, 2019, 5:35 PM

To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>, Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>

Subject: RE: Spravato External Communication Draft

Hi Tom & Jenn –

Attached are my edits to the external document.

I've also made edits to the internal document as well, but still need some time to further flesh out the (b) (5) [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED] I would appreciate your thoughts on this and how PBM processes might be employed to address this need.

More to come on Monday after further discussion with folks in Ethics and OMHSP re informed consent.

Thanks,
Ilse

(b) (5)

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Sent: Friday, March 08, 2019 12:28 PM
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Cc: Thomas Emmendorfer <(b6)@va.gov>
Subject: RE: Spravato Internal Communication Draft

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Subject: RE: Spravato Internal Communication Draft

Hi,

Based on how (b) (5)

I will know more in the next day or two though, and I will keep you posted.

JZ

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Subject: RE: Spravato Internal Communication Draft

Thanks – will take a look shortly. I still haven't heard back from ethics, the iMed consent issues will likely need some time next week to further sort out.

Also – regarding the (b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

Ilse

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Thanks much!

Jennifer

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)
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Sent Date:	2019/03/11 19:40:22

Delivered Date:	2019/03/11 19:40:10
Message Flags:	Unread Unsent

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) @va.gov>
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Subject:	RE: Spravato External Communication Draft
Date:	2019/03/12 16:22:19
Priority:	Normal
Type:	Note

Looks good.

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Zacher, Jennifer L. (PBM) <(b6) @va.gov>
Subject: RE: Spravato External Communication Draft

Attached FAQ document ready for final review and clearance.

Question 7 Answer: Changed "OMHO" to "OMHSP"

Question 10 Answer: Changed from "TBD" to "No"

Question 11 Answer: Changed from "TBD" to "Yes. An Update will be provided by OMSHP by March 18, 2019."

From: Emmendorfer, Thomas (PBM)
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Hi Maria,

The internal communication (Frequently Asked Question) document is ready for your review.

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Our thought was (b) (5)

Does that sound reasonable to you?

Thank you!

Tom

From: Thomas Emmendorfer <(b6)@va.gov>
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Hi Tom & Jenn –

Attached are my edits to the external document.

I've also made edits to the internal document as well, but still need some time to further flesh out the privileging and informed consent Q&A. I've attached the draft with edits and placeholders for those two last sections, that I hope we will have further fleshed out on Monday.

Regarding (b) (5) [REDACTED]

[REDACTED]

[REDACTED]

More to come on Monday after further discussion with folks in Ethics and OMHSP re informed consent.

Thanks,
Ilse

(b) (5) [REDACTED]

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[REDACTED]

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Delivered Date:	2019/03/12 16:22:19

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Subject:	RE: Spravato External Communication Draft
Date:	2019/03/12 10:55:35
Priority:	Normal
Type:	Note

Perfect! I am going to setup the call from 3pm eastern and send the calendar invite.

From: Wiechers, Ilse
Sent: Tuesday, March 12, 2019 10:18 AM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Spravato External Communication Draft

Alright – I’m free from 12 noon PT/ 3 pm onward for a call.

From: Emmendorfer, Thomas (PBM)
Sent: Tuesday, March 12, 2019 7:00 AM
To: Llorente, Maria D. <(b6) [REDACTED]@va.gov>; Wiechers, Ilse <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: Re: Spravato External Communication Draft

Hi Ilse,

I will setup the call for us today. By chance will a call starting at 3pm eastern work for you?

If not, could you send me your availability starting at 3pm eastern?

Thank you,

Tom

From: "Llorente, Maria D." <(b6) va.gov>
Date: Tuesday, March 12, 2019 at 8:20 AM
To: "Wiechers, Ilse" (b6) @va.gov>, Thomas Emmendorfer <(b6) va.gov>
Cc: Michael Valentino <(b6) va.gov>, Jennifer Zacher <(b6) va.gov>
Subject: RE: Spravato External Communication Draft

Ok, we will set up a call. Appreciate all the work you and your team have completed.

From: Wiechers, Ilse
Sent: Monday, March 11, 2019 8:42 PM
To: Llorente, Maria D. <(b6) va.gov>; Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Spravato External Communication Draft

Maria -

I think talking through how to operationalize this at a facility level would benefit from a call. And I'm honestly not sure re sorting out iMed consent by April 1. My understanding from people who've worked on these before is they can take some time, but perhaps with the urgency to implement this as soon as possible we can navigate the process more quickly. I'll make a couple more contacts with people tomorrow and give a more firm time line for this piece by end of day.

Ilse

Sent with BlackBerry Work
(www.blackberry.com)

From: Llorente, Maria D. <(b6) va.gov>
Date: Monday, Mar 11, 2019, 5:28 PM
To: Wiechers, Ilse (b6) @va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: Spravato External Communication Draft

Hi Ilse. We have an update due to Dr. Stone on April 1. Do you think there will be enough time to resolve the imed consent by then?

I agree in principle with your response below. However, would like to discuss how to operationalize at the facility level with input from both PBM and OMHSP. Do you think this is something we can do via email, or should we plan to have a call?

From: Wiechers, Ilse

Sent: Monday, March 11, 2019 3:53 PM

To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Llorente, Maria D. <(b6)@va.gov>

Cc: Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Subject: RE: Spravato External Communication Draft

I think it makes (b) (5)

[REDACTED]

[REDACTED]

Do providers need to have special privileging to prescribe Spravato®?

ANSWER: (b) (5)

[REDACTED]

[REDACTED]

What do you think?

Ilse

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[REDACTED]

[REDACTED]).

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Thank you!

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From:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Subject:	RE: Spravato External Communication Draft
Date:	2019/03/11 20:24:00
Priority:	Normal
Type:	Note

Agreed.

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 11, 2019 3:37 PM
To: Llorente, Maria D. <(b6) va.gov>
Cc: Wiechers, Ilse <Ilse.Wiechers@va.gov>; Valentino, Michael (VACO) <(b6) va.gov>;
Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: Re: Spravato External Communication Draft

Hi Maria,

The internal communication (Frequently Asked Question) document is ready for your review.

Ilse,

(b) (5)

Does that sound reasonable to you?

Thank you!

Tom

From: Thomas Emmendorfer <(b6) va.gov>
Date: Monday, March 11, 2019 at 10:28 AM
To: "Llorente, Maria D." <(b6) va.gov>

Cc: "Wiechers, Ilse" (b6) [REDACTED]@va.gov, Michael Valentino <(b6) [REDACTED]va.gov>, Jennifer Zacher <(b6) [REDACTED]va.gov>

Subject: FW: Spravato External Communication Draft

Hi Maria,

The external communication is ready for your review.

We are working on finalizing the internal FAQ document.

Tom

From: Thomas Emmendorfer <(b6) [REDACTED]va.gov>

Date: Friday, March 8, 2019 at 6:14 PM

To: Michael Valentino <(b6) [REDACTED]va.gov>

Cc: "Wiechers, Ilse" (b6) [REDACTED]@va.gov, Jennifer Zacher <(b6) [REDACTED]va.gov>

Subject: FW: Spravato External Communication Draft

Hi Mike,

The external communication document is ready for your review.

Isle,

(b) (5) [REDACTED]

Jenn has made it clear to J&J that we need their educational materials as soon as possible.

Jenn,

Can you make sure J&J includes educational materials that are listed in their REMS form below as one of their deliverables to us?

Thank you,

Tom

Sent with BlackBerry Work
(www.blackberry.com)

From: Wiechers, Ilse (b6) [REDACTED]@va.gov

Date: Friday, Mar 08, 2019, 5:35 PM

To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>, Zacher, Jennifer L. (PBM) <(b6) [REDACTED]va.gov>

Subject: RE: Spravato External Communication Draft

Hi Tom & Jenn –

I've also made edits to the internal document as well, but still need some time to further flesh out the privileging and informed consent Q&A. I've attached the draft with edits and placeholders for those two last sections, that I hope we will have further fleshed out on Monday.

[illegible]

Thanks,
Ilse

(b) (5)

Here is our first draft on the External Communication for your review. I used one of the Hep C. Communications from a few years ago as an example.

Tom

From: "Wiechers, Ilse" (b6) [REDACTED]@va.gov>
Date: Friday, March 8, 2019 at 3:03 PM
To: Jennifer Zacher <(b6) [REDACTED]va.gov>
Cc: Thomas Emmendorfer <(b6) [REDACTED]va.gov>
Subject: RE: Spravato Internal Communication Draft

Got it – thanks. Keep me posted as more details are made clear in the coming days. I've started reading the documents they have made available on the Spravato REMS webpage to try to familiarize myself as well.

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:44 AM
To: Wiechers, Ilse (b6) [REDACTED]a.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>
Subject: RE: Spravato Internal Communication Draft

Hi,

Based on (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

IJZ

From: Wiechers, Ilse
Sent: Friday, March 08, 2019 1:41 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]va.gov>
Cc: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]va.gov>
Subject: RE: Spravato Internal Communication Draft

Thanks – will take a look shortly. I still haven't heard back from ethics, the iMed consent issues will likely need some time next week to further sort out.

Also – (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

Ilse

From: Zacher, Jennifer L. (PBM)
Sent: Friday, March 08, 2019 11:27 AM
To: Wiechers, Ilse (b6) [REDACTED]@va.gov>

Cc: Emmendorfer, Thomas (PBM) <(b6)@va.gov>

Subject: Spravato Internal Communication Draft

Hi Ilse,

As per your conversation with Tom earlier, attached is a draft internal communication that we developed related to Spravato. Can you please review, add any edits you might have and then send back to us?

Thanks much!

Jennifer

Jennifer L. Zacher, PharmD, BCPP
Associate Chief Consultant
VA Pharmacy Benefits Management Services

(b6)

(b6)@va.gov

Sender:	Llorente, Maria D. </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5C91F577D894BD9A0F09305DB34DD4F-LLORENTE, M>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Sent Date:	2019/03/11 20:24:19
Delivered Date:	2019/03/11 20:24:00

From:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
To:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>
CC:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Subject:	RE: Spravato External Communication Draft
Date:	2019/03/12 16:17:44
Priority:	Normal
Type:	Note

Attached FAQ document ready for final review and clearance.

Question 7 Answer: (b) (5)

Question 10 Answer: (b) (5)

Question 11 Answer: (b) (5)

From: Emmendorfer, Thomas (PBM)

Sent: Monday, March 11, 2019 3:37 PM

To: Llorente, Maria D. <(b6)@va.gov>;

Cc: Wiechers, Ilse <(b6)@va.gov>; Valentino, Michael (VACO)

<(b6)@va.gov>; Zacher, Jennifer L. (PBM)

<(b6)@va.gov>;

Subject: Re: Spravato External Communication Draft

Hi Maria,

The internal communication (Frequently Asked Question) document is ready for your review.

Ilse,

Our thought was to (b) (5)

Does that sound reasonable to you?

Thank you!

Tom

From: Thomas Emmendorfer <(b6)@va.gov>;

Date: Monday, March 11, 2019 at 10:28 AM

To: "Llorente, Maria D." <(b6)@va.gov>;

Cc: "Wiechers, Ilse" <(b6)@va.gov>; Michael Valentino

<(b6)@va.gov>; Jennifer Zacher <(b6)@va.gov>;

Subject: FW: Spravato External Communication Draft

(b) (5)

More to come on Monday after further discussion with folks in Ethics and OMHSP re informed consent.

Thanks,

Ilse

(b) (5)

From: Emmendorfer, Thomas (PBM)

Sent: Friday, March 08, 2019 12:28 PM

To: Wiechers, Ilse <(b) (5)@va.gov>; Zacher, Jennifer L. (PBM) & (b) (5)@va.gov>;

Subject: Re: Spravato External Communication Draft

Hi Ilse,

Here is our first draft on the External Communication for your review. I used one of the Hep C. Communications from a few years ago as an example.

Tom

From: "Wiechers, Ilse" <(b) (5)@va.gov>;

Date: Friday, March 8, 2019 at 3:03 PM

To: Jennifer Zacher <(b) (5)@va.gov>;

Cc: Thomas Emmendorfer <(b) (5)@va.gov>;

Subject: RE: Spravato Internal Communication Draft

Got it – thanks. Keep me posted as more details are made clear in the coming days. I've started reading the documents they have made available on the Spravato REMS webpage to try to familiarize myself as well.

From: Zacher, Jennifer L. (PBM)

Sent: Friday, March 08, 2019 11:44 AM

To: Wiechers, Ilse <(b) (5)@va.gov>;

Cc: Emmendorfer, Thomas (PBM) & (b) (5)@va.gov>;

Subject: RE: Spravato Internal Communication Draft

Hi,

Based on how this REMS is written, I don't think so. Right now (b) (5)

|| will know more in the next day or two though, and I will keep you posted.

JZ

From: Wiechers, Ilse

Sent: Friday, March 08, 2019 1:41 PM

To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>;

Cc: Emmendorfer, Thomas (PBM) <(b6)@va.gov>;

Subject: RE: Spravato Internal Communication Draft

Thanks – will take a look shortly. I still haven't heard back from ethics, the iMed consent issues will likely need some time next week to further sort out.

Also – (b) (5)

[REDACTED]

[REDACTED] cess.

Ilse

From: Zacher, Jennifer L. (PBM)

Sent: Friday, March 08, 2019 11:27 AM

To: Wiechers, Ilse <(b6)@va.gov>;

Cc: Emmendorfer, Thomas (PBM) <(b6)@va.gov>;

Subject: Spravato Internal Communication Draft

Hi Ilse,

As per your conversation with Tom earlier, attached is a draft internal communication that we developed related to Spravato. Can you please review, add any edits you might have and then send back to us?

Thanks much!

Jennifer

Jennifer L. Zacher, PharmD, BCPP

Associate Chief Consultant

VA Pharmacy Benefits Management Services

(b6)

(b6)@va.gov

Sender:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
Recipient:	Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <Ilse.Wiechers@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
Sent Date:	2019/03/12 16:17:43
Delivered Date:	2019/03/12 16:17:44

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6) va.gov>
To:	Pomerantz, Andrew /c=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, (b6) va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka (b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6) va.gov>
Subject:	RE: SPRAVATO draft informed consent
Date:	2019/03/14 16:02:43
Priority:	Normal
Type:	Note

(b) (5)

Sent with BlackBerry Work
(www.blackberry.com)

From: Pomerantz, Andrew <(b6) va.gov>
Date: Thursday, Mar 14, 2019, 12:34 PM
To: Carroll, David (VACO) <(b6) va.gov>, Katz, Ira R. <(b6) va.gov>, Wiechers, Ilse (b6) @va.gov>, VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Drexler, Karen MD (Atlanta) <(b6) va.gov>, Emmendorfer, Thomas (PBM) <(b6) va.gov>, Valentino, Michael (VACO) <(b6) va.gov>, Zacher, Jennifer L. (PBM) <(b6) va.gov>
Subject: RE: SPRAVATO draft informed consent

We're elevating this to the level of a procedure and that requires followup call. Perhaps we should be having such a call rather than waiting for the patient to call

(b6)

From: Carroll, David (VACO)

Sent: Thursday, March 14, 2019 3:14 PM

To: Katz, Ira R. (b6) <(b6)@va.gov>; Wiechers, Ilse (b6) <(b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>

Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Subject: RE: SPRAVATO draft informed consent

All the comments are making this better. I appreciate Ira's question about (b) (5)

From: Katz, Ira R.

Sent: Thursday, March 14, 2019 3:01 PM

To: Wiechers, Ilse <(b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>

Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Subject: RE: SPRAVATO draft informed consent

I wonder if it would make (b) (5)

From: Wiechers, Ilse

Sent: Thursday, March 14, 2019 11:49 AM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>

Cc: Katz, Ira R. (b6) <(b6)@va.gov>; Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>

Subject: SPRAVATO draft informed consent

Importance: High

Hello everyone –

I am sending this message to a larger combined OMHSP and PBM group all at once, to get as many eyes on this as I can quickly. Please find attached the following:

1. • VA Form 10-0431a – prepopulated for use with SPRAVATO
2. • SPRAVATO pi (prescribing information) document – includes detailed risks/adverse events list and graphics describing use/administration of the device
3. • SPRAVATO medication guide – patient-friendly language, to be given as patient education handout

Plan moving forward once we have concurrence on the language in the 10-0431a would be as follows:

- Disseminate these 3 documents with outgoing 10N memo for use as hardcopies in the field in the short term
- Send materials to iMed for digital processing, ETA on electronic version 2-3 weeks from receipt

If there are other SMEs who you feel should review this, please forward for their input. Please provide feedback on this by **COB today**.

Thanks!

Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell: (b6)

email: (b6)@va.gov | (b6)@yale.edu

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Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6)@va.gov>
Recipient:	Pomerantz, Andrew /c=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29a9288df9a34e84bddfd00cde79f11b-Pomerantz, <(b6)@va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6)@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka

<(b6) va.gov>;
Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer
<(b6) va.gov>;
Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino,
<(b6) va.gov>;
Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen
<(b6) va.gov>

Sent Date: 2019/03/14 16:02:42

Delivered Date: 2019/03/14 16:02:43

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
To:	Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka (b6)@va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma (b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
CC:	Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer (b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6)@va.gov>
Subject:	RE: SPRAVATO draft informed consent
Date:	2019/03/14 14:41:33
Priority:	Normal
Type:	Note

Thanks, Karen & Marsden for the feedback. I'll work to incorporate these changes.

Re (b) (5)

Ilse

From: Drexler, Karen MD (Atlanta)
Sent: Thursday, March 14, 2019 11:26 AM
To: McGuire, Marsden H. (b6)@va.gov>; Wiechers, Ilse (b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. (b6)@va.gov>; Emmendorfer, Thomas (PBM) (b6)@va.gov>; Valentino, Michael (VACO) (b6)@va.gov>; Zacher, Jennifer L. (PBM) (b6)@va.gov>
Subject: RE: SPRAVATO draft informed consent

Dear Ilse,

Thank you for taking the lead on this and for the chance to review.

I think the (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]"

-Karen

From: McGuire, Marsden H.

Sent: Thursday, March 14, 2019 2:13 PM

To: Wiechers, Ilse (b6) [REDACTED]@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>

Cc: Katz, Ira R. (b6) [REDACTED]@va.gov>; Drexler, Karen MD (Atlanta) <(b6) [REDACTED]va.gov>;

Emmendorfer, Thomas (PBM) <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO)

<(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED] va.gov>

Subject: RE: SPRAVATO draft informed consent

My comments on Form 10-0431a:

4) (b5)

8) (b5) [REDACTED]
[REDACTED]?

9) (b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

10)(b5) [REDACTED] ?

11) (b5) [REDACTED]
[REDACTED])"

12)(b5) _____
 _____)"

M

From: Wiechers, Ilse

Sent: Thursday, March 14, 2019 11:49 AM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>

Cc: Katz, Ira R. <(b6)@va.gov>; Drexler, Karen MD (Atlanta) <(b6)va.gov>; Emmendorfer, Thomas (PBM) <(b6)va.gov>; Valentino, Michael (VACO) <(b6)va.gov>; Zacher, Jennifer L. (PBM) <(b6)va.gov>

Subject: SPRAVATO draft informed consent

Importance: High

Hello everyone –

I am sending this message to a larger combined OMHSP and PBM group all at once, to get as many eyes on this as I can quickly. Please find attached the following:

1. • VA Form 10-0431a – prepopulated for use with SPRAVATO
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3. • SPRAVATO medication guide – patient-friendly language, to be given as patient education handout

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Thanks!

Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell (b6)

email: (b6).gov | (b6)yale.edu

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Sender: Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

	(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6F04F-WIECHERS, I <(b6) [REDACTED] va.gov>
Recipient:	Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bd09b6f88bdf45-Drexler, Ka <(b6) [REDACTED] va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) [REDACTED] va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) [REDACTED] va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED] va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED] va.gov>
Sent Date:	2019/03/14 14:41:31
Delivered Date:	2019/03/14 14:41:33

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
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CC:	Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b6)@va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka (b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen (b6)@va.gov>
Subject:	RE: SPRAVATO draft informed consent
Date:	2019/03/14 14:46:15
Priority:	Normal
Type:	Note

Thanks, Tom.

I had the same question (b) (5))?

Also – we may run out of space in the administration section with your edits (though I like them) – I’ll reach out and we can backchannel to wordsmith something that fits into space provided in the box.

Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 14, 2019 11:42 AM
To: McGuire, Marsden H. (b6)@va.gov>; Wiechers, Ilse (b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: Katz, Ira R. <Ira.Katz2@va.gov>; Drexler, Karen MD (Atlanta) (b6)@va.gov>; Valentino, Michael (VACO) (b6)@va.gov>; Zacher, Jennifer L. (PBM) (b6)@va.gov>
Subject: RE: SPRAVATO draft informed consent

Hi Ilse,

I reviewed the administration section of the form and have a few suggests in "purple below".

Also, (b) (5)

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Tom

From: McGuire, Marsden H.

Sent: Thursday, March 14, 2019 2:13 PM

To: Wiechers, Ilse <(b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>

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<(b6)va.gov>; Zacher, Jennifer L. (PBM) <(b6)va.gov>

Subject: RE: SPRAVATO draft informed consent

My comments on Form 10-0431a:

4) (b5) "

8) (b5)

al?

9) (b5)

10) (b5) ?

11) (b5)

)"

12) (b5)

)"

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Sent Date:	2019/03/14 14:46:11
Delivered Date:	2019/03/14 14:46:15

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
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Subject:	RE: SPRAVATO draft informed consent
Date:	2019/03/14 14:52:32
Priority:	Normal
Type:	Note

So we've got 475 characters in the administration box. Text + spaces below = 527.

I'm about to head out to a F2F meeting at Palo Alto VA, but will get back online around 2:15 PT, and will see what I can do to condense this then.

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Subject: RE: SPRAVATO draft informed consent

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4) (b) (5) "

8) (b) (5) [REDACTED]
[REDACTED] ?

9) (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]."

10) (b) (5) [REDACTED]

11) (b) (5) [REDACTED]
[REDACTED])"

12) (b) (5) [REDACTED]
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Sent Date:	2019/03/14 14:52:31
Delivered Date:	2019/03/14 14:52:32

To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
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Subject:	RE: SPRAVATO draft informed consent
Date:	2019/03/14 14:38:24
Priority:	Normal
Type:	Note

Hi Ilse,

Consider (b) (5)

[REDACTED]

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	<(b6) [REDACTED] va.gov>
Sent Date:	2019/03/14 14:31:56
Delivered Date:	2019/03/14 14:38:24
Message Flags:	Unread Unsent

From:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>
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Priority:	Normal
Type:	Note

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[REDACTED]

[REDACTED]x.

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1. • VA Form 10-0431a – prepopulated for use with SPRAVATO
2. • SPRAVATO pi (prescribing information) document – includes detailed risks/adverse events list and graphics describing use/administration of the device

3. • SPRAVATO medication guide – patient-friendly language, to be given as patient education handout

Plan moving forward once we have concurrence on the language in the 10-0431a would be as follows:

- • Disseminate these 3 documents with outgoing 10N memo for use as hardcopies in the field in the short term
- • Send materials to iMed for digital processing, ETA on electronic version 2-3 weeks from receipt

If there are other SMEs who you feel should review this, please forward for their input. Please provide feedback on this by **COB today**.

Thanks!

Ilse

Ilse R. Wiechers, MD, MPP, MHS

National Director, Psychotropic Drug Safety Initiative (PDSI)

Co-Director, Care for Patients with Complex Problems (CP)²

Associate Director, Northeast Program Evaluation Center

Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs

Assistant Clinical Professor of Psychiatry, Yale University School of Medicine

cell: (b6)

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Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Sent Date:	2019/03/14 14:46:11
Delivered Date:	2019/03/14 14:46:14
Message Flags:	Unread

From:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6) [REDACTED]@va.gov>
To:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED]@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>
Subject:	RE: Spravato A word to the Wise
Date:	2019/06/18 12:04:04
Priority:	Normal
Type:	Note

Thanks Mike.

Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Date: Tuesday, Jun 18, 2019, 10:35 AM
To: Wiechers, Ilse <(b6) [REDACTED]@va.gov>, Llorente, Maria D. <(b6) [REDACTED]@va.gov>, Glassman, Peter A. <(b6) [REDACTED]@va.gov>, Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>, Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Subject: FW: Spravato A word to the Wise

Sent with BlackBerry Work
(www.blackberry.com)

From: Itebejac, Ivan S. <(b6) [REDACTED]@va.gov>
Date: Tuesday, Jun 18, 2019, 9:19 AM
To: VHAPBM VPE Formulary Committee <VPEFormularyCommittee@va.gov>
Subject: FW: re: Spravato A word to the Wise

Heads up

From: Gardner, Bryan J.
Sent: Tuesday, June 18, 2019 9:20 AM

To: VHA Clinical Pharmacists <vha.clinical.pharmacists@va.gov>
Subject: RE: re: Spravato

And case in point others are concerned as well.

https://www.medscape.com/viewarticle/914296?src=wnl_edit_tpal&uac=102049SV&impID=1993887&af=1#vp_2

Bryan

From: Gardner, Bryan J.
Sent: Tuesday, June 18, 2019 8:53 AM
To: VHA Clinical Pharmacists <vha.clinical.pharmacists@va.gov>
Subject: re: Spravato

I know Spravato is being hailed as new potentially miracle option in the treatment of depression for our Veterans and I hope it is. But given changes for approval that were made at the FDA when approving this drug, the speed to which pricing was nailed down, and the push for access in the VA. Not sure if others feel this way, but (b6)

(b6)
(b6)

Just my thoughts and concerns.

Bryan

Sender:	Glassman, Peter A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90608D43EF14423DB308FB6C71ED750B-GLASSMAN, P <(b6)@va.gov>
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Delivered Date:	2019/06/18 12:04:04
Message Flags:	Unread

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CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <(b6) [REDACTED]@va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) [REDACTED]@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED]@va.gov>
Subject:	RE: Spravato 10N memo materials - full packet for final review
Date:	2019/03/15 12:55:18
Priority:	Normal
Type:	Note

Thanks, Dave.

I think within 30 days is reasonable, though I recall Maria & Tom indicating the next update with Dr. Stone on this is scheduled for April 1st. So I will defer to them on due date.

Ilse

From: Carroll, David (VACO)
Sent: Friday, March 15, 2019 9:32 AM
To: McGuire, Marsden H. <(b6) [REDACTED]@va.gov>; Wiechers, Ilse <(b6) [REDACTED]@va.gov>;
Cc: VHA 10NC5 Action <(b6) [REDACTED]@va.gov>; Drexler, Karen MD (Atlanta) <(b6) [REDACTED]@va.gov>; Katz, Ira R. <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>;
Subject: RE: Spravato 10N memo materials - full packet for final review
Cleared for 10NC5 – with two caveats. (b) (5)

[REDACTED] bly

(b) (5)

I did not include all of the attachments here – Ilse sent them last evening at 6:52 PM. Thanks.

From: McGuire, Marsden H.

Sent: Friday, March 15, 2019 10:50 AM

To: Wiechers, Ilse <(b6)@va.gov>;

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Katz, Ira R. <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>;

Valentino, Michael (VACO) <(b6)@va.gov>;

Llorente, Maria D. <(b6)@va.gov>;

Subject: RE: Spravato 10N memo materials - full packet for final review

All good from my vantage point, Ilse. Great work.

M

From: Wiechers, Ilse

Sent: Thursday, March 14, 2019 6:52 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta)

<(b6)@va.gov>; Katz, Ira R. <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Zacher, Jennifer L. (PBM) <(b6)@va.gov>;

Valentino, Michael (VACO) <(b6)@va.gov>;

Llorente, Maria D. <(b6)@va.gov>;

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4. • Attachment C: Informed Consent Materials
 - a. • Attachment C1: VA Form 10-1043a pre-filled for esketamine
 - b. • Attachment C2: Spravato REMS prescribing information document
 - c. • Attachment C3: Spravato REMS medication guide

The 10N memo has been split, (b) (5)

[REDACTED]

– (b) (5)

[REDACTED]

(b) (5)

(b) (5)

If this all looks good, let's proceed to send it up for clearance.
Thanks to everyone for your help moving this along so quickly!
Ilse

Sender:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>
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Subject:	RE: Spravato 10N memo materials - full packet for final review
Date:	2019/03/15 09:38:34
Priority:	Normal
Type:	Note

Hi Ilse,
Great job on all of this! No edits from me on the Draft Memo or the Healthcare Setting Certification Guidance.

I did copy the Esketamine Frequently Asked Questions document as well.

NOTE: Some responses state additional guidance will be provided on 3/18.

Tom

From: Wiechers, Ilse

Sent: Thursday, March 14, 2019 6:52 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta) <(b6) [REDACTED]@va.gov>; Katz, Ira R. <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>;

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If this all looks good, let's proceed to send it up for clearance.

1003	Sender: Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED] va.gov>
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1004	Recipient: Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) [REDACTED] va.gov>;
	Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) [REDACTED] va.gov>;
	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group

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From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b6)@va.gov>
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Thanks, Dave.

I think within 30 days is reasonable, though I recall Maria & Tom indicating the next update with Dr. Stone on this is scheduled for April 1st. So I will defer to them on due date.

Ilse

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Sent: Friday, March 15, 2019 9:32 AM
To: McGuire, Marsden H. (b6)@va.gov>; Wiechers, Ilse <Ilse.Wiechers@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta) (b6)@va.gov>; Katz, Ira R. (b6)@va.gov>; Emmendorfer, Thomas (PBM) (b6)@va.gov>; Zacher, Jennifer L. (PBM) (b6)@va.gov>; Valentino, Michael (VACO) (b6)@va.gov>; Llorente, Maria D. (b6)@va.gov>
Subject: RE: Spravato 10N memo materials - full packet for final review

Cleared for 10NC5 – with two caveats. (b) (5)

Otherwise it can go forward from my perspective. I did not include all of the attachments here – Ilse sent them last evening at 6:52 PM. Thanks.

From: McGuire, Marsden H.

Sent: Friday, March 15, 2019 10:50 AM

To: Wiechers, Ilse (b6) @va.gov>

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta)

<(b6) va.gov>; Katz, Ira R. (b6) @va.gov>; Emmendorfer, Thomas (PBM)

<(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino,

Michael (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>

Subject: RE: Spravato 10N memo materials - full packet for final review

All good from my vantage point, Ilse. Great work.

M

From: Wiechers, Ilse

Sent: Thursday, March 14, 2019 6:52 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta)

<(b6) va.gov>; Katz, Ira R. (b6) @va.gov>; Emmendorfer, Thomas (PBM)

<(b6) va.gov>; Zacher, Jennifer L. (PBM) <(b6) va.gov>; Valentino,

Michael (VACO) <(b6) va.gov>; Llorente, Maria D. <(b6) va.gov>

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Here's a full packet of revised materials for the Spravato memo.

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 - a. • Attachment C1: VA Form 10-1043a pre-filled for esketamine
 - b. • Attachment C2: Spravato REMS prescribing information document
 - c. • Attachment C3: Spravato REMS medication guide

(b) (5)

(b) (5)

?

- (b) (5)

If this all looks good, let's proceed to send it up for clearance.

Thanks to everyone for your help moving this along so quickly!

Ilse

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6) va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da <(b6) va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED] va.gov>
Sent Date:	2019/03/15 12:55:16
Delivered Date:	2019/03/15 12:55:18

From:	Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96B44E7AE2C94C43B55D094-EMMENDORFER <(b6) [REDACTED]@va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) [REDACTED]@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) [REDACTED]@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6) [REDACTED]@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6) [REDACTED]@va.gov>
Subject:	RE: Spravato 10N memo materials - full packet for final review
Date:	2019/03/15 09:38:35
Priority:	Normal
Type:	Note

Hi Ilse,

Great job on all of this! No edits from me on the Draft Memo or the Healthcare Setting Certification Guidance.

I did copy the Esketamine Frequently Asked Questions document as well.

NOTE: Some responses state additional guidance will be provided on 3/18.

Tom

From: Wiechers, Ilse

Sent: Thursday, March 14, 2019 6:52 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta)

<(b6) [REDACTED]@va.gov>; Katz, Ira R. <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM)

<(b6) [REDACTED]@va.gov>; Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>; Valentino,

Michael (VACO) <(b6) [REDACTED]@va.gov>; Llorente, Maria D. <(b6) [REDACTED]@va.gov>

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(b) (5)

•

[Redacted]

[Redacted]

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Thanks to everyone for your help moving this along so quickly!
Ilse

Sender: Emmendorfer, Thomas (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER <(b6)@va.gov>

	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6)@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6)@va.gov>; Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>; Law, Cassandra M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f888d507d6c54eb5a92fc44199eb5838-Law, Cassan <(b6)@va.gov>
Recipient:	
Sent Date:	2019/03/15 09:38:30
Delivered Date:	2019/03/15 09:38:35

From:	Smith, Clifford A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B729882079394F37AF66F66722F99400-SMITH, CLIF (b6) @va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: Spravato (esketamine) iMed documents
Date:	2019/03/26 14:54:02
Priority:	Normal
Type:	Note

Approved.

Blaze on!

From: Wiechers, Ilse
Sent: Tuesday, March 26, 2019 10:00 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: FW: Spravato (esketamine) iMed documents

Hello 10NC5 Action –

Please see highlighted text below from iMed consent. Do I have authority to act on behalf of Mental Health to finalize these Spravato iMed consent documents?

Thanks,
Ilse

From: Tompkins, Paul A.
Sent: Tuesday, March 26, 2019 6:24 AM
To: Wiechers, Ilse (b6) @va.gov>; (b6) taylorcommunications.com) <(b6) @taylorcommunications.com>; (b6) (b6) @taylorcommunications.com>
Cc: Strickland, Julie A (b6) @va.gov>
Subject: FW: Spravato (esketamine) iMed documents

Ilse – Thanks for the documents. A couple of notes/questions...

In the consent form, you added the following text to the “Comments” section. (b) (5)

[REDACTED]

(b) (5) [REDACTED]

[REDACTED]

(b) (5) [REDACTED]

[REDACTED]

[REDACTED]

(b6) [REDACTED] y (iMedConsent™ contractors) – This is a new FDA approved treatment, that will need your support. Feel free to respond with any relevant input.

(b6) [REDACTED] | Program Analyst | National Center for Ethics in Health Care (10E1E) | Office –
(b6) [REDACTED] [va.gov](https://www.va.gov)

From: Wiechers, Ilse
Sent: Monday, March 25, 2019 2:53 PM
To: Tompkins, Paul A. <(b6) [REDACTED] [va.gov](mailto:[REDACTED]@va.gov)>
Subject: Spravato (esketamine) iMed documents

Hi Paul –

I have materials for you to start the process for iMed consent for Spravato (esketamine). Attached are the following:

1. • Form 10-0431a pre-filled for Spravato (esketamine)
2. • Spravato REMS prescribing information
3. • Spravato REMS medication guide
4. • Spravato REMS instructions for use

Items 2-4 come from the FDA REMS and are materials we want providers to be able to print and review with patients when completing informed consent.

Let me know if you have any questions about these materials. I have a few sites that can help pilot this once it is ready to go. I'd be grateful if you could give me a sense after looking at the materials on the timeline on your end.

Thanks so much for your help!
Ilse

Sender:	Smith, Clifford A. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B729882079394F37AF66F66722F99400-SMITH, CLIF <(b6)@va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/26 14:54:01
Delivered Date:	2019/03/26 14:54:02

From:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA <(b6)@va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: Spravato (esketamine) iMed documents
Date:	2019/03/26 19:08:32
Priority:	Normal
Type:	Note

You have authority to act on behalf of the Office of Mental Health and Suicide Prevention. Thank you.

David Carroll, PhD
Executive Director, Office of Mental Health and Suicide Prevention (10NC5)

(b6)

Suicide Prevention is Everyone's Business. **#BeThere.**



[cid:image003.jpg@01D34E71.BBA06B80](#)

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(b) (5)

(b) (5)

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Paul Tompkins | Program Analyst | National Center for Ethics in Health Care (10E1E) | Office – (b6) 0281 | (b6)@va.gov

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Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)>@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/26 19:08:31
Delivered Date:	2019/03/26 19:08:32

From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
Subject:	RE: Spravato
Date:	2019/03/18 14:29:00
Priority:	Normal
Type:	Note

Agree.

We only need the educational programming they developed for ALL their customers. We do NOT want anything created specifically for VA.

It would also be great to get a look at the sales piece to see if it 100% conforms to the labeling.....

Mike

From: Zacher, Jennifer L. (PBM)
Sent: Monday, March 18, 2019 2:12 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Cc: Valentino, Michael (VACO) <(b6) va.gov>
Subject: RE: Spravato

Hi,
I was given a sales piece on the value that this product offers a healthcare system. I did have someone review, and I will respond to them today....

In terms of (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

From what Phillip was told, the product was shipped to McKesson today and should be available some time this week. It isn't loaded into McKesson as of right now...

More to come!
JZ

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 18, 2019 11:56 AM

To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: Spravato

Hi Jenn,

By chance, did J&J provide the educational materials for review by March 15th and did they confirm if Spravato® is in the supply chain today for VA medical facilities to order?

I think I know the answer to both 😊

Tom

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
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Sent Date:	2019/03/18 14:30:01
Delivered Date:	2019/03/18 14:29:00

To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) [REDACTED]@va.gov>
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Subject:	RE: Spravato
Date:	2019/03/18 14:28:15
Priority:	Normal
Type:	Note

Thank you Jenn!

Could you send us a copy of the sales piece that J&J provided (realizing it is still being reviewed)?

Now that Rob is back in the office, is Phillip working with someone from Clinical Informatics on the Pharmacy guidance to provide to the VA medical facilities on how to maintain dispensing records? Last Friday, I was working with Lynn on a different topic (bad permanent addresses) and she thinks the Inpatient Meds for Outpatient Use (Class III) has been replaced with something called "Clinic Orders" (Class I).

Also, what are your thoughts on (b) (5) [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED].

Tom

From: Zacher, Jennifer L. (PBM)
Sent: Monday, March 18, 2019 2:12 PM
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Sent Date:	2019/03/18 14:22:41
Delivered Date:	2019/03/18 14:28:15
Message Flags:	Unread Unsent

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Subject:	RE: SMEs/Talking Points for Spravato® (esketamine)
Date:	2019/03/22 09:24:07
Priority:	Normal
Type:	Note

Good morning, and thanks Tom! I will clear.

From: Emmendorfer, Thomas (PBM)
Sent: Friday, March 22, 2019 7:10 AM
To: Smith, Monica (VACO) <(b6) va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Monica,

Very good point. I made the edit to the sentence so it matches exactly what is in the press release....

If OPIA gets a question from a reporter on the number of Veterans that will receive the drug, the sentence in red below is the suggested response (b) (5)

[REDACTED]

If Ilse concurs, I think this should be the updated response:

2. • (b) (5)

[REDACTED]?

(b) (5)

[REDACTED]

From: Smith, Monica (VACO)
Sent: Thursday, March 21, 2019 2:29 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Tom – While prepping for the news release, I thought this sentence caused confusion (b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED] ans.

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:48 PM
To: VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Adding communications team for review and clearance

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 1:43 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Smith, Avery <(b6) [REDACTED]@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

I concur.

CC'ing 10NC5 Action FYSA.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 21, 2019 10:42 AM
To: Smith, Avery <(b6) [REDACTED]@va.gov>; Wiechers, Ilse <(b6) [REDACTED]@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Avery,

If OPIA gets a question from a reporter on the number of Veterans that will receive the drug, the sentence in red below is the suggested response. (b) (5) [REDACTED],

(b) (5)

If Ilse concurs, I think this should be the updated response:

2. • (b) (5)

?

(b) (5)

From: Smith, Avery

Sent: Thursday, March 21, 2019 1:32 PM

To: Wiechers, Ilse (b6) <(b6)@va.gov>; Emmendorfer, Thomas (PBM)

<(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>

Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Ok so you are sending me and update??

From: Wiechers, Ilse

Sent: Thursday, March 21, 2019 1:25 PM

To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Smith, Avery

Ilse <(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>

Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

I agree with Tom that we should stick with a broad statement.

Ilse

From: Emmendorfer, Thomas (PBM)

Sent: Thursday, March 21, 2019 10:22 AM

To: Smith, Avery Ilse <(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Wiechers, Ilse

<(b6)@va.gov>

Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Avery,

I have included Ilse to the e-mail as I believe the PERC has been working on potential estimates of eligible Veterans....Saying that, I think the answer should be a broad statement that the number of

eligible Veterans will be evaluated on a case by case basis by the VA provider and the individual Veteran's health care needs.

Tom

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:18 PM
To: VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
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Sorry, 10P4P, you are just getting this,

Can you review and let me know how long you will need to respond, need as soon as possible?

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Thursday, March 21, 2019 6:53 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Good morning,

Please review the request below and submit your concurrence to **10P NLT 11 a.m., today.**

Request:

Will you look at the below request from OPIA and let us know if you concur on items 1 and 2.

Requesting responses by tomorrow (March 21) by noon ET.

V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b6)
Cell: (b6)
Email: (b6) [va.gov](mailto:(b6)@va.gov)

From: Greilsamer, Alan

Sent: Wednesday, March 20, 2019 6:18 PM

To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10N Action <VHA10NAction@va.gov>

Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

10P, 10N,

Will you look at the below request from OPIA and let us know if you concur on items 1 and 2.

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Thanks, Alan

From: Mojay, Ndidi <(b6) [REDACTED]@va.gov>

Date: Wednesday, Mar 20, 2019, 2:58 PM

To: Greilsamer, Alan <(b6) [REDACTED]@va.gov>

Cc: Carter, Susan <(b6) [REDACTED]@va.gov>, Noller, Randal <(b6) [REDACTED]@va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Alan,

Can you check with your folks? Is this accurate to say? Need this today.

1. • Do vets have any out of pocket costs associated with taking this drug?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

2. • And, any estimate of how many vets the VA expects will receive the drug, say over the next year or so?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

From: Greilsamer, Alan

Sent: Monday, March 18, 2019 4:21 PM

To: Mojay, Ndidi <(b6) [REDACTED] va.gov>

Cc: Carter, Susan <(b6) [REDACTED] va.gov>; Noller, Randal <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: SMEs/Talking Points for Spravato® (esketamine)

Ndidi,

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for VHA Mental Health. We also will be providing an SME from Pharmacy. Additionally, Pharmacy will be providing answers to questions b and h.

Please let us know if you need anything else at this point.

Thank you, Alan

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

- b. • When/if will it be VA wide?

(b) (5) [REDACTED]

- c. • Talking points need to stress that administration needs to be in a medical setting?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- d. • What are the side effects? How long do you have to be on this treatment?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

How long do you have to be on this treatment

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]

e. • Can we add how quickly does it take to work and how long does it last.

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

f. • What type of depression will this address?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

h. • How much does it cost?

(b) (5) [REDACTED]

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b6) [REDACTED]
(b6) [REDACTED] [va.gov](mailto:[REDACTED]@va.gov)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>
Sent Date:	2019/03/22 09:24:05
Delivered Date:	2019/03/22 09:24:07

From:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC968B44E7AE2C94C43B55D094-EMMENDORFER>
To:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver (b6) va.gov>
Subject:	RE: SMEs/Talking Points for Spravato® (esketamine)
Date:	2019/03/21 14:02:00
Priority:	Normal
Type:	Note

No worries...that was an easy one!

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:55 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Thanks, sorry about the delayed tasking. Will let communications team handle from here

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 21, 2019 1:42 PM
To: Smith, Avery (b6) va.gov>; Wiechers, Ilse (b6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Avery,

If OPIA gets a question from a reporter on the number of Veterans that will receive the drug, the sentence in red below is the suggested response. (b) (5)

[REDACTED]
[REDACTED]

If Ilse concurs, I think this should be the updated response:

2. • (b) (5) [REDACTED]
[REDACTED] ?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:32 PM
To: Wiechers, Ilse <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Ok so you are sending me and update??

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 1:25 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Smith, Avery <(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

I agree with Tom that we should stick with a broad statement.
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 21, 2019 10:22 AM
To: Smith, Avery <(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Wiechers, Ilse <(b6)@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Avery,

I have included Ilse to the e-mail as I believe the PERC has been working on potential estimates of eligible Veterans....Saying that, I think the answer should be a broad statement that the number of eligible Veterans will be evaluated on a case by case basis by the VA provider and the individual Veteran's health care needs.

Tom

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:18 PM
To: VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Sorry, 10P4P, you are just getting this,

Can you review and let me know how long you will need to respond, need as soon as possible?

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Thursday, March 21, 2019 6:53 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

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Request:

Will you look at the below request from OPIA and let us know if you concur on items 1 and 2.

Requesting responses by tomorrow (March 21) by noon ET.

V/r,

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for Policy and Services (10P)
Work ph: (b6)
Cell: (b6)
Email: (b6) [va.gov](mailto:(b6)@va.gov)

From: Greilsamer, Alan
Sent: Wednesday, March 20, 2019 6:18 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10N Action <VHA10NAction@va.gov>
Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

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Thanks, Alan

From: Mojay, Ndidi <(b6) va.gov>
Date: Wednesday, Mar 20, 2019, 2:58 PM
To: Greilsamer, Alan <(b6) va.gov>
Cc: Carter, Susan <(b6) va.gov>, Noller, Randal <(b6) va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Alan,

Can you check with your folks? Is this accurate to say? Need this today.

1. • Do vets have any out of pocket costs associated with taking this drug?

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

2. • And, any estimate of how many vets the VA expects will receive the drug, say over the next year or so?

(b) (5)

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 4:21 PM
To: Mojay, Ndidi <(b6) va.gov>
Cc: Carter, Susan <(b6) va.gov>; Noller, Randal <(b6) va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: SMEs/Talking Points for Spravato® (esketamine)

Ndidi,

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for VHA Mental Health. We also will be providing an SME from Pharmacy. Additionally, Pharmacy will be providing answers to questions b and h.

Please let us know if you need anything else at this point.

Thank you, Alan

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b) (5)

(b) (5)

- b. • When/if will it be VA wide?

(b5)

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(b5)

- d. • What are the side effects? How long do you have to be on this treatment?

(b5)

How long do you have to be on this treatment

(b5)

e. • Can we add how quickly does it take to work and how long does it last.

(b5) [REDACTED]
[REDACTED]
[REDACTED]
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(b5) [REDACTED]
[REDACTED]
[REDACTED]
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(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

h. • How much does it cost?

(b5) [REDACTED].

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration

P: (b) (6) [REDACTED]

E: (b6) [REDACTED]@va.gov

Sender:	Emmendorfer, Thomas (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5E0978BC96BB44E7AE2C94C43B55D094-EMMENDORFER>
Recipient:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b6) [REDACTED]@va.gov>
Sent Date:	2019/03/21 14:02:42
Delivered Date:	2019/03/21 14:02:00

	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
To:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
CC:	
Subject:	RE: SMEs/Talking Points for Spravato® (esketamine)
Date:	2019/03/21 13:36:51
Priority:	Normal
Type:	Note

Hi Avery,

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(b5) [REDACTED]

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V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6)

Cell: (b6)

Email: (b6)@va.gov

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Sent: Wednesday, March 20, 2019 6:18 PM

To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10N Action <VHA10NAction@va.gov>

Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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1. • Do vets have any out of pocket costs associated with taking this drug?

(b5)

- (b5) [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]

2. • And, any estimate of how many vets the VA expects will receive the drug, say over the next year or so?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

From: Greilsamer, Alan

Sent: Monday, March 18, 2019 4:21 PM

To: Mojay, Ndidi <(b6) [REDACTED]@va.gov>

Cc: Carter, Susan <(b6) [REDACTED]@va.gov>; Noller, Randal <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: SMEs/Talking Points for Spravato® (esketamine)

Ndidi,

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for VHA Mental Health. We also will be providing an SME from Pharmacy. Additionally, Pharmacy will be providing answers to questions b and h.

Please let us know if you need anything else at this point.

Thank you, Alan

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5) [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

- b. • When/if will it be VA wide?

(b5) [REDACTED]

- c. • Talking points need to stress that administration needs to be in a medical setting?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- d. • What are the side effects? How long do you have to be on this treatment?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

How long do you have to be on this treatment

(b5) [REDACTED]
[REDACTED]
[REDACTED]

- e. • Can we add how quickly does it take to work and how long does it last.

(b5) [REDACTED]
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[REDACTED]
[REDACTED]

- f. • What type of depression will this address?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

h. • How much does it cost?

(b5)

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration

P: (b) (6)

E: (b6)@va.gov

Recipient:	Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b6)@va.gov>;
	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>;
	VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>;
	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
Sent Date:	2019/03/21 13:36:55
Delivered Date:	2019/03/21 13:36:51
Message Flags:	Unread Unsent

From:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER <(b6) va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: SMEs/Talking Points for Spravato® (esketamine)
Date:	2019/03/21 13:21:50
Due Date:	2019/03/20 20:00:00
Priority:	Normal
Type:	Note

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:21 PM
To: Emmendorfer, Thomas (PBM) <(b6) va.gov>; Valentino, Michael (VACO) <(b6) va.gov>
Cc: Smith, Avery <(b6) va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Guys, (b) (6), I asked for more time until 3pm.
But please do what you can

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Thursday, March 21, 2019 6:53 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PAActions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Good morning,

Please review the request below and submit your concurrence to **10P NLT 11 a.m., today.**

Request:

Will you look at the below request from OPIA and let us know if you concur on items 1 and 2.

Requesting responses by tomorrow (March 21) by noon ET.

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6)

Cell: (b6)

Email: (b6)@va.gov

From: Greilsamer, Alan

Sent: Wednesday, March 20, 2019 6:18 PM

To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10N Action <VHA10NAction@va.gov>

Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

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Requesting responses by tomorrow (March 21) by noon ET.

Thanks, Alan

From: Mojay, Ndidi <(b6)@va.gov>

Date: Wednesday, Mar 20, 2019, 2:58 PM

To: Greilsamer, Alan <(b) (6)@va.gov>

Cc: Carter, Susan <(b6)@va.gov>, Noller, Randal <(b6)@va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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Can you check with your folks? Is this accurate to say? Need this today.

1. • Do vets have any out of pocket costs associated with taking this drug?

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[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]
[Redacted]

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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

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Sent: Monday, March 18, 2019 4:21 PM

To: Mojay, Ndidi <(b6) [REDACTED]@va.gov>

Cc: Carter, Susan <(b6) [REDACTED]@va.gov>; Noller, Randal <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for VHA Mental Health. We also will be providing an SME from Pharmacy. Additionally, Pharmacy will be providing answers to questions b and h.

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(b5) [REDACTED]
[REDACTED]
[REDACTED].

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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
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[REDACTED]
[REDACTED]
[REDACTED].

h. • How much does it cost?

(b5) [REDACTED].

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b) (6)
E: (b6) va.gov

Sender:	Smith, Avery /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9471C2D02A8B472B8543E09CB140085F-SMITH, AVER <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/21 13:21:48
Delivered Date:	2019/03/21 13:21:50
Message Flags:	Unread

From:	McGuire, Marsden H. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29E9D648C29F4885828C10446FDD7379-MCGUIRE, MA <(b6)@va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b6)@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: SMEs/Talking Points for Spravato® (esketamine)
Date:	2019/03/21 13:46:11
Priority:	Normal
Type:	Note

Concur/clear.

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 1:43 PM
To: Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Smith, Avery <(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

I concur.

CC'ing 10NC5 Action FYSA.

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 21, 2019 10:42 AM
To: Smith, Avery <(b6)@va.gov>; Wiechers, Ilse (b) (6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Avery,

If OPIA gets a question from a reporter on the number of Veterans that will receive the drug, the sentence in red below is the suggested response. (b5)

(b5)

If Ilse concurs, I think this should be the updated response:

2. • [REDACTED]
[REDACTED]?

(b5)

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:32 PM
To: Wiechers, Ilse (b) (6) [REDACTED]@va.gov; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Ok so you are sending me and update??

From: Wiechers, Ilse
Sent: Thursday, March 21, 2019 1:25 PM
To: Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>; Smith, Avery (b6) [REDACTED]@va.gov; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

I agree with Tom that we should stick with a broad statement.
Ilse

From: Emmendorfer, Thomas (PBM)
Sent: Thursday, March 21, 2019 10:22 AM
To: Smith, Avery (b6) [REDACTED]@va.gov; VHA 10P4P Action <vha10P4Paction@va.gov>; Wiechers, Ilse (b) (6) [REDACTED]@va.gov
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SMEs/Talking Points for Spravato® (esketamine)

Hi Avery,

I have included Ilse to the e-mail as I believe the PERC has been working on potential estimates of eligible Veterans....Saying that, I think the answer should be a broad statement that the number of

eligible Veterans will be evaluated on a case by case basis by the VA provider and the individual Veteran's health care needs.

Tom

From: Smith, Avery
Sent: Thursday, March 21, 2019 1:18 PM
To: VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Sorry, 10P4P, you are just getting this,

Can you review and let me know how long you will need to respond, need as soon as possible?

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Thursday, March 21, 2019 6:53 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

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V/r,

Maria Sandifer
Office of the Deputy Under Secretary for Health
for Policy and Services (10P)
Work ph: (b6)
Cell: (b) (6)
Email: (b6) va.gov

From: Greilsamer, Alan

Sent: Wednesday, March 20, 2019 6:18 PM

To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10N Action <VHA10NAction@va.gov>

Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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Thanks, Alan

From: Mojay, Ndidi <(b6) [REDACTED]@va.gov>

Date: Wednesday, Mar 20, 2019, 2:58 PM

To: Greilsamer, Alan (b) (6) [REDACTED]@va.gov>

Cc: Carter, Susan <(b6) [REDACTED]@va.gov>, Noller, Randal <(b6) [REDACTED]@va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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[REDACTED]
[REDACTED]
[REDACTED]
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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

From: Greilsamer, Alan

Sent: Monday, March 18, 2019 4:21 PM

To: Mojay, Ndidi <(b6) [REDACTED] va.gov>

Cc: Carter, Susan <(b6) [REDACTED] va.gov>; Noller, Randal <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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[REDACTED]

[REDACTED]
[REDACTED]

- b. • When/if will it be VA wide?

(b5) [REDACTED]

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(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- d. • What are the side effects? How long do you have to be on this treatment?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(b5) [REDACTED]
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[REDACTED]
[REDACTED]

How long do you have to be on this treatment

(b5) [REDACTED]
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e. • Can we add how quickly does it take to work and how long does it last.

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f. • What type of depression will this address?

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g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

h. • How much does it cost?

(b5) [REDACTED]

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b) (6) [REDACTED]
[REDACTED] va.gov

Sender:	McGuire, Marsden H. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29E9D648C29F4885828C10446FDD7379-MCGUIRE, MA (b) (6) @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b) (6) @va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b) (6) @va.gov>; Smith, Avery /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9471c2d02a8b472b8543e09cb140085f-Smith, Aver <(b) (6) @va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/21 13:46:10
Delivered Date:	2019/03/21 13:46:11

From:	Gavin, Stacy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4017313DE0A84F8E8CEADE280F77D235-GAVIN, STAC (b6) va.gov>
To:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
CC:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: SMEs/Talking Points for Spravato® (esketamine)
Date:	2019/03/21 10:06:59
Priority:	Normal
Type:	Note

Good morning,

10NC5 concurs. Thanks for asking.

Stacy

From: Dudley, Tracy
Sent: Thursday, March 21, 2019 6:58 AM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

Good Morning 10NC5

Please see highlight below and provide your response by **11am today**.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)
202.461.5687 (Direct)
(202) 257-9264 (iPhone)

From: Greilsamer, Alan
Sent: Wednesday, March 20, 2019 6:18 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10N Action <VHA10NAction@va.gov>

Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: SMEs/Talking Points for Spravato® (esketamine)

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To: Greilsamer, Alan <(b6)@va.gov>
Cc: Carter, Susan <(b6)@va.gov>, Noller, Randal <(b6)@va.gov>, VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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[Redacted]

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 4:21 PM

To: Mojay, Ndidi <(b6) [REDACTED] va.gov>
Cc: Carter, Susan <(b6) [REDACTED] va.gov>; Noller, Randal <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: SMEs/Talking Points for Spravato® (esketamine)

Ndidi,

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for VHA Mental Health. We also will be providing an SME from Pharmacy. Additionally, Pharmacy will be providing answers to questions b and h.

Please let us know if you need anything else at this point.

Thank you, Alan

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5) [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

- b. • When/if will it be VA wide?

(b5) [REDACTED]

- c. • Talking points need to stress that administration needs to be in a medical setting?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- d. • What are the side effects? How long do you have to be on this treatment?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

How long do you have to be on this treatment

(b5) [REDACTED]
[REDACTED]
[REDACTED].

e. • Can we add how quickly does it take to work and how long does it last.

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

f. • What type of depression will this address?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

h. • How much does it cost?

(b5) [REDACTED].

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b) (6) [REDACTED]
E: (b6) [REDACTED]@va.gov

Sender: Gavin, Stacy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4017313DE0A84F8E8CEADE280F77D235-GAVIN, STAC (b5) [REDACTED]@va.gov>

Recipient:	VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFHSSs@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/21 10:06:57
Delivered Date:	2019/03/21 10:06:59

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6)@va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>
Subject:	RE: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 15:37:26
Priority:	Normal
Type:	Note

Perfect. And what is the response about a PBM SME?

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 18, 2019 3:36 PM
To: Smith, Monica (VACO) <(b6)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6)@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Hi Monica,

b. • When/if will it be VA wide? PBM

Response: (b5)

h. How much does it cost? PBM

Response: (b5)

(b5)

From: Smith, Monica (VACO)
Sent: Monday, March 18, 2019 3:33 PM
To: VHA 10P4P Action <vha10P4Paction@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>; Valentino, Michael (VACO) <(b6)@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>; Llorente, Maria D. <(b6)@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)

PBM – see below and let me know your input ASAP. 10N is asking for your input on items b and h and to provide a PBM SME to help address any media queries. Thanks.

From: Davis, Lashelle (VHACO)

Sent: Monday, March 18, 2019 3:21 PM

To: Greilsamer, Alan <(b6) [REDACTED] va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>

Subject: FW: SME Needed for Spravato® (esketamine)

Good afternoon, Alan –

On behalf of 10NC, Dr. Sherrie Schuldheis clears the response below submitted by OMHSP.

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for 10NC5. PBM should also be asked to provide a SME, as well as responses to questions b and h (noted below). Thank you.

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5) [REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]

- b. • When/if will it be VA wide? (b5)

- c. • Talking points need to stress that administration needs to be in a medical setting? (b5)

[REDACTED]
[REDACTED]
[REDACTED]

- d. • What are the side effects? How long do you have to be on this treatment?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

(b5)

How long do you have to be on this treatment – (b5)

e. • Can we add how quickly does it take to work and how long does it last. (b5)

f. • What type of depression will this address? (b5)

g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b5)

h. • How much does it cost? (b5)

Thank you,

Lashelle

From: Schuldheis, Sherrie L, Ph.D

Sent: Monday, March 18, 2019 2:55 PM

To: Dudley, Tracy <(b) (6)@va.gov>; VHA 10NC Clearance <VHA10NCClearance2@va.gov>

Subject: RE: SME Needed for Spravato® (esketamine)

10NC clears

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations

VHA 10NC
810 Vermont NW
Washington, DC 20420
(b5) (cell)
(b5) va.gov

From: Gavin, Stacy
Sent: Monday, March 18, 2019 2:51 PM
To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b) (6) @va.gov; VHA 10P4P Action <vha10P4Paction@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)

Good afternoon,

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for 10NC5. PBM should also be asked to provide a SME, as well as responses to questions b and h (noted below). Thank you.

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5) [REDACTED]
[REDACTED]
[REDACTED].

(b5) [REDACTED]
[REDACTED].

- b. • When/if will it be VA wide? (b5)

- c. • Talking points need to stress that administration needs to be in a medical setting? (b5)

[REDACTED]
[REDACTED]
[REDACTED].

- d. • What are the side effects? How long do you have to be on this treatment?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED].

(b5) [REDACTED]
[REDACTED]

How long do you have to be on this treatment – (b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

e. • Can we add how quickly does it take to work and how long does it last. (b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

f. • What type of depression will this address? (b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?
(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

h. • How much does it cost? (b5) [REDACTED]

From: Davis, Lashelle (VHACO)
Sent: Monday, March 18, 2019 12:39 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)
Importance: High

EXPEDITE ACTION ITEM

Please provide your response to the questions below ASAP, today.

Thank you,

Lashelle

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 12:26 PM
To: VHA 10N Action <VHA10NAction@va.gov>
Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)

Good morning 10N,

Apologies for this hot request. OPIA would like to get this information today as a press release on this topic is scheduled to go out later today/tomorrow at the latest.

Requests:

1. • By today ASAP please provide an SME(s) to be available for potential media interviews. Requesting name(s), title(s) and short bio (if available).
2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.
 - a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?
 - b. • When/if will it be VA wide?
 - c. • Talking points need to stress that administration needs to be in a medical setting?
 - d. • What are the side effects? How long do you have to be on this treatment?
 - e. • Can we add how quickly does it take to work and how long does it last.
 - f. • What type of depression will this address?
 - g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?
 - h. • How much does it cost?

Thanks, Alan

From: Forte, Kimberly P.
Sent: Monday, March 18, 2019 12:17 PM
To: Greilsamer, Alan <(b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Good afternoon,

10P respectfully request this item be deferred to Office of Mental Health. They are the best to offer a SME and the experts given the direct communication to patients. PCS is happy to review and assist as needed.

v/r

Kimberly Forte'
Health Systems Specialist to the
Deputy Under Secretary for Health for Policy & Services
Office: (b) (6)
Fax: (202) 273-9274

True leaders don't create followers, they create more leaders!!!

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 9:38 AM
To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: Smith, Monica (VACO) <(b6)@va.gov>; VHA CO 10B2B Media
<VHACO10B2BMedia@va.gov>
Subject: SME Needed for Spravato® (esketamine)

10P Action,

OPIA is moving forward with getting concurrence on the attached press release. Additionally, they want to start pitching the story on VA providing Spravato® (esketamine) to Veterans based on their individual medical needs combined with the provider's clinical assessment.

Requests:

1. • By today noon ET, please provide an SME(s) to be available for potential media interviews. Requesting name(s), title(s) and short bio (if available).
2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.

Please let us know if you have any questions .

Thanks, Alan

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b) (6) 7
E: (b6)@va.gov

Sender: Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6)@va.gov>

	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; Llorente, Maria D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5c91f577d894bd9a0f09305db34dd4f-Llorente, M <(b6)@va.gov>
Sent Date:	2019/03/18 15:37:20
Delivered Date:	2019/03/18 15:37:26
Message Flags:	Unread

From:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
To:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Subject:	RE: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 10:16:15
Priority:	Normal
Type:	Note

Maria – PBM is recommending this be deferred to Office of Mental Health. They are the best to offer a SME and the experts given the direct communication to patients. PCS is happy to review and assist as needed.

From: Smith, Monica (VACO)
Sent: Monday, March 18, 2019 10:01 AM
To: Valentino, Michael (VACO) <(b6) va.gov>; Smith, Avery <(b6) va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Thanks, just needed the office name to relay.

From: Valentino, Michael (VACO)
Sent: Monday, March 18, 2019 9:56 AM
To: Smith, Monica (VACO) <(b6) va.gov>; Smith, Avery <(b6) va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Probably the Office of Mental Health and Suicide Prevention but that would be 10NC's call.

Mike

From: Smith, Monica (VACO)
Sent: Monday, March 18, 2019 9:55 AM

To: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Smith, Avery <(b6) [REDACTED]@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Thanks, Mike – redirected to whom?

From: Valentino, Michael (VACO)
Sent: Monday, March 18, 2019 9:52 AM
To: Smith, Avery <(b6) [REDACTED]@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Yes, it should be redirected.....

From: Smith, Avery
Sent: Monday, March 18, 2019 9:50 AM
To: VHA 10P4P Action <vha10P4Paction@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)
Importance: High

10P4P,

Please review and provide response to **VHA 10P4 Actions before 10:30am today**, also advise if this should be redirected as soon as possible.

Thanks

Avery

From: Sandifer, Estella (Maria)
Sent: Monday, March 18, 2019 9:45 AM
To: VHA 10P4 Actions <VHA10P4Actions@va.gov>
Cc: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)

10P4,

Please see the request below and provide to **10P the name of SME NLT 11 a.m. today and TPs/short bio NLT 3 p.m. today**.

Requests:

1. • By today noon ET, please provide an SME(s) to be available for potential media interviews. Requesting name(s), title(s) and short bio (if available).
2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.

V/r,

Maria Sandifer

Office of the Deputy Under Secretary for Health
for Policy and Services (10P)

Work ph: (b6)

Cell: (b6)

Email: (b6) [va.gov](#)

From: Greilsamer, Alan

Sent: Monday, March 18, 2019 9:38 AM

To: VHA 10P Actions <VHA10PActions@va.gov>

Cc: Smith, Monica (VACO) <(b6) [va.gov](#)>; VHA CO 10B2B Media
<VHACO10B2BMedia@va.gov>

Subject: SME Needed for Spravato® (esketamine)

10P Action,

OPIA is moving forward with getting concurrence on the attached press release. Additionally, they want to start pitching the story on VA providing Spravato® (esketamine) to Veterans based on their individual medical needs combined with the provider's clinical assessment.

Requests:

1. • By today noon ET, please provide an SME(s) to be available for potential media interviews. Requesting name(s), title(s) and short bio (if available).
2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.

Please let us know if you have any questions .

Thanks, Alan

--

Alan Greilsamer

Director, Media Relations (10B2B)

Office of Communications

Veterans Health Administration

P: (b) (6)

E: (b6) [va.gov](#)

Sender:	Smith, Monica (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=511EA9E77A234375A91A7B34CE23719D-SMITH, MONI <(b6) va.gov>
Recipient:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PAActions@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/18 10:16:13
Delivered Date:	2019/03/18 10:16:15
Message Flags:	Unread

From:	McGuire, Marsden H. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29E9D648C29F4885828C10446FDD7379-MCGUIRE, MA <(b6)@va.gov>
To:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6)@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6)@va.gov>
Subject:	RE: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 13:56:01
Priority:	Normal
Type:	Note

Looks good

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:54 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Katz, Ira (b) (6) <(b6)@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

I've added our known data re IV ketamine in answer a.

Please review response to D (Q2) and E now inline below.

From: Katz, Ira R.
Sent: Monday, March 18, 2019 10:31 AM
To: Wiechers, Ilse (b) (6) <(b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Should the answer to the question about "esketamine in other forms" include ketamine?

Otherwise your responses are very good

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:28 PM
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Cc: Katz, Ira R. <(b) (6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6) va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Since this is urgent I'm sending back partial response for additional review/input now. I'm still working on D (Q2) and E.

Ilse

From: Wiechers, Ilse

Sent: Monday, March 18, 2019 9:58 AM

To: Gavin, Stacy <(b5) va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>

Subject: RE: SME Needed for Spravato® (esketamine)

Here is my suggestion for dividing up answers on these questions, let me know what people think. I'm draft the ones with my name now and will circulate back with this group shortly.

Ilse

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5)
[Redacted text block]

(b5)
[Redacted text block]

- b. • When/if will it be VA wide? PBM
c. • Talking points need to stress that administration needs to be in a medical setting?

(b5)
[Redacted text block]

- d. • What are the side effects? How long do you have to be on this treatment? (b5)

[Redacted text block]

How long do you have to be on this treatment – (b5)
[Redacted text block]

(b5)

- e. • Can we add how quickly does it take to work and how long does it last. (b5)

- f. • What type of depression will this address? (b5)

- g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b5)

- h. • How much does it cost? (b5)

From: Gavin, Stacy

Sent: Monday, March 18, 2019 9:53 AM

To: VHA 10P4P Action <vha10P4Paction@va.gov>

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b) (6) <[\(b\)\(6\)@va.gov](mailto:(b)(6)@va.gov)>

Subject: FW: SME Needed for Spravato® (esketamine)

Importance: High

PBM,

Did you receive this (**due ASAP today**)? Ilse is actually out of the office, but is starting to draft a response now. I wanted to give you a heads up so you can be ready to edit/add to it, if you hadn't seen it yet.

If you want to provide a SME as well, that would be great.

Thanks.

Stacy

From: Davis, Lashelle (VHACO)
Sent: Monday, March 18, 2019 12:39 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)
Importance: High

EXPEDITE ACTION ITEM

Please provide your response to the questions below ASAP, today.

Thank you,

Lashelle

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 12:26 PM
To: VHA 10N Action <VHA10NAction@va.gov>
Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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Good morning 10N,

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Requests:

1. • By today ASAP please provide an SME(s) to be available for potential media interviews.
Requesting name(s), title(s) and short bio (if available).
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Thanks, Alan

From: Forte, Kimberly P.
Sent: Monday, March 18, 2019 12:17 PM

To: Greilsamer, Alan <(b6) [REDACTED] va.gov>; VHA 10P Actions <VHA10PActions@va.gov>
Cc: Smith, Monica (VACO) <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media
<VHACO10B2BMedia@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Good afternoon,

10P respectfully request this item be deferred to Office of Mental Health. They are the best to offer a SME and the experts given the direct communication to patients. PCS is happy to review and assist as needed.

v/r

Kimberly Forte'
Health Systems Specialist to the
Deputy Under Secretary for Health for Policy & Services
Office: (b) (6) [REDACTED]
Fax: (202) 273-9274

True leaders don't create followers, they create more leaders!!!

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2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.

Please let us know if you have any questions .

Thanks, Alan

--

Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration

P: (b) (6) 7

E: (b6) va.gov

Sender:	McGuire, Marsden H. /o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=29E9D648C29F4885828C10446FDD7379-MCGUIRE, MA (b) (6) @va.gov>
Recipient:	Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b) (6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6) va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R (b) (6) va.gov>
Sent Date:	2019/03/18 13:56:00
Delivered Date:	2019/03/18 13:56:01

From:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA <(b6)@va.gov>
To:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446dd7379-McGuire, Ma <(b6)@va.gov>; Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b) (6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b) (6)@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
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Subject:	RE: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 13:50:34
Priority:	Normal
Type:	Note

Thanks for the rapid turn on this.

From: McGuire, Marsden H.
Sent: Monday, March 18, 2019 1:42 PM
To: Katz, Ira R. <(b) (6)@va.gov>; Wiechers, Ilse <(b) (6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

I agree with Ira.

From: Katz, Ira R.
Sent: Monday, March 18, 2019 1:31 PM
To: Wiechers, Ilse <(b) (6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
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(b5) [REDACTED]
[REDACTED]
[REDACTED]

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(b5) [REDACTED]
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[REDACTED]
[REDACTED]

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[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

How long do you have to be on this treatment – (b5) [REDACTED]

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[REDACTED]

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Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b) (6) <[\(b\)\(6\)@va.gov](mailto:(b)(6)@va.gov)>

Subject: FW: SME Needed for Spravato® (esketamine)

Importance: High

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Stacy

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Sent: Monday, March 18, 2019 12:39 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>

Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>

Subject: FW: SME Needed for Spravato® (esketamine)

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Thanks, Alan

From: Forte, Kimberly P.

Sent: Monday, March 18, 2019 12:17 PM

To: Greilsamer, Alan <(b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PACTIONS@va.gov>

Cc: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: SME Needed for Spravato® (esketamine)

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Kimberly Forte'
Health Systems Specialist to the
Deputy Under Secretary for Health for Policy & Services
Office: (b) (6)
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Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b) (6)
E: (b6)@va.gov

Sender:	Carroll, David (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA <(b6) [REDACTED]@va.gov>
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Sent Date:	2019/03/18 13:50:33
Delivered Date:	2019/03/18 13:50:34

From:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I (b) (6) @va.gov>
To:	Harpaz-Rotem, Ilan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2c6c2b35e02404681ba609a7329eb77-Harpaz-Rote (b) (6) @va.gov>; OMHO PEC Directors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=655a22eace794dd0a90ebdaeab53514c-OMHO PEC Di <OMHOPECDirectors@va.gov>
CC:	VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Subject:	RE: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 13:07:02
Priority:	Normal
Type:	Note

Got it. So this is what I will respond:

(b5)

From: Harpaz-Rotem, Ilan
Sent: Monday, March 18, 2019 10:03 AM
To: Wiechers, Ilse (b) (6) @va.gov>; OMHO PEC Directors <OMHOPECDirectors@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

In the table I sent you before from the Ira file for the GAO there was a cross tab of MDD and MH services and also "other depression" with MH % for the FY18 data?

Ilan

*Ilan Harpaz-Rotem, Ph.D. ABPP
Associate Director, NEPEC
Project Director – PTSD Treatment Programs
Northeast Program Evaluation Center
VA Office of Mental Health and Suicide Prevention (10NC5), VACO
Director, Advanced Fellowship MIRECC/NCPTSD VACTHS
Cell: (b) (6)*

[NEPEC Portal](#)

[MBC SharePoint Site](#)

Suicide prevention is *everybody's* business: [#BeThere](#)

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:00 PM
To: OMHO PEC Directors <OMHOPECDirectors@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>

Subject: FW: SME Needed for Spravato® (esketamine)
Importance: High

Hi PEC Directors – can I please have urgent assistance on item G?

Jodie – I was going to use our number that we calculated last week as the answer to the second questions here. Do you agree?

Ilse

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 9:58 AM
To: Gavin, Stacy <(b5)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>
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Ilse/OMHSP PEC
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From: Forte, Kimberly P.

Sent: Monday, March 18, 2019 12:17 PM

To: Greilsamer, Alan <(b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Cc: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: RE: SME Needed for Spravato® (esketamine)

Good afternoon,

10P respectfully request this item be deferred to Office of Mental Health. They are the best to offer a SME and the experts given the direct communication to patients. PCS is happy to review and assist as needed.

v/r

Kimberly Forte'

Health Systems Specialist to the

Deputy Under Secretary for Health for Policy & Services

Office: (b) (6) [REDACTED]

Fax: (202) 273-9274

True leaders don't create followers, they create more leaders!!!

From: Greilsamer, Alan

Sent: Monday, March 18, 2019 9:38 AM

To: VHA 10P Actions <VHA10PActions@va.gov>

Cc: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: SME Needed for Spravato® (esketamine)

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OPIA is moving forward with getting concurrence on the attached press release. Additionally, they want to start pitching the story on VA providing Spravato® (esketamine) to Veterans based on their individual medical needs combined with the provider's clinical assessment.

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2. • By today EOD, talking points about Spravato® (esketamine) and its benefits.

Please let us know if you have any questions .

Thanks, Alan

--

Alan Greilsamer
 Director, Media Relations (10B2B)
 Office of Communications
 Veterans Health Administration
 P: (b) (6)
 E: (b6)@va.gov

Sender:	Wiechers, Ilse /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F0C7B1428D9E4233A641F125C5B6FC4F-WIECHERS, I <(b6)@va.gov>
Recipient:	Harpaz-Rotem, Ilan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2c6c2b35e02404681ba609a7329eb77-Harpaz-Rote (b) (6)@va.gov>; OMHO PEC Directors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=655a22eace794dd0a90ebdaeb53514c-OMHO PEC Di <OMHOPECDirectors@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>
Sent Date:	2019/03/18 13:06:59
Delivered Date:	2019/03/18 13:07:02

From:	Greilsamer, Alan /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FC02807AF08443FBB5C68C590D58FA4B-GREILSAMER, <(b6)@va.gov>
To:	Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bfd03b3b47daa8b6db6f8933a7e7-Davis, Lash <(b) (6)@va.gov>
CC:	VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFHSSs@va.gov>
Subject:	RE: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 15:55:54
Priority:	Normal
Type:	Note

Thank you.

From: Davis, Lashelle (VHACO)
Sent: Monday, March 18, 2019 3:21 PM
To: Greilsamer, Alan <(b6)@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs <VHACO10NCFHSSs@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)

Good afternoon, Alan –

On behalf of 10NC, Dr. Sherrie Schuldheis clears the response below submitted by OMHSP.

Dr. Ilse Wiechers, National Director, Psychotropic Drug Safety Initiative, is the SME for 10NC5. PBM should also be asked to provide a SME, as well as responses to questions b and h (noted below). Thank you.

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

b. • When/if will it be VA wide? (b5)

c. • Talking points need to stress that administration needs to be in a medical setting? (b5)

d. • What are the side effects? How long do you have to be on this treatment?

(b5)

How long do you have to be on this treatment – (b5)

e. • Can we add how quickly does it take to work and how long does it last. (b5)

f. • What type of depression will this address? (b5)

g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b5)

h. • How much does it cost? (b5)

Thank you,

Lashelle

From: Schuldheis, Sherrie L, Ph.D

Sent: Monday, March 18, 2019 2:55 PM

To: Dudley, Tracy (b) (6) @va.gov; VHA 10NC Clearance <VHA10NCClearance2@va.gov>

Subject: RE: SME Needed for Spravato® (esketamine)

10NC clears

Sherrie Schuldheis, PhD, RN, CENP
Special Assistant, ADUSH Clinical Operations
VHA 10NC
810 Vermont NW
Washington, DC 20420
(b5) (cell)
(b5) va.gov

From: Gavin, Stacy

Sent: Monday, March 18, 2019 2:51 PM

To: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse <(b) (6) @va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>

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From: Davis, Lashelle (VHACO)
Sent: Monday, March 18, 2019 12:39 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: SME Needed for Spravato® (esketamine)
Importance: High

EXPEDITE ACTION ITEM

Please provide your response to the questions below ASAP, today.

Thank you,

Lashelle

From: Greilsamer, Alan
Sent: Monday, March 18, 2019 12:26 PM
To: VHA 10N Action <VHA10NAction@va.gov>
Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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 - h. • How much does it cost?

Thanks, Alan

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Sent: Monday, March 18, 2019 12:17 PM

To: Greilsamer, Alan <(b6) [REDACTED]@va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Cc: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration

P: (b) (6)

E: (b) (6)@va.gov

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Recipient:	Davis, Lashelle (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0c9bffd03b3b47daa8b6db6f8933a7e7-Davis, Lash <(b) (6)@va.gov>; VHA CO 10B2B Media /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12e0caca48054b8da1e793651a89d81c-VHA CO 10B2 <VHACO10B2BMedia@va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA CO 10NC Front Office HSSs /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf91f73967a49c287d8747b7aee675e-VHA CO 10NC <VHACO10NCFOHSSs@va.gov>
Sent Date:	2019/03/18 15:55:53
Delivered Date:	2019/03/18 15:55:54

From:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b6)@va.gov>
To:	Katz, Ira R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=65f4e28aa7574641932c29fed7c0b4b8-Katz, Ira R <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b) (6) @va.gov>; VHA 10NC5 Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a044c3cb71cc4ebc9b7a8c9a8e0a0688-VHA 10NC5 A <VHA10NC5Action@va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	Drexler, Karen MD (Atlanta) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c456a9bf391415bb4bdb9b6f88bdf45-Drexler, Ka <(b6)@va.gov>
Subject:	RE: SME Needed for Spravato® (esketamine)
Date:	2019/03/18 13:42:08
Priority:	Normal
Type:	Note

I agree with Ira.

From: Katz, Ira R.

Sent: Monday, March 18, 2019 1:31 PM

To: Wiechers, Ilse <(b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>;

Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>;

Subject: RE: SME Needed for Spravato® (esketamine)

Should the answer to the question about “esketamine in other forms” include ketamine? Otherwise your responses are very good

From: Wiechers, Ilse

Sent: Monday, March 18, 2019 1:28 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>;

Cc: Katz, Ira R. <(b6)@va.gov>; Drexler, Karen MD (Atlanta) <(b6)@va.gov>;

Subject: RE: SME Needed for Spravato® (esketamine)

Since this is urgent I'm sending back partial response for additional review/input now. I'm still working on D (Q2) and E.

Ilse

From: Wiechers, Ilse

Sent: Monday, March 18, 2019 9:58 AM

To: Gavin, Stacy <(b5)@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>;

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>;

Subject: RE: SME Needed for Spravato® (esketamine)

Here is my suggestion for dividing up answers on these questions, let me know what people think. I'm draft the ones with my name now and will circulate back with this group shortly. Ilse

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5) [REDACTED]

- b. • When/if will it be VA wide? (b5)
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[REDACTED]

- d. • What are the side effects? How long do you have to be on this treatment? (b5)

[REDACTED]

How long do you have to be on this treatment – (b5).

- e. • Can we add how quickly does it take to work and how long does it last. Ilse – (b5)s
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[REDACTED]

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(b5) [REDACTED]

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Sent: Monday, March 18, 2019 9:53 AM

To: VHA 10P4P Action <vha10P4Paction@va.gov>;

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse
<(b6)@va.gov>;

Subject: FW: SME Needed for Spravato® (esketamine)

Importance: High

PBM,

Did you receive this (**due ASAP today**)? Ilse is actually out of the office, but is starting to draft a response now. I wanted to give you a heads up so you can be ready to edit/add to it, if you hadn't seen it yet.

If you want to provide a SME as well, that would be great.

Thanks.

Stacy

From: Davis, Lashelle (VHACO)

Sent: Monday, March 18, 2019 12:39 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>;

Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>;

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To: VHA 10N Action <VHA10NAction@va.gov>;

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To: Greilsamer, Alan <(b6)@va.gov>; VHA 10P Actions

<VHA10PAActions@va.gov>;

Cc: Smith, Monica (VACO) <(b6)@va.gov>; VHA CO 10B2B Media

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Alan Greilsamer

Director, Media Relations (10B2B)

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P: (b) (6)

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Sender:	McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma <(b) (6)@va.gov>
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Sent Date:	2019/03/18 13:42:06
Delivered Date:	2019/03/18 13:42:08
Message Flags:	Unread

From:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6)@va.gov>
Subject:	RE: SME Needed for Spravato(r) (esketamine)
Date:	2019/03/18 15:28:51
Priority:	Normal
Type:	Note

Looks good to me

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 18, 2019 2:24 PM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>;
Cc: Valentino, Michael (VACO) <(b6)@va.gov>;
Subject: RE: SME Needed for Spravato(r) (esketamine)

Hi Jenn,

Draft response below

b. • When/if will it be VA wide? PBM

Response: (b5) [REDACTED]

h. How much does it cost? PBM

Response: (b5) [REDACTED]

Tom

From: Gavin, Stacy
Sent: Monday, March 18, 2019 2:44 PM
To: Wiechers, Ilse <(b6)@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <yha10P4Paction@va.gov>;
Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Katz, Ira R. <(b6)@va.gov>;
Subject: RE: SME Needed for Spravato(r) (esketamine)

PBM,

I can send this forward now and ask for reassignment to b and h to you, which should give you a bit longer to work on it and send through 10P.

Stacy

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:54 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action

<vha10P4Paction@va.gov>;

Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Katz, Ira R.

<(b6)@va.gov>;

Subject: RE: SME Needed for Spravato®; (esketamine)

I've added our known data re IV ketamine in answer a.

Please review response to D (Q2) and E now inline below.

From: Katz, Ira R.

Sent: Monday, March 18, 2019 10:31 AM

To: Wiechers, Ilse <(b6)@va.gov>; VHA 10NC5 Action

<VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>;

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<(b6)@va.gov>;

Subject: RE: SME Needed for Spravato®; (esketamine)

Since this is urgent I'm sending back partial response for additional review/input now.

I'm still working on D (Q2) and E.

Ilse

From: Wiechers, Ilse

Sent: Monday, March 18, 2019 9:58 AM

To: Gavin, Stacy <(b5)@va.gov>; VHA 10P4P Action

<vha10P4Paction@va.gov>;

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>;

Subject: RE: SME Needed for Spravato®; (esketamine)

Here is my suggestion for dividing up answers on these questions, let me know what people think. I'm draft the ones with my name now and will circulate back with this group shortly.

Ilse

- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5)
[Redacted]

[Redacted]

[Redacted]

- b. • When/if will it be VA wide? (b5)
- c. • Talking points need to stress that administration needs to be in a medical setting? (b5)

- d. • What are the side effects? How long do you have to be on this treatment? (b5)

- e. • Can we add how quickly does it take to work and how long does it last. (b5)

- f. • What type of depression will this address? (b5)

- g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?

(b5)

From: Gavin, Stacy

Sent: Monday, March 18, 2019 9:53 AM

To: VHA 10P4P Action <vha10P4Paction@va.gov>

Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse

<(b6) va.gov>

Subject: FW: SME Needed for Spravato®; (esketamine)

Importance: High

PBM,

Did you receive this (**due ASAP today**)? Ilse is actually out of the office, but is starting to draft a response now. I wanted to give you a heads up so you can be ready to edit/add to it, if you hadn't seen it yet.

If you want to provide a SME as well, that would be great.

Thanks.

Stacy

From: Davis, Lashelle (VHACO)

Sent: Monday, March 18, 2019 12:39 PM

To: VHA 10NC5 Action <VHA10NC5Action@va.gov>

Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>

Subject: FW: SME Needed for Spravato®; (esketamine)

Importance: High

EXPEDITE ACTION ITEM

Please provide your response to the questions below ASAP, today.

Thank you,

Lashelle

From: Greilsamer, Alan

Sent: Monday, March 18, 2019 12:26 PM

To: VHA 10N Action <VHA10NAction@va.gov>

Cc: VHA 10NC Action <vha10ncaction@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: SME Needed for Spravato®; (esketamine)

Good morning 10N,

Apologies for this hot request. OPIA would like to get this information today as a press release on this topic is scheduled to go out later today/tomorrow at the latest.

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 - g. • What is the percentage of Veterans receiving VA health care who suffer from depression? What is the percentage who would benefit from this treatment?
 - h. • How much does it cost?

Thanks, Alan

From: Forte, Kimberly P.

Sent: Monday, March 18, 2019 12:17 PM

To: Greilsamer, Alan <(b6)@va.gov>; VHA 10P Actions <VHA10PACTIONS@va.gov>;

Cc: Smith, Monica (VACO) <(b6)@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>;

Subject: RE: SME Needed for Spravato®; (esketamine)

Good afternoon,

10P respectfully request this item be deferred to Office of Mental Health. They are the best to offer a SME and the experts given the direct communication to patients. PCS is happy to review and assist as needed.

v/r

Kimberly Forte'

Health Systems Specialist to the
Deputy Under Secretary for Health for Policy & Services

Office: (b) (6)

Fax: (202) 273-9274

True leaders don't create followers, they create more leaders!!!

From: Greilsamer, Alan

Sent: Monday, March 18, 2019 9:38 AM

To: VHA 10P Actions <VHA10PACTIONS@va.gov>;

Cc: Smith, Monica (VACO) <(b6)@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>;

Subject: SME Needed for Spravato®; (esketamine)

10P Action,

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Please let us know if you have any questions .

Thanks, Alan

--

Alan Greilsamer

Director, Media Relations (10B2B)

Office of Communications

Veterans Health Administration

P: (b) (6)

E: (b6)@va.gov

Sender: Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6) va.gov>
Recipient:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/03/18 15:28:47
Delivered Date:	2019/03/18 15:28:51
Message Flags:	Unread

From:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) [REDACTED]@va.gov>
To:	Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>
CC:	Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) [REDACTED]@va.gov>
Subject:	RE: SME Needed for Spravato(r) (esketamine)
Date:	2019/03/18 15:28:51
Priority:	Normal
Type:	Note

Looks good to me

From: Emmendorfer, Thomas (PBM)
Sent: Monday, March 18, 2019 2:24 PM
To: Zacher, Jennifer L. (PBM) <(b6) [REDACTED]@va.gov>
Cc: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: SME Needed for Spravato(r) (esketamine)

Hi Jenn,

Draft response below

b. • When/if will it be VA wide? PBM

Response: (b5) [REDACTED]

h. How much does it cost? PBM

Response: (b5) [REDACTED]

[REDACTED]

[REDACTED] (b5)

Tom

From: Gavin, Stacy
Sent: Monday, March 18, 2019 2:44 PM
To: Wiechers, Ilse (b) (6) [REDACTED]@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: Drexler, Karen MD (Atlanta) <(b6) [REDACTED]@va.gov>; Katz, Ira R. (b) (6) [REDACTED]@va.gov>
Subject: RE: SME Needed for Spravato(r) (esketamine)

PBM,

I can send this forward now and ask for reassignment to b and h to you, which should give you a bit longer to work on it and send through 10P.

Stacy

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:54 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>; Katz, Ira R. (b) (6) @va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

I've added our known data re IV ketamine in answer a.

Please review response to D (Q2) and E now inline below.

From: Katz, Ira R.
Sent: Monday, March 18, 2019 10:31 AM
To: Wiechers, Ilse (b) (6) @va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: Drexler, Karen MD (Atlanta) <(b6)@va.gov>
Subject: RE: SME Needed for Spravato® (esketamine)

Should the answer to the question about "esketamine in other forms" include ketamine?

Otherwise your responses are very good

From: Wiechers, Ilse
Sent: Monday, March 18, 2019 1:28 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: Katz, Ira R. (b) (6) @va.gov>; Drexler, Karen MD (Atlanta) <(b6)@va.gov>
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- a. • What clinics currently utilize esketamine in other forms? How many Veterans are currently using it?

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- b. • When/if will it be VA wide? (b5)
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(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- d. • What are the side effects? How long do you have to be on this treatment? Ilse

(b5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
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- e. • Can we add how quickly does it take to work and how long does it last. (b5)

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

- f. • What type of depression will this address? (b5)

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[REDACTED]
[REDACTED]

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(b5) [REDACTED]
[REDACTED]
[REDACTED]

(b5)

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Cc: VHA 10NC5 Action <VHA10NC5Action@va.gov>; Wiechers, Ilse (b) (6) <[\(b\)\(6\)@va.gov](mailto:(b)(6)@va.gov)>
Subject: FW: SME Needed for Spravato® (esketamine)
Importance: High

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From: Forte, Kimberly P.

Sent: Monday, March 18, 2019 12:17 PM

To: Greilsamer, Alan <(b6) [REDACTED] va.gov>; VHA 10P Actions <VHA10PActions@va.gov>

Cc: Smith, Monica (VACO) <(b6) [REDACTED] va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

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Kimberly Forte'

Health Systems Specialist to the

Deputy Under Secretary for Health for Policy & Services

Office: ((b) (6) [REDACTED])

Fax: (202) 273-9274

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To: VHA 10P Actions <VHA10PActions@va.gov>
Cc: Smith, Monica (VACO) <(b6) [REDACTED]@va.gov>; VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
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Alan Greilsamer
Director, Media Relations (10B2B)
Office of Communications
Veterans Health Administration
P: (b) (6) [REDACTED]
E: (b6) [REDACTED]@va.gov

Sender:	Zacher, Jennifer L. (PBM) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9027C425646E4DE8A7D196908016331B-ZACHER, JEN <(b6) [REDACTED]@va.gov>
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From:	Nazario, Mitchell /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E909581B30643148BA99AB7FF79CAE0-NAZARIO, MI <(b6) [REDACTED]@va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) [REDACTED]@va.gov>
Subject:	RE: Slides for F2F
Date:	2019/06/12 10:15:38
Priority:	Normal
Type:	Note

Noted, thanks!

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, June 12, 2019 10:11 AM
To: Nazario, Mitchell <(b6) [REDACTED]@va.gov>
Subject: RE: Slides for F2F

Hi Mitch,

I have two esketamine slide decks that should already have been uploaded to the agenda. Thanks.

Matthew

From: Nazario, Mitchell
Sent: Wednesday, June 12, 2019 9:30 AM
To: VHAPBM PBM Clinical Only <PBMClinicalOnly@va.gov>
Subject: Slides for F2F

Hi all,

Jen informed that she will need the slide set for our F2F by 2pm central time on Monday. I would like to shoot for COB this Friday for the slides to give me time to set them up since it's my first time. I can give you to NLT 10AM ET on Monday morning if you still need time but please, let me know in a separate email by when will your slides be ready if not by COB Friday. Thanks!

Mitch

Sender:	Nazario, Mitchell /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E909581B30643148BA99AB7FF79CAE0-NAZARIO, MI <(b6) [REDACTED]@va.gov>
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Subject:	RE: Slides for F2F
Date:	2019/06/17 08:39:19
Priority:	Normal
Type:	Note

That's it, got them, thanks!

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 17, 2019 8:20 AM
To: Nazario, Mitchell <(b6) [REDACTED]@va.gov>
Subject: RE: Slides for F2F

I uploaded to the draft agenda folder. Are they supposed to go somewhere else too? Thanks.

From: Nazario, Mitchell
Sent: Monday, June 17, 2019 8:15 AM
To: Fuller, Matthew A. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Slides for F2F

We typically upload the slides to the folder ourselves. You can send them to me and I'll upload them. Thanks!

From: Fuller, Matthew A. (PBM)
Sent: Monday, June 17, 2019 8:07 AM
To: Nazario, Mitchell <(b6) [REDACTED]@va.gov>
Subject: RE: Slides for F2F

Not sure why not. I submitted them a week or so ago. Do you want me to send them directly to you?

From: Nazario, Mitchell
Sent: Monday, June 17, 2019 8:03 AM
To: Fuller, Matthew A. (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: Slides for F2F

Matt,

I don't see your slide decks in the slide folder

Mitch

From: Fuller, Matthew A. (PBM)
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Sent Date:	2019/06/17 08:39:17
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From:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
To:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja <(b6)@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6)@va.gov>
Subject:	RE: SECVA Call -
Date:	2019/06/25 15:13:00
Priority:	Normal
Type:	Note

This is the statement we put together last Friday for the Press Secretary to provide to media folks who asked about our decision.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to “prior authorization” formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA’s commitment to seek new ways to provide the best health care available for our nation’s Veterans.

Mike

From: Brooks, Aja
Sent: Tuesday, June 25, 2019 3:11 PM
To: Valentino, Michael (VACO) <(b6)@va.gov>; Emmendorfer, Thomas (PBM) <(b6)@va.gov>
Subject: RE: SECVA Call -

I wish I had them. All I know is folks are now chanting “Ketamine for all” in OCLA. I missed the call and (b6).

From: Valentino, Michael (VACO)
Sent: Tuesday, June 25, 2019 3:10 PM
To: Brooks, Aja <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: RE: SECVA Call -

If someone can send them to me I should be able to tell if they originated in our office.

Could also be the office of mental health.

From: Brooks, Aja
Sent: Tuesday, June 25, 2019 3:07 PM
To: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) <(b6) [REDACTED]@va.gov>
Subject: SECVA Call -

Hi Team-

Do you all know where the SecVA received his talking points from in re Spravato/Eskatamine?

v/r
AJ

AJ Brooks, JD, HCISPP
Congressional Relations Officer
Office of Congressional & Legislative Affairs
Department of Veterans Affairs
(b6) [REDACTED]@va.gov
Office: (b6) [REDACTED]
Cell: (b6) [REDACTED]

Sender:	Valentino, Michael (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO,>
Recipient:	Brooks, Aja /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c59e6730234420da11251416b699f1c-Brooks, Aja <(b6) [REDACTED]@va.gov>; Emmendorfer, Thomas (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e0978bc96bb44e7ae2c94c43b55d094-Emmendorfer <(b6) [REDACTED]@va.gov>
Sent Date:	2019/06/25 15:13:11
Delivered Date:	2019/06/25 15:13:00

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	McCarren, Madeline (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ca84ad6a2ed46fa97266f2b62eb9ce5-McCarren, M (b6)@va.gov>
Subject:	RE: SA/LA
Date:	2019/03/18 16:29:00
Priority:	Normal
Type:	Note

SPRAVATO™ is a non-competitive N-methyl D-aspartate (NMDA) receptor antagonist indicated, in conjunction with an oral antidepressant, for the treatment of treatment-resistant depression (TRD) in adults.

Nasal Spray: 28 mg of esketamine per device. Each nasal spray device delivers two sprays containing a total of 28 mg esketamine.

From: McCarren, Madeline (PBM)
Sent: Monday, March 18, 2019 4:18 PM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>
Subject: RE: SA/LA

Sure. Please also give me indication and dose info.

Thanks

M

From: Fuller, Matthew A. (PBM)
Sent: Monday, March 18, 2019 2:42 PM
To: McCarren, Madeline (PBM) <(b6)@va.gov>
Cc: Burk, Muriel (b6)@va.gov>
Subject: SA/LA

Hi Madeline,

I am working on the esketamine (SPRAVATO) monograph. Can you provide SA/LA information? Thanks.

Matthew

Matthew A. Fuller, BS, Pharm.D., FASHP, BCPP
National PBM Clinical Pharmacy Program Manager – Psychiatry and Geriatrics
VHA Pharmacy Benefits Management Services (10P4P)
1st Avenue – 1 Block North of Cermak (Bldg 37)
Hines, IL 60141

(b6)

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	McCarren, Madeline (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ca84ad6a2ed46fa97266f2b62eb9ce6-McCarren, M (b6)@va.gov>
Sent Date:	2019/03/18 16:29:10
Delivered Date:	2019/03/18 16:29:00

From:	Yesavage, Jerome /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D313692E0A154D689E73CE5CE0A1A2D5-YESAVAGE, J (b6)@va.gov>
To:	(b6) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d20b3a61dad4335 (b6)@muscd.edu>; (b6) R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fc55623e052486aae753f6616328029 (b6)@mednet.ucla.edu>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6)@va.gov>; Hauser, Peter /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb84c51ec5364f8bfff66791460f8a-Hauser, Peter (b6)@va.gov>; Marder, Stephen R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2de44bfb64a4af093928caf67c3baaa-Marder, Stephen R. (b6)@va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Marsden H. (b6)@va.gov>; Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave (b6)@va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Matthew A. (b6)@va.gov>
CC:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Daina L. (b6)@va.gov>
Subject:	RE: Request for STFAC committee input on Treatment Resistant Depression educational materials
Date:	2019/06/14 13:53:15
Priority:	Normal
Type:	Note

We of course can help on rTMS but Mark knows both sides.

From: (b6) (b6)@muscd.edu
Sent: Thursday, June 13, 2019 12:15 PM
To: (b6)@mednet.ucla.edu>; Wiechers, Ilse (b6)@va.gov>; Hauser, Peter (b6)@va.gov>; Marder, Stephen R. (b6)@va.gov>; McGuire, Marsden H. (b6)@va.gov>; Oslin, Dave (Philadelphia VAMC) (b6)@va.gov>; Yesavage, Jerome (b6)@va.gov>; Fuller, Matthew A. (PBM) (b6)@va.gov>
Cc: Wells, Daina L. (b6)@va.gov>
Subject: [EXTERNAL] Re: Request for STFAC committee input on Treatment Resistant Depression educational materials

This message was sent securely by MUSC

Recommend (b6) who is an expert in TMS and ECT. Both at affiliate and MUSC. He is more than willing to take part.

(b6)
ACOS, Mental Health Service Line
Ralph H. Johnson VAMC
Director, Addiction Sciences Division
Director, Military Sciences Division
MUSC, Charleston SC

From: (b6)@mednet.ucla.edu>
Sent: Thursday, June 13, 2019 2:53 PM
To: Wiechers, Ilse; (b6); Hauser, Peter; (b6) R.; McGuire, Marsden H.; Oslin, Dave (Philadelphia VAMC); Yesavage, Jerome; Fuller, Matthew A. (PBM)
Cc: Wells, Daina L.
Subject: RE: Request for STFAC committee input on Treatment Resistant Depression educational materials

CAUTION: External

I recommend Walter Dunn who runs our rTMS program. Not sure about a VA expert on ECT.

Steve

From: Wiechers, Ilse [mailto:(b6)s@va.gov]
Sent: Thursday, June 13, 2019 11:15 AM
To: (b6)@musc.edu>; Hauser, Peter <(b6)va.gov>; Marder, Stephen R. (b6)@va.gov>; (b6) (b6)@mednet.ucla.edu>; McGuire, Marsden H. <(b6)va.gov>; Oslin, Dave (Philadelphia VAMC) <(b6)va.gov>; Wiechers, Ilse (b6)@va.gov>; Yesavage, Jerome (b6)@va.gov>; Fuller, Matthew A. (PBM) <(b6)va.gov>
Cc: Wells, Daina L. <(b6)va.gov>
Subject: Request for STFAC committee input on Treatment Resistant Depression educational materials

Dear STFAC members -

Academic Detailing will be updating a provider handout on Treatment Resistant Depression (TRD) last updated in 2012. The previous content on somatic treatment options was small and needs to be updated and expanded to provide more accurate and comprehensive information for the field on TRD treatment options. The goal is to have this document updated by January 2020 so that it can be used as education for the field in the context of rolling out esketamine more broadly across the system.

Specifically, we are seeking subject matter expertise on ECT and rTMS.

If you have the bandwidth to participate in either writing or reviewing the TRD provider handout, please email (b6)va.gov.

Thanks,
Ilse

UCLA HEALTH SCIENCES IMPORTANT WARNING: This email (and any attachments) is only intended for the use of the person or entity to which it is addressed, and may contain information that is privileged and confidential. You, the recipient, are obligated to maintain it in a safe, secure and confidential manner. Unauthorized redisclosure or failure to maintain confidentiality may subject you to federal and state penalties. If you are not the intended recipient, please immediately notify us by return email, and delete this message from your computer.

This message was secured via TLS by **MUSC**.

Sender:	Yesavage, Jerome /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D313692E0A154D689E73CE5CE0A1A2D5-YESAVAGE, J (b6) @va.gov>
Recipient:	(b6) /o=ExchangeLabs/ou=Exchange Administrative Group (b6) edu>; (b6) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fc55623e052486aae753f6616328025(b6) ednet.udu.edu>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6) va.gov>; Hauser, Peter /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb84c51ec5364f8fbff6676791460f8a-Hauser, Pet <(b6) va.gov>; Marder, Stephen R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2de44bfb64a4af093928caf67c3baaa-Marder, Ste (b6) @va.gov>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446dd7379-McGuire, Ma <(b6) va.gov>; Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave <(b6) va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6) va.gov>; Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain <(b6) va.gov>
Sent Date:	2019/06/14 13:53:13
Delivered Date:	2019/06/14 13:53:15

From:	Madore, Michelle R. /o=EXCHANGELABS/ou=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=73DAACA95F32485194225DA4ACB2693A-MADORE, MIC <(b6)@va.gov>
	Yesavage, Jerome /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d313692e0a154d689e73ce5ce0a1a2d5-Yesavage, J <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; (b6) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d20b3a61dad4335b63dacdfe2370be(b6)@muscd.edu>; Hauser, Peter /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb84c51ec5364f8bfff66791460f8a-Hauser, Peter <(b6)@va.gov>; Marder, Stephen R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2de44bfb64a4af093928caf67c3baaa-Marder, Stephen <(b6)@va.gov>; (b6) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8fc55623e052486aae753f6616328029(b6)@dnet.uda.edu>; McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Marsden <(b6)@va.gov>; Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave <(b6)@va.gov>; Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Matthew <(b6)@va.gov>
CC:	Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Daina <(b6)@va.gov>
Subject:	RE: Request for STFAC committee input on Treatment Resistant Depression educational materials
Date:	2019/06/19 13:04:42
Priority:	Normal
Type:	Note

I am happy to help out with writing and/or reviewing.

Best,
Michelle

Michelle Madore, Ph.D.

From: Yesavage, Jerome

Sent: Friday, June 14, 2019 11:02 AM

To: Wiechers, Ilse <(b6)@va.gov>; (b6)rickh@musc.edu>; Hauser, Peter <(b6)va.gov>; Marder, Stephen R. <(b6)@va.gov>; Marder, Stephen R. <(b6)@mednet.ucla.edu>; McGuire, Marsden H. <(b6)va.gov>; Oslin, Dave (Philadelphia VAMC) <(b6)va.gov>; Fuller, Matthew A. (PBM) <(b6)va.gov>
Cc: Wells, Daina L. <(b6)va.gov>; Madore, Michelle R. <(b6)va.gov>

Subject: RE: Request for STFAC committee input on Treatment Resistant Depression educational materials

Ilse, let me copy Michelle who has lots of information at hand on rTMS.

From: Wiechers, Ilse

Sent: Thursday, June 13, 2019 11:15 AM

To: (b6)musc.edu>; Hauser, Peter <(b6)va.gov>; Marder, Stephen R. <(b6)@va.gov>; Marder, Stephen R. <(b6)@mednet.ucla.edu>; McGuire, Marsden H. <(b6)va.gov>; Oslin, Dave (Philadelphia VAMC) <(b6)va.gov>; Wiechers, Ilse <(b6)@va.gov>; Yesavage, Jerome <(b6)@va.gov>; Fuller, Matthew A. (PBM) <(b6)va.gov>

Cc: Wells, Daina L. <(b6)va.gov>

Subject: Request for STFAC committee input on Treatment Resistant Depression educational materials

Dear STFAC members -

Academic Detailing will be updating a provider handout on Treatment Resistant Depression (TRD) last updated in 2012. The previous content on somatic treatment options was small and needs to be updated and expanded to provide more accurate and comprehensive information for the field on TRD treatment options. The goal is to have this document updated by January 2020 so that it can be used as education for the field in the context of rolling out esketamine more broadly across the system.

Specifically, we are seeking subject matter expertise on ECT and rTMS.

If you have the bandwidth to participate in either writing or reviewing the TRD provider handout, please email (b6)va.gov.

Thanks,
Ilse

Sender:	Madore, Michelle R. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73DAACA95F32485194225DA4ACB2693A-MADORE, MIC <(b6)va.gov>
Recipient:	Yesavage, Jerome /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d313692e0a154d689e73ce5ce0a1a2d5-Yesavage, J <(b6)@va.gov>;

Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I
<(b6) /a.gov>;
(b6) /ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8d20b3a61dad4335b63dacdf2370bec-(b6)
@muscd.edu>;
Hauser, Peter /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=bb84c51ec5364f8fbff6676791460f8a-Hauser, Pet
<(b6) /a.gov>;
Marder, Stephen R. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2de44bfb64a4af093928caf67c3baaa-Marder, Ste
(b6) @va.gov>;
Marder, Stephen R. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8fc55623e052486aae753f6616328029-StephenMard
(b6) @mednet.udel.edu>;
McGuire, Marsden H. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=29e9d648c29f4885828c10446fdd7379-McGuire, Ma
<(b6) /a.gov>;
Oslin, Dave (Philadelphia VAMC) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=45a9248804ff41a195408861537ee66d-Oslin, Dave
<(b6) /a.gov>;
Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat
<(b6) /a.gov>;
Wells, Daina L. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2256099a3577421182c5516b56f40815-Wells, Dain
<(b6) /a.gov>

Sent Date: 2019/06/19 13:04:40

Delivered Date: 2019/06/19 13:04:42

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>; Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Subject:	RE: Request for Dates for Spravato (esketamine) clinical review
Date:	2019/03/20 11:54:00
Priority:	Normal
Type:	Note

Ok. Thanks.

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 11:53 AM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>; Szudarski, Lucy (PBM) <(b6)@va.gov>
Subject: RE: Request for Dates for Spravato (esketamine) clinical review

Either a call or webinar.....I will leave it up to them.....My appointments are limited to 30 minutes, so that is all the time we are giving them

From: Fuller, Matthew A. (PBM)
Sent: Wednesday, March 20, 2019 10:52 AM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Szudarski, Lucy (PBM) <(b6)@va.gov>
Subject: RE: Request for Dates for Spravato (esketamine) clinical review

Will the call with Phillip be a webinar, conference call, etc? How long should I plan for?

My hard "no" dates in April are CPNP (April 7-10), April 12th and the afternoon of April 24th. Thanks.

Matthew

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 11:46 AM
To: Szudarski, Lucy (PBM) <(b6)@va.gov>; Fuller, Matthew A. (PBM) <(b6)@va.gov>
Subject: RE: Request for Dates for Spravato (esketamine) clinical review

Yes, this is a clinical call.....that was a "business" call

From: Szudarski, Lucy (PBM)
Sent: Wednesday, March 20, 2019 10:46 AM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Fuller, Matthew A. (PBM) <(b6)@va.gov>
Subject: RE: Request for Dates for Spravato (esketamine) clinical review

Ok, sorry I'm confused I scheduled a call for you with Jeremy Wallace regarding Spravato today at 2:30, is this completely different then?

From: Zacher, Jennifer L. (PBM)
Sent: Wednesday, March 20, 2019 9:43 AM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>
Cc: Szudarski, Lucy (PBM) <(b6)@va.gov>
Subject: FW: Request for Dates for Spravato (esketamine) clinical review

Hi Matt,
So, I HAD to agree to this...I made it clear that I didn't want to listen to this. But since I have to, so do you.....

Lucy, can you work with Matt to identify a few dates/times in April that we can send back to them?

Thanks Lucy, and Sorry Matt!
JZ

From: (b6)@ITS.JNJ.com>
Sent: Wednesday, March 20, 2019 8:37 AM
To: Zacher, Jennifer L. (PBM) <(b6)@va.gov>; Szudarski, Lucy (PBM) <(b6)@va.gov>
Subject: [EXTERNAL] Request for Dates for Spravato (esketamine) clinical review

Good morning Jennifer & Lucy -

I'm writing to find a few dates to circulate to my team e for a Spravato (esketamine) review. The hard conflicts on our side: 4/2-4/5 and 4/17 & 4/18, beyond these, I'll do my best to make it work for your team.

I fully recognize the external forces that have created this out-of-character environment we're living through and know I appreciate your partnership during this process.

Thanks so much -

(b6)

PharmD, MS

Scientific Director, National Accounts

Janssen Scientific Affairs

Real World Value & Evidence - Field (fka HECOR)

e: (b6)@its.jnj.com

t: (b6)

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Zacher, Jennifer L. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9027c425646e4de8a7d196908016331b-Zacher, Jen <(b6)@va.gov>; Szudarski, Lucy (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d92492f1757463da2417401f68a598e-Szudarski, (b6)@va.gov>
Sent Date:	2019/03/20 11:54:11
Delivered Date:	2019/03/20 11:54:00

From:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6) [REDACTED]@va.gov>
To:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) [REDACTED]@va.gov>
Subject:	RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Date:	2019/08/27 18:00:35
Priority:	Normal
Type:	Note

There are no contract issues to discuss Jon.

(b6)

(b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Jensen, Jon M. <(b6) [REDACTED]@va.gov>
Date: Tuesday, Aug 27, 2019, 5:05 PM
To: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Understand. He will not be discussing any contractual concerns.

Jon M. Jensen
VHA Acting Deputy Chief of Staff
(b6) [REDACTED]
Sent with BlackBerry Work
(www.blackberry.com)

From: Valentino, Michael (VACO) <(b6) [REDACTED]@va.gov>
Date: Tuesday, Aug 27, 2019, 12:29 PM
To: Jensen, Jon M. <(b6) [REDACTED]@va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Hi Jon,

(b6)

(b6)

Mike

From: Williams, Jessica D.

Sent: Tuesday, August 27, 2019 12:04 PM

To: Valentino, Michael (VACO) <(b6) va.gov>; O'Toole, Thomas P.

(b6) va.gov>; Jensen, Jon M. <(b6) va.gov>

Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi

<(b6) va.gov>; Adams, Jennifer L. (VHACO) (b6) va.gov>; (b6) (OGC)

(b6) va.gov>

Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Thank you all you're your willingness to take this meeting on behalf of Dr. Stone. However, we will not be meeting today; (b6) is requesting to meet solely with Dr. Stone.

We appriecate everyone's effort this morning with this.

V/r

Jessica

From: Williams, Jessica D.

Sent: Tuesday, August 27, 2019 10:29 AM

To: Valentino, Michael (VACO) <(b6) va.gov>; O'Toole, Thomas P.

(b6) va.gov>; Jensen, Jon M. <(b6) va.gov>

Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi

<(b6) va.gov>; Adams, Jennifer L. (VHACO) (b6) va.gov>; (b6) (OGC)

(b6) va.gov>

Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Thank you sir for the documents. We appreciate your feedback. I will circle back with regarding specific times.

V/r

Jessica

From: Valentino, Michael (VACO)

Sent: Tuesday, August 27, 2019 10:21 AM

To: Williams, Jessica D. (b6) va.gov>; O'Toole, Thomas P. (b6) va.gov>;

Jensen, Jon M. <(b6) va.gov>

Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi

<(b6) va.gov>; Adams, Jennifer L. (VHACO) (b6) va.gov>; (b6) (OGC)

(b6) a.gov>

Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Hi Jessica,

Is there a reason Johnson and Johnson isn't following VA's established procedures to contact the PBM formulary management group in Chicago to discuss Spravato? Anything we could do to encourage them to do what we require other companies to do would be greatly appreciated.

I have to leave for a (b6) appointment at 3pm today and I have a few other things on my schedule. I'm available today from 10:30 to 11:30 1:00 to 1:30 and 2:00 to 3:00 if any of those times work for a call. If not, I can ask someone else from PBM to join the call.

Tom,

Here is some updated information (some of which should be kept in house which is why J&J should be referred to PBM):

- • March 5, 2019 – Spravato was approved by FDA
- • March 8, 2019 – Spravato was added to FSS contract for purchase by VA sites
- • March 11-12, 2019 – Product overview presented to internal clinical groups (CMOs, MH leads, VISN Pharmacist Executives)
- • March 15, 2019 – FAQ document distributed to the field
- • March 18, 2019 – Memo issued to field with instructions on how to obtain REMS certification as required by FDA
- • March 19, 2019 – Spravato became available in the U.S. pharmaceutical supply chain
- • May 13-15, 2019 – The Spravato drug monograph, draft criteria for use, and field comments were presented to both the VISN Pharmacist Executive Committee and the Medical Advisory Panel. Draft documents were developed in collaboration with the Office of Mental Health. After discussion, the issue was tabled until the June face to face committee meeting so that feedback from the VPE/MAP committee and field commenters could be incorporated.
- • June 12, 2019 – launched Esketamine Community of Practice monthly teleconference, open to anyone in VHA interested in learning about esketamine
- • June 20, 2019 – based on careful review of available evidence, the MAP/VPE committee voted to:
 - • Designate esketamine as a non-formulary drug which will be made available with an approved prospective review
 - • Approve evidence-based prescribing guidance
 - • Establish an ongoing clinical monitor to assess the drug's safety and effectiveness in the Veteran population
 - • Provide clear and consistent messaging to VA providers
- • July 1, 2019 – launched Esketamine Community of Practice SharePoint site, which serves as a repository of resources related to clinical use of esketamine within VHA
- • July 15, 2019 – Date that the clinical monitor to assess Spravato's safety and effectiveness (aka MUET) went live

Here is the patient specific data from Ilse:

- • 3 patients to date at 2 sites
- • VA Boston began treatment of Patient #1 on (b6), 2019

- • VA New Mexico began treatment of Patient #2 on (b6), 2019 and Patient #3 on (b6) 2019
- • All three patients are continuing to receive treatments, no significant adverse events reported to date, tolerating treatment well

37 Dose kits purchased at 5 VA medical facilities up thru 8/22/2019.

VA Medical Facilities

- • Nashville =4
- • Lom Linda =4
- • Albuquerque = 21
- • Fayetteville, AR =2

Boston = 6

Mike

From: Williams, Jessica D.

Sent: Tuesday, August 27, 2019 10:11 AM

To: Valentino, Michael (VACO) <(b6)@va.gov>; O'Toole, Thomas P.

(l(b6)@va.gov); Jensen, Jon M. <(b6)@va.gov>

Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi

<(b6)@va.gov>; Adams, Jennifer L. (VHACO) (t(b6)@va.gov); (b6) (OGC)

(l(b6)@va.gov)

Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Importance: High

Good Morning Dr. Valentino,

On behalf of Dr. Stone, would you mind joining this call along with Dr. O'Toole, to discuss Spravato with (b6) (t(b6) from Johnson & Johnson. Also, if you could provide any materials regarding Spravato, we would greatly appreciate it.

Once we receive confirmation of participation, I will follow up with Johnson & Johnson for an actual time. We thank you for your time and participation.

V/r

Jessica

From: Jensen, Jon M.

Sent: Tuesday, August 27, 2019 9:54 AM

To: O'Toole, Thomas P. <(b6)@va.gov>; Williams, Jessica D. <(b6)@va.gov>;

Adams, Jennifer L. (VHACO) <(b6)@va.gov>; (b6) (OGC) <(b6)@va.gov>

Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi

(b6)@va.gov

Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Mike Valentino has updates on this

Jon M. Jensen
VHA Acting Deputy Chief of Staff
(b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: O'Toole, Thomas P. <(b6) va.gov>
Date: Tuesday, Aug 27, 2019, 9:48 AM
To: Williams, Jessica D. <(b6) va.gov>, Jensen, Jon M. <(b6) va.gov>, Adams, Jennifer L. (VHACO) <(b6) va.gov>, (b6) (OGC) <(b6) va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>, Howard, Kristi <(b6) va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

I'm happy to field the call but not aware of any specifics to the topic (Spravato) - does Dave Carroll or someone from MH also need to be on the call (or in my place) or can anyone get me up to speed on either information to convey or messaging? I defer to your preference

Thanks
Tom

From: Williams, Jessica D.
Sent: Tuesday, August 27, 2019 9:09 AM
To: O'Toole, Thomas P. <(b6) va.gov>; Jensen, Jon M. <(b6) va.gov>; Adams, Jennifer L. (VHACO) <(b6) va.gov>; (b6) (OGC) <(b6) va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi <Kristi.Howard@va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Good Morning Dr. O' Toole,

On behalf of Dr. Stone, will you be able to take this call with (b6) from Johnson & Johnson, today.

Dr. Stone is on a site in West Virginia with poor connectivity.

V/r
Jessica

From: Jensen, Jon M.
Sent: Tuesday, August 27, 2019 8:55 AM
To: Williams, Jessica D. <(b6) va.gov>; Adams, Jennifer L. (VHACO) <(b6) va.gov>; (b6) (OGC) <(b6) va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Howard, Kristi <(b6) va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Won't be able to do it today we are in WV. And connectivity is spotty. The day tomorrow is fully booked. Both days are emergent issues that need his direct attention. Can you check with Tom O'Toole to see if he is spun up enough to take the call?

Jon M. Jensen
VHA Acting Deputy Chief of Staff
(b6)

Sent with BlackBerry Work
(www.blackberry.com)

From: Williams, Jessica D. (b6) @va.gov>
Date: Tuesday, Aug 27, 2019, 8:46 AM
To: Jensen, Jon M. <(b6) va.gov>, Adams, Jennifer L. (VHACO) <(b6) va.gov>, (b6) (OGC) <(b6) va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>, Howard, Kristi <(b6) va.gov>
Subject: FW: Request for a 15-min call with Dr. Stone on Tues, 8/27

Morning Jon -

Dr. Stone needs to connect with (b6) from Johnson & Johnson for 15 minutes today, hopefully this afternoon. Just need a time that will work while you all are in the car. Advise please. Nicole will be reaching out to you as well.

V/r
Jessica

From: Williams, Jessica D.
Sent: Tuesday, August 27, 2019 8:34 AM
To: (b6) @its.jnj.com>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Adams, Jennifer L. (VHACO) <(b6) va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Good Morning (b6),

Please let us verify Dr. Stone's calendar for the remainder of today. Dr. Stone has unexpected official travel for today. I will follow back up with you shortly. Thanks!

V/r
Jessica

From: (b6) @its.jnj.com>
Sent: Tuesday, August 27, 2019 8:28 AM
To: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>

Subject: [EXTERNAL] RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Good morning,

I am following up regarding this request for a call with Dr. Stone. I also left a voicemail message to follow up on this request as well.

Please let me know when Dr. Stone will be available to accommodate a 15-minute call with Courtney Billington in follow up to a May 14th meeting regarding Spravato. The nature of this call is time sensitive, hence my follow-up.

Thank you,

(b6) | Executive Assistant to Courtney Billington – President, Neuroscience
Janssen Pharmaceuticals, Inc. | 1125 Trenton-Harbourton Road | A1.300.19 | Titusville, NJ 08560
Office (b6) | email (b6)@jnj.com

From: (b6)
Sent: Friday, August 23, 2019 1:45 PM
To: vhaushmeetingrequests@va.gov
Subject: Request for a 15-min call with Dr. Stone on Tues, 8/27

Hi Kristi (and team),

Thank you for taking my call and providing me with this e-mail address. As mentioned, (b6) has requested a 15-minute call with Dr. Stone to follow up on a discussion that they had on May 14. (b6) and (b6) met with Dr. Stone regarding Spravato in May.

My contact information is below. I look forward to hearing back regarding Dr. Stone's availability.

Thank you... and Kristi, enjoy your week off.

(b6)

(b6) | Executive Assistant to Courtney Billington – President, Neuroscience
Janssen Pharmaceuticals, Inc. | 1125 Trenton-Harbourton Road | A1.300.19 | Titusville, NJ 08560
Office: (b6) | email: (b6)@ts.jnj.com

Sender:	Valentino, Michael (VACO) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6519E043DF55494A98F3C0074F52F8E0-VALENTINO, <(b6)@va.gov>
Recipient:	Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group

	(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) va.gov>
Sent Date:	2019/08/27 18:00:34
Delivered Date:	2019/08/27 18:00:35

From:	Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J <(b6)@va.gov>
To:	(b6)@its.jnj.com>
CC:	VHA USH Meeting Requests /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca775dc76d6140fdb5fc70e6c695c9f1-VHA USH Mee <VHAUSHMeetingRequests@va.gov>; Adams, Jennifer L. (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d6fa69f6594473691f5f4d87a9d4412-Adams, Jenn <(b6)@va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6)@va.gov>; (b6) (OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a9b57dad55f493e885bea3565f65e5a-Katikos, Ni <(b6)@va.gov>
Subject:	RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Date:	2019/08/27 11:53:57
Priority:	Normal
Type:	Note

Hi (b6),

Thank you for your response. Understanding (b6) preference to speak directly with Dr. Stone, please give us the opportunity to follow up with our team. I will reply back to you shortly.

V/r
Jessica

From: (b6)@its.jnj.com>
Sent: Tuesday, August 27, 2019 11:41 AM
To: Williams, Jessica D. <(b6)@va.gov>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Adams, Jennifer L. (VHACO) <(b6)@va.gov>; Jensen, Jon M. <(b6)@va.gov>; (b6) (OGC) <(b6)@va.gov>
Subject: [EXTERNAL] RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Hi Jessica,

Thank you for reaching out to me. I was able to speak with (b6) to see if he is can have this discussion with two of Dr. Stone's senior leaders. (b6) preference is to speak directly with Dr. Stone.

As mentioned, the purpose of this quick call is a follow-up to a commercial discussion that they had at the May 14th meeting. This call is unrelated to Healthy Heroes project that was also discussed at the 5/14 meeting, this call would be related to Spravato. Can you check with your team to see when Dr. Stone would be available this week for a

quick call with (b6) ? The only times that (b6) cannot accommodate a call will be tomorrow (8/28) from 7:30-10:30am; 11am-12:30pm; or 3:45-5:30pm. Anytime outside of these time frames on Wednesday or any time on Thursday or Friday can be accommodated by (b6).

Thank you again for your kind assistance with this request. I will look forward to hearing back from you.

Best regards,

(b6) | Executive Assistant to Courtney Billington – President, Neuroscience
Janssen Pharmaceuticals, Inc. | 1125 Trenton-Harbourton Road | A1.300.19 | Titusville, NJ 08560
Office: (b6) | (b6)@its.inj.com

From: Williams, Jessica D. <(b6)@va.gov>
Sent: Tuesday, August 27, 2019 10:42 AM
To: (b6)@its.inj.com>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Adams, Jennifer L. (VHACO) <(b6)@va.gov>; Jensen, Jon M. <(b6)@va.gov>; (b6) (OGC) <(b6)@va.gov>
Subject: [EXTERNAL] RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Good Morning (b6)

Circling back, unfortunately Dr. Stone does not have any availability for this call. However, we have two senior leaders who will take this call on his behalf. Our most feasible time for today's call will be from 2:00-2:15pm Please provide call in details. Thanks!

V/r
Jessica

From: Williams, Jessica D.
Sent: Tuesday, August 27, 2019 8:34 AM
To: (b6)@its.inj.com>
Cc: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>; Adams, Jennifer L. (VHACO) <(b6)@va.gov>
Subject: RE: Request for a 15-min call with Dr. Stone on Tues, 8/27

Good Morning (b6)

Please let us verify Dr. Stone's calendar for the remainder of today. Dr. Stone has unexpected official travel for today. I will follow back up with you shortly. Thanks!

V/r

Jessica

From: (b6) d2@its.inj.com>
Sent: Tuesday, August 27, 2019 8:28 AM
To: VHA USH Meeting Requests <VHAUSHMeetingRequests@va.gov>
Subject: [EXTERNAL] RE: Request for a 15-min call with Dr. Stone on Tues, 8/27
Importance: High

Good morning,

I am following up regarding this request for a call with Dr. Stone. I also left a voicemail message to follow up on this request as well.

Please let me know when Dr. Stone will be available to accommodate a 15-minute call with (b6) in follow up to a May 14th meeting regarding Spravato. The nature of this call is time sensitive, hence my follow-up.

Thank you,

(b6) d | Executive Assistant to Courtney Billington – President, Neuroscience
Janssen Pharmaceuticals, Inc. | 1125 Trenton-Harbourton Road | A1.300.19 | Titusville, NJ 08560
Office: (b6) (b6)@its.inj.com

From: (b6)]
Sent: Friday, August 23, 2019 1:45 PM
To: vhaushmeetingrequests@va.gov
Subject: Request for a 15-min call with Dr. Stone on Tues, 8/27

Hi Kristi (and team),

Thank you for taking my call and providing me with this e-mail address. As mentioned, (b6) has requested a 15-minute call with Dr. Stone to follow up on a discussion that they had on May 14. (b6) met with Dr. Stone regarding Spravato in May.

My contact information is below. I look forward to hearing back regarding Dr. Stone's availability.

Thank you... and Kristi, enjoy your week off.

(b6)

(b6) | Executive Assistant to Courtney Billington – President, Neuroscience
Janssen Pharmaceuticals, Inc. | 1125 Trenton-Harbourton Road | A1.300.19 | Titusville, NJ 08560
Office: (b6) (b6)@its.inj.com

Sender:	Williams, Jessica D. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=007F83F1989E48888DAB9C5D712C99B4-WILLIAMS, J <(b6) [REDACTED]@va.gov>
Recipient:	(b6) [REDACTED]@ts.jnj.com>; VHA USH Meeting Requests /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca775dc76d6140fdb5fc70e6c695c9f1-VHA USH Mee <VHAUSHMeetingRequests@va.gov>; Adams, Jennifer L. (VHACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d6fa69f6594473691f5f4d87a9d4412-Adams, Jenn <(b6) [REDACTED]@va.gov>; Jensen, Jon M. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddeb735ace76400db5c3f10603188a14-Jensen, Jon <(b6) [REDACTED]@va.gov>; (b6) [REDACTED] (OGC) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a9b57dad55f493e885bea3565f65e5a-Katikos, Ni <(b6) [REDACTED]@va.gov>
Sent Date:	2019/08/27 11:53:55
Delivered Date:	2019/08/27 11:53:57
Message Flags:	Unread

From:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
To:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6)@va.gov>
Subject:	RE: quick question
Date:	2019/08/16 16:23:00
Priority:	Normal
Type:	Note

Happy to help. Have a great weekend!

From: Schreiber, Matthew A.
Sent: Friday, August 16, 2019 4:23 PM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>
Subject: RE: quick question

Thank you for clarifying. I'm getting a lot of local questions here so want to be very careful about what I can share, but on pricing—that is a never-share, I understand!

Thank you for the quick update, I appreciate it!

From: Fuller, Matthew A. (PBM)
Sent: Friday, August 16, 2019 1:21 PM
To: Schreiber, Matthew A. <(b6)@va.gov>
Subject: RE: quick question

Hi Matt,

Yes, I believe so. We are not allowed to share pricing information though.

Matthew

From: Schreiber, Matthew A.
Sent: Friday, August 16, 2019 4:19 PM
To: Fuller, Matthew A. (PBM) <(b6)@va.gov>
Subject: quick question

Hi Matthew,
I'm sorry to bother you with such a minor point and I probably should know the answer to this, but at this point the esketamine national protocol and CFU were approved and it's ok to share these with non-MAP/PDM colleagues, is that right? I just wanted to triple check, thank you for any advice and I hope you are doing well!
Matt

Sender:	Fuller, Matthew A. (PBM) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=62D9CBB23B184CACB98895776E36A471-FULLER, MAT>
Recipient:	Schreiber, Matthew A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db4d0324bf0945f183f33816c7fd1db0-Schreiber, <(b6) va.gov>
Sent Date:	2019/08/16 16:23:48
Delivered Date:	2019/08/16 16:23:00

From:	Festin, Fe Erlita /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CC0692D6C3FA4D20BD21AADE22D20A51-FESTIN, FE <(b6)@va.gov>
To:	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Shiroma, Paulo R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cae9fb698bb245669c11a3564784e24e-Shiroma, Pa <(b6)@va.gov>; Yoon, Gihyun /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aec946e46a224f4ea66ce2078a8115d3-Yoon, Gihyu <(b6)@va.gov>; Ranganathan, Mohini /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a929509685bd4ad2895c66775c05d7b5-Ranganathan <(b6)@va.gov>; Mathew, Sanjay (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67422a5cc3904b40bff8fca2b9cd1b48-Mathew, San <(b6)@va.gov>; Krystal, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d5500f300d74e0dba7f8b30a5b42f02-Krystal, Jo <(b6)@va.gov>; (b6) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37831d1786914522b90bb85b2a8e1441-Mohamed, So <(b6)@va.gov>
CC:	Ma, Demin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b5cfd22ddd4265b8462d236c50dd7e-Ma, Denim <(b6)@va.gov>; Houranieh, Antoun /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410da6eb674c495d975601207f29adb6-Houranieh, <(b6)@va.gov>; Dantzler, Anne /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f5acd16706148918ba6b1552b149061-Dantzler, A <(b6)@va.gov>; Kirby, Shawn /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d696ac8397624f14ab7e349554ac036c-Kirby, Shaw <(b6)@va.gov>
Subject:	RE: question re patients on Methadone
Date:	2019/08/19 14:53:52
Priority:	Normal
Type:	Note

Noted. Thanks for sharing the updated criteria.

Fe

From: Fuller, Matthew A. (PBM)

Sent: Monday, August 19, 2019 11:10 AM

To: Festin, Fe Erlita <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Shiroma, Paulo R. <(b6)@va.gov>; Yoon, Gihyun <(b6)@va.gov>; Ranganathan, Mohini <(b6)@va.gov>; Mathew, Sanjay (HOU) <(b6)@va.gov>; Krystal, John <(b6)@va.gov>; (b6) <(b6)@va.gov>

Cc: Ma, Demin <(b6)@va.gov>; Houranieh, Antoun <(b6)@va.gov>; Dantzler, Anne

<(b6) [REDACTED] va.gov>; Kirby, Shawn (b6) [REDACTED]@va.gov>

Subject: RE: question re patients on Methadone

The exclusion criteria you have listed are not the most recent.

The Esketamine Community of Practice SharePoint has the most recent documents.

From: Festin, Fe Erlita

Sent: Monday, August 19, 2019 10:56 AM

To: Fuller, Matthew A. (PBM) <(b6) [REDACTED] va.gov>; Wiechers, Ilse (b6) [REDACTED]@va.gov>; Shiroma, Paulo R. <(b6) [REDACTED] va.gov>; Yoon, Gihyun <(b6) [REDACTED] va.gov>; Ranganathan, Mohini <(b6) [REDACTED] va.gov>; Mathew, Sanjay (HOU) <(b6) [REDACTED] va.gov>; Krystal, John <(b6) [REDACTED] va.gov>; (b6) [REDACTED] <(b6) [REDACTED] va.gov>
Cc: Ma, Demin <(b6) [REDACTED]@va.gov>; Houranieh, Antoun <(b6) [REDACTED] va.gov>; Dantzler, Anne <(b6) [REDACTED] va.gov>; Kirby, Shawn (b6) [REDACTED]@va.gov>

Subject: RE: question re patients on Methadone

Noted.

Based on our current exclusion criteria highlighted below, having positive Methadone on urine screen (**with an active prescription**) does not preclude use of Esketamine. Agree with local adjudication. However, should we just change our exclusion criteria below and state opioid use disorder as an exclusion even with prescribed Methadone just like medical marijuana so patients don't challenge our decision?

This patient has been abstinent from opioids for a year now due to Methadone maintenance. He is also willing to reduce Methadone and Xanax doses to least effective dose and stop Adderall.

Thanks.

Exclusion Criteria

- • Hypersensitivity to esketamine, ketamine, or any of the excipients
- • Aneurysmal vascular disease (including thoracic and abdominal aorta, intracranial, and peripheral arterial vessels) or arteriovenous malformation.
- • History of intracerebral hemorrhage.
- • History of seizures
- • Current or recent (within 30 days) delirium
- • Current uncontrolled hypertension (systolic blood pressure >140 mm Hg or diastolic blood pressure >90 mm Hg)
- • Severe cardiac decompensation (Class IV heart failure or unstable angina)

- • Severe hepatic impairment (Child-Pugh Class C)
- • Current or previous interstitial or ulcerative cystitis
- • Active suicidal ideation
- • Comorbid psychiatric condition is present (schizophrenia, schizoaffective disorder, MDD with psychotic symptoms), bipolar disorder, obsessive-compulsive disorder, intellectual disability, autism, or cluster B personality disorder, or a major neurocognitive disorder diagnosis).
- • History of non-response to ketamine, esketamine or ECT
- • History of Vagal Nerve Stimulation (VNS) or deep brain stimulation in current episode of depression
- • Current or previous abuse of ketamine or esketamine
- • Current use of prescribed cannabis (“medical marijuana”).
- • Current moderate or severe substance use disorder (SUD) or untreated SUD not in remission
- • Positive urine drug screen for specified drugs of abuse (cannabinoids, barbiturates, methadone, opioids, cocaine, phencyclidine, and amphetamine/methamphetamine) not attributable to active prescriptions.
- • Pregnancy (known pregnancy or positive pregnancy test).
- • Patient is breastfeeding

From: Fuller, Matthew A. (PBM)

Sent: Monday, August 19, 2019 9:07 AM

To: Wiechers, Ilse <(b6)@va.gov>; Festin, Fe Erlita <(b6)va.gov>; Shiroma, Paulo R. <(b6)va.gov>; Yoon, Gi Hyun <(b6)va.gov>; Ranganathan, Mohini <(b6)va.gov>; Mathew, Sanjay (HOU) <(b6)va.gov>; Krystal, John <(b6)va.gov>; (b6) <(b6)va.gov>

Cc: Ma, Demin (b6)@va.gov>; Houranieh, Antoun <(b6)va.gov>

Subject: RE: question re patients on Methadone

Hi Ilse,

You are correct. One of the exclusion criteria for esketamine is “current barbiturate, cannabis or opioid use”. Local adjudication would be needed.

Matthew

From: Wiechers, Ilse

Sent: Saturday, August 17, 2019 1:32 PM

To: Festin, Fe Erlita <(b6)@va.gov>; Shiroma, Paulo R. <(b6)@va.gov>; Yoon, Gihyun <(b6)@va.gov>; Ranganathan, Mohini <(b6)@va.gov>; Mathew, Sanjay (HOU) <(b6)@va.gov>; Krystal, John <(b6)@va.gov>; (b6) <(b6)@va.gov>

Cc: Ma, Demin <(b6)@va.gov>; Houranieh, Antoun <(b6)@va.gov>; Fuller, Matthew A. (PBM) <(b6)@va.gov>

Subject: RE: question re patients on Methadone

Hi Fe –

Unfortunately methadone or suboxone maintenance would be considered exclusions for consideration of using esketamine based on the current Criteria For Use approved by PBM. You would need to seek local P&T adjudication for approval to use in this case, should you and the team decided to proceed. Adding Matthew Fuller here to make sure I've got that all correct.

Curious to hear more from others about past experience using ketamine in patients on MOUD maintenance treatment.

Thanks,
Ilse

From: Festin, Fe Erlita

Sent: Friday, August 16, 2019 10:49 AM

To: Shiroma, Paulo R. <(b6)@va.gov>; Wiechers, Ilse <(b6)@va.gov>; Yoon, Gihyun <(b6)@va.gov>; Ranganathan, Mohini <(b6)@va.gov>; Mathew, Sanjay (HOU) <(b6)@va.gov>; Krystal, John <(b6)@va.gov>; (b6) <(b6)@va.gov>

Cc: Ma, Demin <(b6)@va.gov>; Houranieh, Antoun <(b6)@va.gov>

Subject: RE: question re patients on Methadone

Hi all,

We have a referral for Esketamine on a patient who is on Alprazolam, Adderall and Methadone maintenance. Have any of you had experience giving Ketamine to anyone who has been on Methadone maintenance for Opioid use disorder?

Best,
Fe

From: Shiroma, Paulo R.

Sent: Wednesday, June 12, 2019 3:15 PM

To: Wiechers, Ilse <(b6)@va.gov>; Yoon, Gihyun <(b6)@va.gov>; Ranganathan, Mohini

<(b6) [REDACTED] va.gov>; Mathew, Sanjay (HOU) <(b6) [REDACTED] va.gov>; Krystal, John
<(b6) [REDACTED] va.gov>; (b6) [REDACTED] <(b6) [REDACTED] va.gov>
Cc: Ma, Demin (b6) [REDACTED]@va.gov>; Festin, Fe Erlita <(b6) [REDACTED] va.gov>; Houranieh, Antoun
<(b6) [REDACTED] va.gov>
Subject: RE: question re Modified Aldrete Score

It is free as far as I know.

From: Wiechers, Ilse
Sent: Wednesday, June 12, 2019 2:10 PM
To: Shiroma, Paulo R. <(b6) [REDACTED] va.gov>; Yoon, Gihyun <(b6) [REDACTED] va.gov>; Ranganathan, Mohini <(b6) [REDACTED] va.gov>; Mathew, Sanjay (HOU) <(b6) [REDACTED] va.gov>; Krystal, John <(b6) [REDACTED] va.gov>; (b6) [REDACTED] <(b6) [REDACTED] va.gov>
Cc: Ma, Demin <(b6) [REDACTED] va.gov>; Festin, Fe Erlita <(b6) [REDACTED] va.gov>; Houranieh, Antoun <(b6) [REDACTED] va.gov>
Subject: question re Modified Aldrete Score

Hi everyone –

A quick question re using the Modified Aldrete Score for determining whether a patient is ready for discharge post-ketamine or post-esketamine dosing. Is this scale copyrighted or is it available free for use?

Boston is looking to clarify this for their esketamine dosing protocol, which they anticipate using with a patient next Tuesday.

Thanks,
Ilse

Ilse R. Wiechers, MD, MPP, MHS
National Director, Psychotropic Drug Safety Initiative (PDSI)
Associate Director, Northeast Program Evaluation Center
Office of Mental Health and Suicide Prevention (10NC5), Department of Veterans Affairs
Assistant Clinical Professor of Psychiatry, Yale University School of Medicine
cell (b6) [REDACTED]
(b6) [REDACTED] va.gov | (b6) [REDACTED] yale.edu

Suicide Prevention is Everyone's Business. #BeThere.

-



VCL

Sender: Festin, Fe Erlita /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CC0692D6C3FA4D20BD21AADE22D20A51-FESTIN, FE <(b6) [REDACTED] va.gov>

	Fuller, Matthew A. (PBM) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d9cbb23b184cacb98895776e36a471-Fuller, Mat <(b6)@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I <(b6)@va.gov>; Shiroma, Paulo R. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cae9fb698bb245669c11a3564784e24e-Shiroma, Pa <(b6)@va.gov>; Yoon, Gihyun /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aec946e46a224f4ea66ce2078a8115d3-Yoon, Gihyu <(b6)@va.gov>; Ranganathan, Mohini /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a929509685bd4ad2895c66775c05d7b5-Ranganathan <(b6)@va.gov>; Mathew, Sanjay (HOU) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=67422a5cc3904b40bff8fca2b9cd1b48-Mathew, San <(b6)@va.gov>; Krystal, John /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3d5500f300d74e0dba7f8b30a5b42f02-Krystal, Jo <(b6)@va.gov>; (b6) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37831d1786914522b90bb85b2a8e1441-Mohamed, So <(b6)@va.gov>; Ma, Demin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6b5cfd22ddd4265b8462d236c50dd7e-Ma, Denim <(b6)@va.gov>; Houranieh, Antoun /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410da6eb674c495d975601207f29adb6-Houranieh, <(b6)@va.gov>; Dantzler, Anne /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f5acd16706148918ba6b1552b149061-Dantzler, A <(b6)@va.gov>; Kirby, Shawn /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d696ac8397624f14ab7e349554ac036c-Kirby, Shaw <(b6)@va.gov>
Recipient:	
Sent Date:	2019/08/19 14:53:51
Delivered Date:	2019/08/19 14:53:52
Message Flags:	Unread

From:	Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FBA8EA7CD941B3A0A4F79CA3C6EE87-LAHL, DENNI (b6) @va.gov>
To:	Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e90923522067a767-Graham, Chr (b6) @va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>
CC:	VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, (b6) @va.gov>
Subject:	RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request
Date:	2019/08/21 11:53:30
Due Date:	2019/08/20 20:00:00
Priority:	Normal
Type:	Note

10P Actions,

10P4 concurs with the submitted OPIA statement – note after discussion with VHA Communications we were asked to approve the statement even though it does not address the questions.

After reviewing the available published evidence regarding the safety and effectiveness of esketamine (Spravato), a team of VA clinicians approved on June 20 the use of esketamine (Spravato) on a non-formulary basis. This process is similar to “prior authorization” formulary designations used in non-VA health care systems, and will enable VA psychiatrists to offer esketamine to patients when clinically indicated.

In addition, VA developed clinical and procedural guidance and other tools to promote thoughtful patient selection and safe administration practices, in keeping with the FDA-approved indications for esketamine use and safety requirements. These evidence-based processes will ensure the medication is prioritized for use in Veterans who have not previously responded to adequate trials of other available treatments for major depression.

VA will closely monitor the use of esketamine in Veterans to more fully understand its relative safety and effectiveness as compared to other available treatments. Based on this information, VA may revise its clinical guidance and formulary status if warranted.

This decision reflects VA’s commitment to seek new ways to provide the best health care available for our nation’s Veterans.

Dennis

Dennis Lahl FAC-P/PM

Office of the Assistant Deputy Under Secretary for Health for
Patient Care Services (10P4)

VACO PCS IT/BCAG/ISO Liaison

TMS OPCS DM

ph: (b6)(3)

fax: 202-273-5483

Dennis Lahl

From: Graham, Christopher L.

Sent: Wednesday, August 21, 2019 11:36 AM

To: VHA 10P4 Actions <VHA10P4Actions@va.gov>

Cc: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group
<vha10p4comm@va.gov>

Subject: FW: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Importance: High

10P4 Actions-FYI.

From: Hammonds, Michele

Sent: Wednesday, August 21, 2019 11:28 AM

To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group
<vha10p4comm@va.gov>

Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Subject: FW: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Importance: High

10P for Mike and Tom in Pharmacy – This is a time sensitive (b6) [REDACTED], Producer/Editor, of Vice News about the controversial drug esketamine (Spravato)

Is the following response still accurate?

(b) (5)

[REDACTED]

[REDACTED]

(b) (5)

is.

Deadline: 2pm Today

Michele Hammonds
Office of Communications (10B2B)

(b6)

From: Mandreucci, Christina M.

Sent: Wednesday, August 21, 2019 11:12 AM

To: Piork, Steve (b6) <(b6)@va.gov>; Ballesteros, Mark <(b6)@va.gov>; McConnell, Dillon J. <(b6)@va.gov>; Cashour, Curtis <(b6)@va.gov>; Carter, Susan <(b6)@va.gov>

Cc: Hutton, James <(b6)@va.gov>; Thomas, Tom <(b6)@va.gov>; Baxter, Jessica <(b6)@va.gov>; Noller, Randal <(b6)@va.gov>; McGee, Damian J <(b6)@va.gov>; Hammonds, Michele <(b6)@va.gov>; Screen, Gina <(b6)@va.gov>

Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

VHA, can you confirm?

From: Piork, Steve

Sent: Wednesday, August 21, 2019 9:02 AM

To: Mandreucci, Christina M. <(b6)@va.gov>; Ballesteros, Mark <(b6)@va.gov>; McConnell, Dillon J. <(b6)@va.gov>; Cashour, Curtis <(b6)@va.gov>; Carter, Susan <(b6)@va.gov>

Cc: Hutton, James <(b6)@va.gov>; Thomas, Tom <(b6)@va.gov>; Baxter, Jessica <(b6)@va.gov>; Noller, Randal <(b6)@va.gov>; McGee, Damian J <(b6)@va.gov>; Hammonds, Michele <(b6)@va.gov>; Screen, Gina <(b6)@va.gov>

Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

I believe so... VHA, please confirm.

Regards,

Steve H. Piork
Office of Public Affairs – New York
U.S. Department of Veterans Affairs
245 W Houston Street
New York, NY 10014

(b6) (office)

(b6) (cell)

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From: Mandreucci, Christina M. ((b6) [REDACTED] va.gov)
Date: Wednesday, Aug 21, 2019, 8:54 AM
To: Piork, Steve ((b6) [REDACTED]@va.gov), Ballesteros, Mark <((b6) [REDACTED] va.gov)>, McConnell, Dillon J. ((b6) [REDACTED] va.gov), Cashour, Curtis <((b6) [REDACTED] va.gov)>, Carter, Susan <((b6) [REDACTED] va.gov)>
Cc: Hutton, James <((b6) [REDACTED] va.gov)>, Thomas, Tom ((b6) [REDACTED] va.gov), Baxter, Jessica ((b6) [REDACTED]@va.gov), Noller, Randal <((b6) [REDACTED] va.gov)>, McGee, Damian J ((b6) [REDACTED] va.gov), Hammonds, Michele ((b6) [REDACTED] va.gov), Screen, Gina ((b6) [REDACTED] va.gov)
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Is the following response still accurate?

(b) (5) [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]

[REDACTED]
[REDACTED] is.

From: Piork, Steve
Sent: Wednesday, August 21, 2019 8:45 AM
To: Ballesteros, Mark <((b6) [REDACTED] va.gov)>; Mandreucci, Christina M. ((b6) [REDACTED] va.gov); McConnell, Dillon J. <((b6) [REDACTED] va.gov)>; Cashour, Curtis <((b6) [REDACTED] va.gov)>; Carter, Susan <((b6) [REDACTED] va.gov)>
Cc: Hutton, James <((b6) [REDACTED] va.gov)>; Thomas, Tom <((b6) [REDACTED] va.gov)>; Baxter, Jessica ((b6) [REDACTED]@va.gov); Noller, Randal <((b6) [REDACTED] va.gov)>; McGee, Damian J <((b6) [REDACTED] va.gov)>; Hammonds, Michele <((b6) [REDACTED] va.gov)>; Screen, Gina

<(b6) [REDACTED]@va.gov>

Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Good morning.

The queries came from the Connecticut I-Team. I've also included the last follow up response that went out to the reporter.

Can we find out if we started to prescribe this drug in VA yet? If so, when did VA start?

Answer: The first dose of intranasal esketamine was safely administered on June 18, 2019, to a Veteran with [REDACTED] treatment-resistant depression at the VA Boston Healthcare System.

How many veterans have been treated with Spravato since the VA started offering it?

Answer: One Veteran has received treatment with intranasal esketamine as of today, July 23, 2019.

Regards,

Steve
NY OPA
o. (b6) [REDACTED]
[REDACTED]

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From: Ballesteros, Mark

Sent: Wednesday, August 21, 2019 7:53 AM

To: Mandreucci, Christina M. <(b6) [REDACTED]@va.gov>; McConnell, Dillon J. <(b6) [REDACTED]@va.gov>; Cashour, Curtis <(b6) [REDACTED]@va.gov>; Carter, Susan <(b6) [REDACTED]@va.gov>; Piork, Steve <(b6) [REDACTED]@va.gov>

Cc: Hutton, James <(b6) [REDACTED]@va.gov>; Thomas, Tom <(b6) [REDACTED]@va.gov>; Baxter, Jessica <(b6) [REDACTED]@va.gov>; Noller, Randal <(b6) [REDACTED]@va.gov>; McGee, Damian J <(b6) [REDACTED]@va.gov>; Hammonds, Michele <(b6) [REDACTED]@va.gov>; Screen, Gina <(b6) [REDACTED]@va.gov>

Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Adding Steve Piork from the NY team as he worked on a Spravato query last month.

I believe this was the approved response:

"(b) (5) [REDACTED]
[REDACTED]
[REDACTED]"

To: Cashour, Curtis <(b6) [REDACTED] va.gov>, Mandreucci, Christina M. <(b6) [REDACTED] va.gov>, Carter, Susan <(b6) [REDACTED] va.gov>
Cc: Hutton, James <(b6) [REDACTED] va.gov>, Ballesteros, Mark <(b6) [REDACTED] va.gov>, Thomas, Tom <(b6) [REDACTED] va.gov>, Baxter, Jessica <(b6) [REDACTED]@va.gov>, Noller, Randal <(b6) [REDACTED] va.gov>, McGee, Damian J <(b6) [REDACTED] va.gov>
Subject: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Good Evening Curt/Christine,

The San Francisco PAO received the following inquiry from VICE News requesting an interview RE: Ketamine. Reporter is also interested in Spravato and why VA hasn't been prescribing the drug to veterans. Since the request is national in scope from a national outlet, we recommend OMR handle but let us know how you'd like to proceed. Thanks!

QUERY:

Outlet: VICE News, airs weekly on HBO.

Subject: Ketamine-Spravato interview request

Reporter: (b6) [REDACTED], Producer/Editor,

Phone: 512-468-8807

Email: (b6) [REDACTED]@vice.com

Deadline: No Deadline

Summary of request: (b6) [REDACTED] with VICE News is requesting a background interview with Dr. Tobias Marton to discuss the use of ketamine and Spravato to treat depression and PTSD in Veterans at the SFVAMC. However, her questions are about national VA policy.

Questions:

- • "The use of ketamine at VA isn't common. Veterans are paying out of pocket for this type of treatment outside of VA."
 - • What legislation allows VA to use ketamine in treatment?
 - • Is the San Francisco VA the only VA facility using ketamine?
 - • Are other VA medical centers being encouraged to use ketamine in treatment?
 - • What is the national policy for using ketamine to treat Veterans?
- • "Spravato (esketamine) is FDA approved, but hasn't been rolled out to all VA clinics."
 - • What is the hold up?
 - • What are the benefits of it?

Thanks,
Dillon

Dillon McConnell
Public Affairs Specialist

cid:image002.gif@01D3FF1B.AEBB0B90

Los Angeles Regional Office of Public Affairs*
Office of Public and Intergovernmental Affairs (OPIA)
Department of Veterans Affairs
* Region includes: AK, CA, HI, ID, NV, OR, WA
Ph: (b6) Email: (b6)@va.gov

Lahl, Dennis /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP	
Sender:	(b6) va.gov>
Recipient:	Graham, Christopher L. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ff0fe692b31483e909235222067a767-Graham, Chr <(b6) va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5098b521b1f34f8a97f74be24709d62f-VHA 10P Act <VHA10PActions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Valentino, Michael (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6519e043df55494a98f3c0074f52f8e0-Valentino, <(b6) va.gov>
Sent Date:	2019/08/21 11:53:29
Delivered Date:	2019/08/21 11:53:30
Message Flags:	Unread

To:	Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b6) @va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>
CC:	VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>
Subject:	RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request
Date:	2019/08/21 11:49:33
Priority:	Normal
Type:	Note

Ok. I concur the statement is accurate

Sent with BlackBerry Work
(www.blackberry.com)

From: Lahl, Dennis (b6) @va.gov>
Date: Wednesday, Aug 21, 2019, 11:43 AM
To: Valentino, Michael (VACO) <(b6) @va.gov>, VHA 10P4P Action <vha10P4Paction@va.gov>
Cc: VHA 10P4 Actions <VHA10P4Actions@va.gov>, VHA 10P4 Communication Group <vha10p4comm@va.gov>, Wiechers, Ilse <(b6) @va.gov>
Subject: RE: QUERY: Ketamine-Spravato// VICE News // No Deadline - interview request

Recipient:	Lahl, Dennis /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39fba8ea7cd941b3a0a4f79ca3c6ee87-Lahl, Denni (b6) @va.gov>; VHA 10P4P Action /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8dc3dab451414f59b9797e8ed199c1e8-VHA 10P4P A <vha10P4Paction@va.gov>; VHA 10P4 Actions /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3032f7b70fa040f4b908d840344740b3-VHA 10P4 Ac <VHA10P4Actions@va.gov>; VHA 10P4 Communication Group /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ba2ff9b4604547be7834a71415253c-VHA 10P4 Co <vha10p4comm@va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>
Sent Date:	2019/08/21 11:49:33
Message Flags:	Unsent

From:	Kearney, Lisa K. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5DB1D2E054154A3B98EEF1F7DEAA6826-KEARNEY, LI (b6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b6) @va.gov>; Lakso, Wendy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6cc1e7a61d4c4823ae2a08bd3e6eb57f-Lasko, Wend (b6) @va.gov>
CC:	Jones, Taunya /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ebc42defb394bc0b4a1e57aa248c3b6-Jones, Taun (b6) @va.gov>
Subject:	RE: President's comments today
Date:	2019/08/21 15:07:06
Importance:	High
Priority:	Urgent
Type:	Note

Dave/Wendy – thank you. We also just got it on this string.
Dave, should we stand down? Sounds like you have Ilse already responding?

From: Carroll, David (VACO)
Sent: Wednesday, August 21, 2019 3:05 PM
To: Lakso, Wendy <(b6) @va.gov>; Kearney, Lisa K. (b6) @va.gov>
Subject: RE: President's comments today

Got it – there is a whole separate string or strings on this. Dr. Wiechers and team are responding.

From: Lakso, Wendy
Sent: Wednesday, August 21, 2019 3:03 PM
To: Kearney, Lisa K. (b6) @va.gov>; Carroll, David (VACO) <(b6) @va.gov>
Subject: FW: President's comments today

Here you go

From: Hutton, James
Sent: Wednesday, August 21, 2019 2:58 PM
To: Miller, Matthew (b6) @va.gov>; Lakso, Wendy (b6) @va.gov>; Screen, Gina <(b6) @va.gov>; Hauptmann, Bobbi (b6) @va.gov>
Cc: Powers, Pamela <(b6) @va.gov>; Tucker, Brooks (b6) @va.gov>; Syrek, Christopher D. (Chris) <(b6) @va.gov>; Mandreucci, Christina M. <(b6) @va.gov>; Van Dahlen, Barbara L. (b6) @va.gov>; Tallman, Gary (b6) @va.gov>
Subject: President's comments today

Matt / Wendy / Gina,

Today the President engaged media on the South Lawn of the White House before departing for Louisville (transcript attached).

Of interest to VA is the following exchange:

PRESIDENT TRUMP: we're doing a lot having to do with veteran suicide. we have a task force set up. there is a product that's made right now that just came out by johnson & johnson which has a tremendously positive, pretty short term but nevertheless a positive effect. i've instructed the head of the v.a. to go out and buy a lot of it and we are buying a lot of it. hopefully we're getting it at a very good cost. and this is a, i guess a form of a trouble from the standpoint of suicide, it can do something. it is pretty well known. just came out. it is made by johnson & johnson and we have calls in now to johnson & johnson. those calls we've been dealing with them for two months on buying a lot of it.

OPIA and the White House has subsequently been inundated with queries from multiple media outlets (CNN, Wall Street Journal, Politico x2, Bloomberg, McClatchy, and Task & Purpose).

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We have been asked to develop a brief overarching statement on the comments to address this **THIS AFTERNOON.**

Please send any fact sheets, memorandums or other information you have on this subject.

James

James Hutton
Assistant Secretary
Office of Public and Intergovernmental Affairs
Department of Veterans Affairs
810 Vermont Ave, NW
Washington, D.C. 20420
Office: (b6)
Email: (b6)@va.gov
Twitter: @jehutton
VA on [Facebook](#) . [Twitter](#) . [YouTube](#) . [Flickr](#) . [Blog](#)

Sender:	Kearney, Lisa K. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5DB1D2E054154A3B98EEF1F7DEAA6826-KEARNEY, LI (b6)@va.gov>
Recipient:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da

	<(b6) [REDACTED]@va.gov>; Lakso, Wendy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6cc1e7a61d4c4823ae2a08bd3e6b57f-Lasko, Wend (b6) [REDACTED]@va.gov>; Jones, Taunya /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ebc42defb394bc0b4a1e57aa248c3b6-Jones, Taun <(b6) [REDACTED]@va.gov>
Sent Date:	2019/08/21 15:07:04
Delivered Date:	2019/08/21 15:07:06
From:	Jones, Taunya /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6EBC42DEFB394BC0B4A1E57AA248C3B6-JONES, TAUN <(b6) [REDACTED]@va.gov>
To:	Kearney, Lisa K. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5db1d2e054154a3b98eef1f7deaa6826-Kearney, Li (b6) [REDACTED]@va.gov>
Subject:	FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Date:	2019/08/21 14:44:39
Importance:	High
Priority:	Urgent
Type:	Note

Wanted to send this to you first before we triage.

From: Dudley, Tracy
Sent: Wednesday, August 21, 2019 2:27 PM
To: VHA 10NC5 Action <VHA10NC5Action@va.gov>; VHA SPP Actions <VHASPPActions1@va.gov>
Cc: VHA CO 10NC Front Office HSSs <VHACO10NCFOHSSs@va.gov>
Subject: FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Good Afternoon 10NC5

HOT TOPIC

Please see below and, if your Program Office is responsive, please provide a response as soon as possible.

Thank You!
Tracy

Tracy L. Dudley
Health System Specialist
ADUSH for Clinical Operations (10NC)

Office: (b6)
Mobile: (b6)
(b6)@va.gov

Integrity, Commitment, Advocacy, Respect, Excellence - I CARE

From: Hammonds, Michele
Sent: Wednesday, August 21, 2019 1:33 PM
To: VHA 10P Actions <VHA10PActions@va.gov>; VHA 10P4 Communication Group <vha10p4comm@va.gov>; VHA 10NC Action <vha10ncaction@va.gov>; VHA 10NC5 Action <VHA10NC5Action@va.gov>
Cc: VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>
Subject: FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide
Importance: High

Dennis /10P – Hot -This is another Spravato/esketamine query from the president's recent comment earlier today.
Seeking written responses to the following questions

Deadline is today

Q1: What is the product?

A1:

Q2: How exactly does it work to reduce veterans suicides? Mental Health 10NC5

A1:

Q3: Has it been approved by the FDA?

A3: Yes (please insert date)

Q4: How can veterans get this product?

A4:

Q5: What results has this product shown in reducing veterans suicides?

A5:

Michele Hammonds
Office of Communications (10b2B)
(b6)

From: Carter, Susan
Sent: Wednesday, August 21, 2019 1:17 PM
To: Hammonds, Michele <(b6)@va.gov>; Greilsamer, Alan <(b6)@va.gov>;

VHA CO 10B2B Media <VHACO10B2BMedia@va.gov>

Cc: Noller, Randal <(b6) [REDACTED] va.gov>; Mandreucci, Christina M. <(b6) [REDACTED] va.gov>

Subject: FW: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

This is another Spravato/esketamine query from the president's recent comment earlier today. Deadline is today. Thanks – Susan

Q1: What is the product?

A1:

Q2: How exactly does it work to reduce veterans suicides?

A1:

Q3: Has it been approved by the FDA?

A3: Yes (please insert date)

Q4: How can veterans get this product?

A4:

Q5: What results has this product shown in reducing veterans suicides?

A5:

Susan Carter

Director, Office of Media Relations

U.S. Department of Veterans Affairs

(b6) [REDACTED] va.gov

Desk: (b6) [REDACTED] 8

Cell: (b6) [REDACTED]



cid:image002.jpg@01D3D61E.49531160

From: (b6) [REDACTED] taskandpurpose.com>

Sent: Wednesday, August 21, 2019 12:49 PM

To: Carter, Susan <(b6) [REDACTED] va.gov>

Subject: [EXTERNAL] Task & Purpose media query: President Trump says the VA is buying a product from Johnson and Johnson to combat veterans suicide

Good afternoon Ms. Carter,

Thank you for taking my call!

President Trump told reporters today that the VA is buying a new product from Johnson and Johnson that has proven to be effective in combating veterans suicide:

"There's a product that's made right now that just came out by Johnson and Johnson, which has a tremendously positive – pretty short-term – but nevertheless a positive effect.

"I've instructed the head of the VA to go out and buy a lot of it, and we are buying a lot of it. Hopefully, we're getting it at a very good cost. And this is a – I guess it's a form of a stimulant, where if somebody is really in trouble, from the standpoint of suicide, it can do something.

"It's pretty well known, just came out. It's made, I believe, by Johnson and Johnson, and we have calls in now to Johnson and Johnson. Those calls – we've been dealing with them for two months and buying a lot of it."

Can the VA say:

1. What is the product?
2. How exactly does it work to reduce veterans suicides?
3. Has it been approved by the FDA?
4. How can veterans get this product?
5. What results has this product shown in reducing veterans suicides?

My deadline is today. Please feel free to email or call me at 703-697-6623.

Thank you.

(b6)

Sender:	Jones, Taunya /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6EBC42DEFB394BC0B4A1E57AA248C3B6-JONES, TAUN <(b6)@va.gov>
Recipient:	Kearney, Lisa K. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5db1d2e054154a3b98eef1f7deaa6826-Kearney, Li (b6)@va.gov>
Sent Date:	2019/08/21 14:44:38
Delivered Date:	2019/08/21 14:44:39

From:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
To:	Hauptmann, Bobbi J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a475776e4144b52be2e670f20428fdf-Hauptmann, (b6)@va.gov>; Kearney, Lisa K. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5db1d2e054154a3b98eef1f7deaa6826-Kearney, Li (b6)@va.gov>
Subject:	RE: President's comments today
Date:	2019/08/21 15:21:00
Priority:	Normal
Type:	Note

Yep – there is a tasker on this. 10P and 10N are working on answers to five questions.

From: Hauptmann, Bobbi J.
Sent: Wednesday, August 21, 2019 3:21 PM
To: Carroll, David (VACO) <(b6)@va.gov>; Kearney, Lisa K. (b6)@va.gov>
Subject: FW: President's comments today

Sharing for awareness. POTUS engaged media today and spoke about Spravato and this has turned into a hot media item for our office.

From: Mandreucci, Christina M.
Sent: Wednesday, August 21, 2019 3:18 PM
To: Hutton, James <(b6)@va.gov>; Miller, Matthew (b6)@va.gov>; Lakso, Wendy (b6)@va.gov>; Screen, Gina <(b6)@va.gov>; Hauptmann, Bobbi J. (b6)@va.gov>; Hammonds, Michele <(b6)@va.gov>
Cc: Powers, Pamela <(b6)@va.gov>; Tucker, Brooks (b6)@va.gov>; Syrek, Christopher D. (Chris) (b6)@va.gov>; Van Dahlen, Barbara L. (b6)@va.gov>; Tallman, Gary (b6)@va.gov>
Subject: RE: President's comments today

+ Michele Hammonds

From: Mandreucci, Christina M.
Sent: Wednesday, August 21, 2019 3:03 PM
To: Hutton, James <(b6)@va.gov>; Miller, Matthew (b6)@va.gov>; Lakso, Wendy (b6)@va.gov>; Screen, Gina <(b6)@va.gov>; Hauptmann, Bobbi J. (b6)@va.gov>
Cc: Powers, Pamela <(b6)@va.gov>; Tucker, Brooks (b6)@va.gov>; Syrek, Christopher D. (Chris) (b6)@va.gov>; Van Dahlen, Barbara L. (b6)@va.gov>; Tallman, Gary (b6)@va.gov>
Subject: RE: President's comments today

Below is a previously approved response on Spravato. VHA, can you confirm it's still accurate?

(b) (5)

From: Hutton, James

Sent: Wednesday, August 21, 2019 2:58 PM

To: Miller, Matthew (b6) <(b6)@va.gov>; Lakso, Wendy <(b6)@va.gov>; Screen, Gina <(b6)@va.gov>; Hauptmann, Bobbi J. <(b6)@va.gov>

Cc: Powers, Pamela <(b6)@va.gov>; Tucker, Brooks (b6) <(b6)@va.gov>; Syrek, Christopher D. (Chris) (b6) <(b6)@va.gov>; Mandreucci, Christina M. <(b6)@va.gov>; Van Dahlen, Barbara L. (b6) <(b6)@va.gov>; Tallman, Gary (b6) <(b6)@va.gov>

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Matt / Wendy / Gina,

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Of interest to VA is the following exchange:

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James

James Hutton
Assistant Secretary
Office of Public and Intergovernmental Affairs
Department of Veterans Affairs
810 Vermont Ave, NW
Washington, D.C. 20420
Office: (b6)
Email: (b6)@va.gov
Twitter: @jehutton
VA on [Facebook](#) . [Twitter](#) . [YouTube](#) . [Flickr](#) . [Blog](#)

Sender:	Carroll, David (VACO) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=95E14EBD3B6745C8952A823B04DABFF5-CARROLL, DA>
Recipient:	Hauptmann, Bobbi J. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a475776e4144b52be2e670f20428fdf-Hauptmann, (b6)@va.gov>; Kearney, Lisa K. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5db1d2e054154a3b98eef1f7deaa6826-Kearney, Li (b6)@va.gov>
Sent Date:	2019/08/21 15:21:59
Delivered Date:	2019/08/21 15:21:00

From:	Lakso, Wendy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6CC1E7A61D4C4823AE2A08BD3E6EB57F-LASKO, WEND (b6) @va.gov>
To:	Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b6) @va.gov>; Kearney, Lisa K. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5db1d2e054154a3b98eef1f7deaa6826-Kearney, Li (b6) @va.gov>
Subject:	RE: President's comments today
Date:	2019/08/21 16:02:25
Priority:	Normal
Type:	Note

Perfect thank you!

Wendy Lakso
Deputy Executive Director PREVENTS EO
Department of Veterans Affairs
(b6)

From: Carroll, David (VACO) <(b6) @va.gov>
Date: Wednesday, Aug 21, 2019, 3:04 PM
To: Lakso, Wendy (b6) @va.gov>, Kearney, Lisa K. (b6) @va.gov>
Subject: RE: President's comments today

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From: Lakso, Wendy
Sent: Wednesday, August 21, 2019 3:03 PM
To: Kearney, Lisa K. (b6) @va.gov>; Carroll, David (VACO) <(b6) @va.gov>
Subject: FW: President's comments today

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Sent: Wednesday, August 21, 2019 2:58 PM
To: Miller, Matthew (b6) @va.gov>; Lakso, Wendy (b6) @va.gov>; Screen, Gina <(b6) @va.gov>; Hauptmann, Bobbi J. (b6) @va.gov>
Cc: Powers, Pamela <(b6) @va.gov>; Tucker, Brooks (b6) @va.gov>; Syrek, Christopher D. (Chris) (b6) @va.gov>; Mandreucci, Christina M. <(b6) @va.gov>; Van Dahlen, Barbara L. (b6) @va.gov>; Tallman, Gary (b6) @va.gov>
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Assistant Secretary
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Washington, D.C. 20420
Office: (b6)
Email: (b6)@va.gov
Twitter: @jehutton
VA on [Facebook](#) . [Twitter](#) . [YouTube](#) . [Flickr](#) . [Blog](#)

Sender: Lakso, Wendy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6CC1E7A61D4C4823AE2A08BD3E6EB57F-LASKO, WEND (b6)@va.gov>

Recipient: Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da
<(b6)@va.gov>;
Kearney, Lisa K. /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5db1d2e054154a3b98eef1f7deaa6826-Kearney, Li
(b6)@va.gov>

Sent Date: 2019/08/21 16:02:24

Delivered Date: 2019/08/21 16:02:25

From:	Scher, Deborah L. /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FEE3389DFA024F25B96B6D75AC2E7B9F-SCHER, DEBO (b6) @va.gov>
To:	Boyd, Teresa D. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6886a7d555a43e0bee23c1e40e1c234-Boyd, Teres (b6) @va.gov>; Carroll, David (VACO) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95e14ebd3b6745c8952a823b04dabff5-Carroll, Da (b6) @va.gov>
CC:	Stone, Richard A., MD /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd16619615d64adea22e45e63ff6462a-Stone, Rich (b6) @va.gov>; Wiechers, Ilse /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0c7b1428d9e4233a641f125c5b6fc4f-Wiechers, I (b6) @va.gov>
Subject:	RE: POC for Spravato clinical implementation
Date:	2019/03/21 15:50:13
Priority:	Normal
Type:	Note

Thank you very much Teresa. This is very helpful.

Ilse,

Nice to meet you by email. Thank you in advance for what sounds like a complex but very important clinical roll out. I will send a separate email to connect you with the J & J support team.

Best,
Deborah

From: Boyd, Teresa D.
Sent: Thursday, March 21, 2019 3:33 PM
To: Scher, Deborah L. (b6) @va.gov>; Carroll, David (VACO) <(b6) @va.gov>
Cc: Stone, Richard A., MD <(b6) @va.gov>; Wiechers, Ilse (b6) @va.gov>
Subject: RE: POC for Spravato clinical implementation

Thanks for the email regarding Spravato, Deborah!

There is a team working on this as there are many important aspects to consider as we roll out safe delivery of care. Adding Ilse Wiecher to the email as the POC/Champion. Ilse - look forward to continued work on careful implementation!

Hope this helps, Deborah, and feel free to contact us for any additional needs.

Teresa

Sent with BlackBerry Work
www.blackberry.com

From: Scher, Deborah L. (b6) @va.gov>