DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Deficiencies in Coordination of Care for Patients with Treatment-Resistant Depression at the VA San Diego Healthcare System in California

HEALTHCARE INSPECTION | REPORT #20-03359-220 | AUGUST 24, 2021

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Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Chairman Mark Takano, and Representatives Julia Brownley, Chris Pappas, and Mike Levin, members of the House Committee on Veterans' Affairs, upon receiving allegations related to a lack of care coordination for patients receiving ketamine for treatment-resistant depression in the community after authorizations for the care lapsed in September 2019 at the VA San Diego Healthcare System (facility) in California. The OIG received similar allegations from three other complainants between May 21 and July 27, 2020.

Specifically, the allegations stated that

1. the facility stopped authorizing community care for patients receiving ketamine for treatment-resistant depression;
2. patients with treatment-resistant depression were transitioned to intranasal esketamine at the facility; and
3. discontinuation of community care and treatment changes following transition of care to the facility negatively affected patient treatment outcomes, to include a patient who died by suicide.

Treatment-resistant depression refers to patients whose depression has failed to respond after multiple treatments. Patients with treatment-resistant depression are more likely to be hospitalized and have a higher incidence of suicide attempts than those whose depression responds to treatment.

Ketamine and esketamine are two drugs used for treatment-resistant depression. Ketamine was approved by the U.S. Food and Drug Administration (FDA) in 1970 for use as a general anesthetic. Emerging research has shown that ketamine can produce rapid but short-term antidepressant effects for patients with treatment-resistant depression. Ketamine for treatment-resistant depression or suicidal thoughts is not FDA-approved and is considered an off-label use of the drug.[1] Clinical studies demonstrating its unique antidepressant properties and media coverage of the potential benefits have led to increased demand for, and growing provision of, ketamine for these conditions. The Veterans Health Administration (VHA) issued

[1] The underlined terms below are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

national protocol guidance for use of intravenous ketamine for treatment-resistant depression in December 2017. [2]

In fiscal year 2018, 15 VA sites provided intravenous ketamine on-site for treatment-resistant depression and another 36 reported referring to another VA site or a community-based, non-VHA provider (community care provider) for ketamine treatment.[3]

Esketamine is chemically related to ketamine, but is a distinctly different drug with a separate formulation. Intranasally administered esketamine was approved by the FDA for treatment-resistant depression in March 2019.[4] Following FDA approval, VHA's Office of Mental Health and Suicide Prevention developed a national implementation plan, including the establishment of a community of practice (Community of Practice) to help provide guidance for facilities on implementing esketamine treatment programs. As of August 2020, 11 VA facilities had initiated treatment with esketamine.

The OIG substantiated that the facility ended authorization of community care for patients receiving ketamine for treatment-resistant depression on two occasions. While no gaps in treatment occurred, the OIG identified deficiencies in facility processes on both occasions:

- In October 2019, new Veterans Community Care Program regulations took effect, ending all previous individual authorizations for community care. Facility Community Care Service leaders failed to take action to secure a Veterans Care Agreement (VCA) with a community care provider prior to September 30, 2019, leaving the facility without a mechanism to authorize continuing care for patients who received ketamine treatment from the community care provider from October 1 until October 18.[5] This failure necessitated urgent action to ensure continued care for 28 patients.
- In March 2020, authorizations under the new VCA, approved on October 18, 2019, began to expire. Facility Community Care Service staff cited administrative justifications for limiting authorizations for continuing episodes of care with the community care provider.

[2] VA Pharmacy Benefits Management Services, Medical Advisory Panel, Veterans Integrated Service Network Pharmacist Executives, and Office of Mental Health Somatic Treatment Field Advisory Committee, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017.

[3] In FY2018, there were approximately 140 medical facilities.

[4] "FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic," FDA news release, March 5, 2019, accessed July 6, 2020, https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified.

[5] "Veterans Care Agreement," VHA Office of Community Care Fact Sheet, accessed September 9, 2019, https://www.va.gov/COMMUNITYCARE/docs/pubfiles/factsheets/VA-FS_Veteran-Care-Agreements.pdf. Veterans Care Agreements are agreements with community care providers that are intended to be used in limited circumstances when contracted services are not provided or not sufficient. The term "authorization" refers to a written or electronic document that details the covered services and gives the community care provider the authority to provide health care to the veteran and provides assurance of payment for those services.

These administrative factors forced abrupt transitions of care to the facility for seven patients.

When interviewed by the OIG, facility Mental Health Service leaders acknowledged communicating with facility Community Care Service leaders in summer 2019 about the upcoming October 2019 changes and having the understanding that facility Community Care Service would implement a VCA if one were required. Facility Community Care Service leaders acknowledged an overall awareness of purchasing authority changes, but cited the large volume of community care consults affected by the regulatory change as the reason this group of 28 patients was overlooked until the day the transition occurred. The facility Chief of Staff acknowledged that the facility should have been better prepared for the transitions required by the Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act and should have initiated work to establish a VCA with the community care provider before September 30, 2019. The Chief of Staff explained that leadership changes and loss of key staff in the facility Community Care Service, as well as the scope of work associated with the transition, affected the execution of these tasks.

In spring 2020, administrative factors in the facility Community Care Service appeared to be the primary driver behind the gap in authorizations, the decision to stop authorizing community care for ketamine treatment, and the timeline for transitioning the seven patients back to the facility for care. The OIG concluded that administrative justifications for limiting the additional authorizations resulted in abrupt discontinuation of community care services and created undesirable, accelerated timelines for transitions of care to the facility. The OIG further concluded that Community Care Service leaders' lack of timely communication, resistance to clinical input from mental health leaders in the disposition of these patients, and lack of proactive collaboration with stakeholders in this process contributed to challenges for care coordination.

The OIG substantiated that when the facility stopped authorizing ketamine treatment for seven patients in spring 2020 and transitioned their care to the facility, they were treated with intranasal esketamine instead of ketamine. While intranasal esketamine was FDA-approved for treatment-resistant depression, there was no direct comparison between esketamine and ketamine. Six of the seven patients were transitioned before intravenous ketamine was available at the facility. The OIG found that each of the seven patients had a poor response to esketamine and were changed to intravenous ketamine after ketamine treatment became available at the facility.

The OIG concluded that the seven patients were prematurely transitioned to esketamine treatment at the facility as a result of administrative issues in the Community Care Service as noted above, despite Mental Health Service leaders request to extend authorizations to avoid abrupt discontinuation of care and allow time to plan transitions of care for these clinically complex patients.

The OIG found that poor communication between the Community Care Service and facility mental health providers, patients, and the community care provider negatively affected coordination of care in October 2019 for the 28 patients at issue and contributed to patient distress when lapses in authorizations for community care occurred. The OIG substantiated that discontinuation of community care and subsequent treatment changes in spring 2020 negatively affected the treatment outcomes for the seven patients whose care was prematurely transitioned from the community care provider to the facility. While distress related to uncertainties about continuing ketamine treatment was identified as a contributory stressor, the OIG did not substantiate that discontinuation of community care resulted in a patient's death by suicide as the community care provider continued to offer ketamine treatment to that patient.

The OIG concluded that risks for negative patient outcomes increased as a result of

- deficits in communication and coordination of care,
- ending community care authorizations despite Mental Health Service leaders clinical input requesting to extend authorizations for care,
- the accelerated timeline for transition of care, and
- uncertainties associated with abruptly discontinuing or changing an established, effective treatment for complex, treatment-resistant patients and transitioning them to a different treatment for which equivalency was not established.

The OIG found that the facility's management of community care administrative processes failed to effectively recognize or mitigate these concerns.

With both intravenous ketamine and intranasal esketamine treatment options fully implemented at the facility as of August 31, 2020, resources to manage the care needs for patients with treatment-resistant depression were available without continuing use of community care mechanisms. Facility and Mental Health Service leaders described steps taken to improve the coordination of care and transitions for patients who had continued to receive intramuscular ketamine in the community. Key factors identified in facility plans for improved coordination of care transitions included

- extended time frames for transitions to improve coordination of care,
- proactive communication between facility mental health providers and patients about transitions,
- shared decision-making, with patients choosing whether to transition to intravenous ketamine or intranasal esketamine,
- processes for enhanced monitoring of care during transitions through the facility's Therapeutic Neuromodulation Program interdisciplinary team,
- expanded capacity for intravenous ketamine treatment at the facility,

- modification of the dosing limits in the facility's intravenous ketamine treatment protocol, and
- consultation with VHA's national Community of Practice for ketamine and esketamine treatment for guidance to develop clinically informed guidelines and individualized transition plans for the remaining patients.

The OIG identified a challenge for VHA related to coordination and oversight of ketamine community care, particularly for patients receiving such care through VCAs. The OIG found that variance in ketamine treatment practices for treatment-resistant depression between the community care provider and the VA National Protocol Guidance raised questions about the acceptable degree of differences in ketamine practices and complicated patient care transition from the community to the facility.[6] Failure to provide clear guidance when contracting for treatment with the community care provider likely contributed to the issue. This points to a need to ensure that community ketamine treatment providers are aware of and follow VA's National Protocol Guidance.

The OIG also recognized there is much knowledge to be gained from conducting further research studying the use of ketamine and esketamine for treatment-resistant depression. The lack of data on the comparative efficacy of ketamine and esketamine that are dependent on route of administration and dose and the lack of safety and efficacy data examining long-term maintenance treatment introduce uncertainties about acceptable degrees of differences in clinical practices and present challenges for providers. As demand for these treatments grow, such research will become increasingly important to inform evidence-based practices.

The OIG made two recommendations to the Under Secretary for Health related to community care providers reviewing VA's National Protocol Guidance for ketamine and esketamine treatment and an evaluation of the need for further research related to the use of ketamine and esketamine for treatment-resistant depression.

The OIG made four recommendations to the Facility Director related to community care processes for coordination of non-VA care and ensuring coordinated, clinically informed plans for transitioning remaining patients to care at the facility.

[6] VA Pharmacy Benefits Management Services, Medical Advisory Panel, Veterans Integrated Service Network Pharmacist Executives, and Office of Mental Health Somatic Treatment Field Advisory Committee, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017.

Comments

The Acting Under Secretary for Health and Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes A, B, and C). The OIG considers recommendation 6 closed. For the remaining open recommendations, the OIG will follow up on the planned and recently implemented actions to ensure that they have been effective and sustained.

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Contents

Abbreviations

ACOS	Associate Chief of Staff
COVID-19	coronavirus disease
EHR	electronic health record
FDA	Food and Drug Administration
MISSION	Maintaining Internal Systems and Strengthening Integrated Outside Networks
OIG	Office of Inspector General
VCA	Veterans Care Agreement
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network

Introduction

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of Chairman Mark Takano, and Representatives Julia Brownley, Chris Pappas, and Mike Levin, members of the House Committee on Veterans' Affairs, upon receiving allegations related to a lack of care coordination for patients receiving ketamine for treatment-resistant depression in the community after authorizations for the care lapsed in September 2019 at the VA San Diego Healthcare System (facility) in California. The OIG received similar allegations from three other complainants between May 21, 2020, and July 27, 2020.

Background

The facility, part of Veterans Integrated Service Network (VISN) 22, includes a main tertiary medical center in San Diego and seven outpatient clinics in southern California. From October 1, 2018, through September 30, 2019, the facility served 86,319 patients and had a total of 272 hospital operating beds, including 164 inpatient beds, 69 domiciliary beds, and 39 community living center beds. A full spectrum of care including inpatient, outpatient, and long-term treatment is provided. The facility has an affiliation with the University of California, San Diego School of Medicine.

Treatment-Resistant Depression

While occasional periods of sadness or low mood are normal aspects of human experience, some people develop severe and persistent symptoms that affect their ability to function in important areas of their lives and may result in them being diagnosed with a psychiatric disorder, such as depression. Symptoms of depression can include depressed mood; loss of interest or pleasure in activities; disturbances in sleep, weight, and appetite; fatigue or loss of energy; feelings of worthlessness and hopelessness; diminished ability to think, concentrate or make decisions; and suicidal thoughts or behaviors.[7] A range of interventions are used to treat depression, including a

[7] American Psychiatric Association, "Major Depressive Disorders" in *Diagnostic and Statistical Manual of Mental Disorders, 5th ed*., eds. Susan K. Schultz and Emily A. Kuhl, (Arlington, Virginia: American Psychiatric Association, 2013), 160-8.

variety of pharmacological, somatic, and psychotherapy approaches.[8] Many people experience remission or reduction of symptoms with treatment; however, a proportion of people with depression do not respond, even after multiple treatment trials. While clinical research literature offers varying definitions and a lack of consensus on what constitutes adequate treatment, the concept of treatment-resistant depression generally refers to patients whose depression has failed to respond after multiple treatments with different antidepressant medications at adequate doses and durations.[9] Treatment-resistant depression is associated with higher direct and indirect medical costs.[10] Patients with treatment-resistant depression are more likely to be hospitalized and to have a higher incidence of suicide attempts than those whose depression responds to treatment.[11]

Impact of Termination and Transitions of Mental Health Care

Mental health clinical research on patients' experiences establishes that the anticipation of ending treatment and loss of the established therapeutic relationship with the treatment provider are emotionally impactful and the way in which treatment termination is collaboratively managed with the patient is important. The anticipation of treatment ending, particularly when the discontinuation was not initiated by the patient, could prompt intense distress, including feelings of anxiety, fear, frustration, and concerns about the ability to manage without the treatment or provider's support. A patient-centered care approach that focuses on collaborative preparation for termination or transition of treatment can help in managing patients' distress, while failure to collaborate can exacerbate distress and leave patients feeling disempowered.[12]

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[8] Bradley N. Gaynes, et al., "Defining treatment-resistant depression," *Depression & Anxiety* 37, no. 2 (February 2020): 134-45, accessed September 9. 2020, https://onlinelibrary.wiley.com/doi/full/10.1002/da.22968. Pharmacological treatments refer to medications, including various classifications of antidepressants and other medications utilized to augment mood disorder treatment. Psychotherapeutic treatments refer to psychological interventions often described as "talk therapies." Somatic treatments refer to brain stimulation treatments such as repetitive transcranial magnetic stimulation (a noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain) and electroconvulsive therapy. American Psychiatric Association, *What is Electroconvulsive Therapy (ECT)?* accessed September 28, 2020, https://www.psychiatry.org/patients-families/ect. Electroconvulsive therapy involves "brief electrical stimulation of the brain while the patient is under anesthesia." It is "most commonly used in patients with severe major depression or bipolar disorder that has not responded to other treatments."

[9] Gin S. Malhi and Yulisha Byrow, "Is treatment-resistant depression a useful concept?" *Evidenced Based Mental Health* 19, no. 1 (February 2016): 1-3; Isidoor O. Bergfeld et al., "Treatment-resistant depression and suicidality," *Journal of Affective Disorders 235* (2018): 362-67.)

[10] Gaynes, "Defining treatment-resistant depression," 134.

[11] Gaynes, "Defining treatment-resistant depression," 134; Bergfeld, "Treatment-resistant depression and suicidality," 362.

[12] Kimberley Webb, Thomas A. Schroder, and David M. Gresswell, "Service users' first accounts of experiencing endings from a psychological service or therapy: A systematic review and meta-ethnographic synthesis," *Psychology and Psychotherapy: Theory, Research and Practice* 92, no. 4 (2018): 584-604.

Ketamine

Ketamine, a drug with analgesic and anesthetic properties, was approved by the U.S. Food and Drug Administration (FDA) in 1970 for use as a general anesthetic.[13] Because of its dissociative and hallucinogenic properties, ketamine has been used illicitly for recreational purposes.[14] When used regularly or heavily over time, individuals may develop physical and psychological dependence on the drug.[15]

Emerging research has shown that ketamine can produce rapid and robust, short-term, antidepressant effects for patients with treatment-resistant depression who have failed more conventional treatment approaches.[16] While the administration of ketamine for treatment-resistant depression or suicidal thoughts is not FDA-approved and is considered an off-label use of the drug, clinical studies demonstrating its unique antidepressant properties and media coverage of the potential benefits have led to increased demand for, and growing provision of, ketamine for these conditions.[17] Researchers have not established data on the safety and efficacy of long-term ketamine use, as most research to date has focused on single dose or brief treatment.[18] The American Psychiatric Association Council of Research Task Force on Novel Biomarkers and Treatments published a consensus statement on the use of ketamine for the treatment of mood disorders in April 2017; the Veterans Health Administration (VHA)

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[13] "Ketamine," PubChem, accessed September 24, 2020, https://pubchem.ncbi.nlm.nih.gov/compound/ketamine. An anesthetic is a drug which induces a partial or total loss of sensation. Food and Drug Administration, "FDA approves new nasal spray medication for treatment-resistant depression; available only at a certified doctor's office or clinic," news release, March 5, 2019, https://www.fda.gov/news-events/press-announcements/fda-approves-new-nasal-spray-medication-treatment-resistant-depression-available-only-certified. VA Pharmacy Benefits Management Services, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation*, December 2017.

[14] The underlined terms below are hyperlinks to a glossary. To return from the glossary, press and hold the "alt" and "left arrow" keys together.

[15] "Ketamine," PubChem.

[16] Fernanda S. Correia-Melo, et al., "Comparative study of esketamine and racemic ketamine in treatment-resistant depression," *Medicine* 97, no. 38 (2018): 1-6. Gerard Sanacora et al., "A Consensus Statement on the Use of Ketamine in the Treatment of Mood Disorders," *Journal of the American Medical Association-Psychiatry* 74, no. 4 (2017): 399-405. VA Pharmacy Benefits Management Services, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation*, December 2017.

[17] Sanacora, "A Consensus Statement," 399; "Understanding Unapproved Use of Approved Drugs "Off Label," U.S. Food and Drug Administration, accessed September 29, 2020, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label. Lack of FDA approval of a medication for a specific use does not mean the drug is not appropriate for that use, but may indicate there is insufficient research or data available on the safety and efficacy of use of the drug for that condition to support the FDA's approval process. Once the FDA approves a drug, healthcare providers may prescribe the drug for non-FDA approved uses when they determine this use is medically appropriate for their patient. Off-label use of a drug may be considered when there is not an approved drug to treat the patient's condition or when other approved treatments have failed. It is estimated that up to 20 percent of prescriptions in the U.S. are for off-label uses.

[18] Samuel Wilkinson and Gerard Sanacora, "A new generation of antidepressants: an update on the pharmaceutical pipeline for novel and rapid-acting therapeutics in mood disorders based on glutamate/GABA neurotransmitter systems," *Drug Discovery Today* 24, no. 2 (February 2019): 606-615.

issued national protocol guidance for use of intravenous ketamine for treatment-resistant depression in December 2017.[19]

Esketamine

Esketamine is chemically related to ketamine, but is a distinctly different drug with a separate formulation.[20] Intranasally administered esketamine was approved by the FDA for treatment-resistant depression in March 2019.[21] According to a VHA official in the Office of Mental Health and Suicide Prevention, a national plan was developed after FDA approval that included the establishment of a community of practice (Community of Practice) to provide guidance for facilities on implementing esketamine treatment programs. In support of the implementation plan, the VHA Acting Deputy Under Secretary for Health Operations and Management issued invitations to select VHA sites to develop esketamine treatment programs under the guidance of the Community of Practice.

Ketamine and Esketamine for Treatment-Resistant Depression at VHA

As noted above, a survey of VHA facilities for fiscal year 2018 showed that 15 sites provided intravenous ketamine on-site for treatment-resistant depression. Of the facilities that did not offer ketamine treatment on-site, 36 reported referring patients to another VHA site or a community-based non-VHA provider (community care provider) for ketamine treatment.

Facility Programs

The Office of Mental Health and Suicide Prevention national lead for esketamine clinical implementation reported that as of August 2020, 51 VHA facilities had volunteered for the esketamine implementation initiative, and 11 of those facilities had initiated treatment with esketamine. The national lead noted that the facility, which was one of the sites invited to become an "early adopter" of esketamine treatment, started an esketamine program prior to offering on-site ketamine treatment. The facility began providing esketamine treatment in January 2020. The national lead for esketamine clinical implementation also informed the OIG that by the end of June 2020, the facility was providing esketamine treatment for more veterans than any other VHA facility.

The facility's Chief of Psychiatry reported that the facility implemented a ketamine treatment program in May 2020, with initially limited capacity. As of August 31, 2020, the facility's ketamine program reached full operational status.

[19] Sanacora, "A Consensus Statement," 399; VA Pharmacy Benefits Management Services, December 2017.
[20] VA Pharmacy Benefits Management Services, December 2017.
[21] FDA news release, March 5, 2019.

Community Care

Community care refers to health care purchased by VHA for eligible veterans based on their individual health care needs and circumstances.[22] VHA facilities may purchase care from a community-based non-VHA provider (community care provider) when the facility is unable to provide the necessary care and services, when a patient cannot safely travel due to medical reasons, when care cannot be provided timely, or when care cannot be provided due to geographic inaccessibility.[23] According to a VHA Community Care Network Fact Sheet issued on September 17, 2019, community care services are coordinated through VHA or contracted third parties.[24]

To initiate purchased care for patients, a requesting provider enters a consult in the patient's electronic health record (EHR) for community care services.[25] A clinical delegated authority reviews the request for medical necessity and clinical appropriateness.[26] Once the care is deemed clinically indicated, facility community care staff authorize services for a specified period or number of sessions, referred to as an episode of care.[27]

The rules governing VHA's utilization of community care and mechanisms for purchasing care in the community have undergone multiple changes. In 2018, Congress passed the Maintaining Internal Systems and Strengthening Integrated Outside Networks (MISSION) Act, replacing the Veterans Access and Choice Accountability Act of 2014. The MISSION Act combined multiple existing VA programs into one consolidated Veterans Community Care Program as of June 2019. According to VHA, the Veterans Community Care Program was developed to simplify the

[22] "Fact Sheet Veteran Community Care General Information," accessed July 15, 2020, https://www.va.gov/COMMUNITYCARE/docs/pubfiles/factsheets/VHA-FS_MISSION-Act.pdf.

[23] VHA Directive 1232(2), *Consult Processes and Procedures*, August 24, 2016, amended June 28, 2019.

[24] "Fact Sheet Community Care Network (CCN)," accessed October 8, 2020, https://www.va.gov/COMMUNITYCARE/docs/pubfiles/factsheets/FactSheet_26-01.pdf#. A third party administrator develops and manages a regional network of licensed healthcare providers in the community.

[25] VHA Directive 1232(1). "A consult is a request for clinical services on behalf of a patient." A sending or receiving provider discontinues a consult when it is "no longer wanted or needed." A receiving service may cancel or deny a consult if there is an error or "the ordering provider did not ask an appropriate consult question or provide sufficient information."

[26] "VHA Office of Community Care Field Guidebook, VA Office of Community Care, *Chapter 2: Eligibility, Referral, and Scheduling*, accessed August 18, 2020 (This is an internal VA website and not available to the general public), https://dvagov.sharepoint.com/sites/VHAOCC/CNM/CI/OCCFGB/Chapter%20Documents/Chapter%202.docx. A delegated authority is a clinical reviewer with subject matter expertise identified by the Chief of Staff who reviews community care consults for medical necessity and clinical appropriateness. At the facility, a team of mental health providers serve as delegated authorities who evaluate requests for mental health care in the community by reviewing documentation, consulting with the referring clinician if needed, and communicating a decision about the care to the Community Care Service.

[27] VHA Office of Community Care Field Guidebook, *Chapter 3: Care Coordination*, accessed August 18, 2020 (This is an internal VA website and not available to the general public), https://dvagov.sharepoint.com/sites/VHAOCC/CNM/CI/OCCFGB/Chapter%20Documents/Chapter%203.docx.

process for veteran community care by streamlining eligibility criteria, creating a single community care program, improving customer service, providing a way for patients to seek non-emergency care, developing a new network of community care providers, and modernizing information technology systems.[28]

Under the MISSION Act, eligibility for community care was expanded beyond the access limitations of services unavailable at the facility or falling outside specified wait times or geographical distance, to include

- the patient and provider determine that receiving care in the community is in the patient's best medical interest, or
- VA medical service line "is not providing care that complies with VA quality standards."[29]

Allegations and Request for Review

Between May 21, 2020, and July 27, 2020, the OIG received three complaints related to the facility discontinuing community care ketamine administration for patients with treatment-resistant depression and transitioning them to the facility to receive esketamine. Further, the alternative treatment offered at the facility had been ineffective and resulted in worsening of mental health symptoms. In June 2020, the OIG received requests from Chairman Mark Takano, and Representatives Julia Brownley, Chris Pappas, and Mike Levin, members of the House Committee on Veterans' Affairs related to the allegations that were also identified in an online news source. A San Diego-based online news source ran a series of media stories detailing concerns about this issue and veterans' perspectives, including references to a patient who allegedly died by suicide after the facility refused to continue the patient's ketamine treatment.[30]

The OIG conducted an inspection to evaluate the following allegations:

1. The facility stopped authorizing community care ketamine for treatment-resistant depression patients.
2. Treatment-resistant depression patients were transitioned to intranasal esketamine at the facility.

[28] Fact Sheet Veteran Community Care General Information.

[29] Fact Sheet Veteran Community Care General Information.

[30] Brad Racino, "San Diego VA moves suicidal veterans off 'life-saving treatment' against doctor's pleas," *inewsource*, June 4, 2020. Brad Racino, "Federal probe underway after San Diego VA stops treatment that helps suicidal vets," *inewsource*, June17, 2020. Brad Racino, "Records Show San Diego VA lied about drug treatment for suicidal vets," *inewsource*, June 26, 2020. Lorie Hearn, "Why we used a word we never use," *inewsource*, June 26, 2020.

3. Discontinuation of community care and treatment changes following transition of care to the facility negatively affected patient treatment outcomes, to include a patient who died by suicide.

During its review, the OIG identified concerns related to communication and coordination of community care that are discussed in sections 3 and 4.

Scope and Methodology

The inspection was initiated in June 2020. Due to COVID-19, the OIG conducted virtual interviews from August 3–12, 2020.[31] The OIG interviewed the Director of Operations for VHA Office of Community Care, and VHA National Director for Psychopharmacology and Somatic Treatments (National Director).[32] Other interviewees included the Facility Director, Chief of Staff, Associate Chiefs of Staff for both Mental Health and Community Care Services, the Chiefs of Quality Management, Pharmacy, and Psychiatry, staff psychiatrists, the Mental Health Director of Clinical Improvement, and a facility suicide prevention coordinator. The OIG also interviewed the treating psychiatrist and Chief Operating Officer for the community care provider.

Relevant facility policies and procedures in place during the time frame of the events (March 2019 through September 2020) were reviewed. The OIG reviewed notes entered into the patients' VHA electronic health records (EHRs) and notes requested under subpoena from the community care provider.[33] The OIG reviewed clinical research literature related to use of ketamine and esketamine for treatment-resistant depression. The OIG also reviewed email correspondence from VHA staff and the community care provider related to the issues under review.

[31] "WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020, accessed October 22, 2020, World Health Organization, https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Merriam Webster, "Definition of pandemic, accessed October 22, 2020, https:/www.merriam-webster.com/dictionary/pandemic. A pandemic is a disease outbreak over a wide geographic area that affects most of the population.COVID-19 is caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a newly discovered coronavirus. "Naming the Coronavirus Disease (COVID-19) and the Virus that Causes It," accessed October 22, 2020, World Health Organization, https://www.who.int/emergencies/diseases/novelcoronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(COVID-19-2019)-and-the-virus-that-causesit.

[32] The National Director for Psychopharmacology and Somatic Treatments also served as the national lead for VHA's esketamine and ketamine Community of Practice and esketamine clinical implementation plan, as well as the Director of the Psychotropic Drug Safety Initiative in the Office of Mental Health and Suicide Prevention.

[33] The OIG team requested notes under subpoena from the community care provider because the full range of the community care provider's notes were not accessible within the patients' VA EHRs.

In the absence of current VA or VHA policy, the OIG considered previous guidance to be in effect until superseded by an updated or recertified directive, handbook, or other policy document on the same or similar issue(s).

The OIG substantiates an allegation when the available evidence indicates that the alleged event or action more likely than not took place. The OIG does not substantiate an allegation when the available evidence indicates that the alleged event or action more likely than not did not take place. The OIG is unable to determine whether an alleged event or action took place when there is insufficient evidence.

Oversight authority to review the programs and operations of VA medical facilities is authorized by the Inspector General Act of 1978, Pub. L. No. 95-452, 92 Stat. 1105, as amended (codified at 5 U.S.C. App. 3). The OIG reviews available evidence to determine whether reported concerns or allegations are valid within a specified scope and methodology of a healthcare inspection and, if so, to make recommendations to VA leaders on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

The OIG conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

Timeline of Events

The OIG compiled the timeline of events from interviews and a review of documents.

March 2017. Patients with treatment-resistant depression began to receive ketamine treatment in the community.[34]

May 7, 2019. VHA's Acting Deputy Under Secretary for Health for Operations and Management issued a memorandum that required Veterans Care Agreements (VCAs) be in place by September 30, 2019, to ensure continued care for services that had been provided under individual authorizations. [35]

July 2019. Community Care and Mental Health Service leaders at the facility corresponded regarding the need for a VCA for community care ketamine treatment by the end of September.

September 30, 2019. In the absence of a VCA for ketamine treatment, a Community Care Service staff member called the community care ketamine treatment provider and advised that "after today veterans shouldn't receive care." The community care provider made the decision to continue to provide ketamine treatment in the absence of an agreement. The Chief of Staff directed the Associate Chief of Staff (ACOS) for Community Care Service to initiate a VCA for ketamine treatment with the community care provider.

October 1, 2019. The ACOS for Community Care Service informed Mental Health Service leaders that ketamine treatment by the community care provider was not authorized as it was "experimental" and not "the standard of care." The ACOS for Community Care Service advised finding alternate care while the VCA was under review.

October 18, 2019. The facility finalized a VCA with the community care provider to continue ketamine treatment to VHA patients.

January 2020. The facility started an intranasal esketamine program for treatment-resistant depression.

February 14, 2020. The community care provider requested authorizations to continue care for patients.

March 2020. Community care authorizations began to expire. A Mental Health Service leader communicated with Community Care Service staff related to 28 patients' authorizations for

[34] The OIG's review of patients' EHRs identified one patient who began receiving ketamine treatment in the community in 2016.

[35] Acting Deputy Under Secretary for Health for Operations and Management VA Memorandum, *Revised Community Care Purchasing Authorities*, May 7, 2019. Subsequent guidance issued on May 14, 2019 specified VCAs "should be limited to instances where there is no other established solution to deliver the care." Acting Deputy Under Secretary for Health for Operations and Management VA Memorandum, *Procedures for Establishing Veterans Care Agreements*, May 14, 2019.

community care ketamine treatment. Community care was not authorized for seven of the 28 patients.[36]

April 27, 2020. The first of seven patients whose authorizations were not approved began transitioning to intranasal esketamine treatment at the facility.

May 13, 2020. Due to intranasal esketamine treatment failure, the first of the seven patients started intravenous ketamine treatment at the facility.

May—July 2020. Transitions of patients receiving community care ketamine treatment resulted in complaints to the OIG, a Congressional query, and media coverage.

August 18, 2020. All seven patients experienced intranasal esketamine treatment failure; the last of the seven patients started intravenous ketamine treatment at the facility.

August 31, 2020. The facility opened a new Therapeutic Neuromodulation Program suite that expanded availability of intravenous ketamine and intranasal esketamine for patients with treatment-resistant depression.

[36] The facility and community care staff provided the OIG documentation of authorizations referencing 28 patients. The OIG compared and reconciled the authorization data from the two sources. The OIG did not independently verify the information contained in the authorizations.

Inspection Results

1. Ending Community Care Authorizations for Ketamine Treatment

The OIG substantiated that the facility ended authorization of community care for patients receiving ketamine for treatment-resistant depression on two occasions. Although no gaps in treatment occurred as a result, the OIG found that Community Care Service leaders failed to timely address expiring authorizations:

- Community Care Service leaders failed to implement a VCA by October 1, 2019, to allow for continuing authorization of care with the community care provider under the new Veterans Community Care Program regulations.[37] This failure necessitated urgent action to ensure continuity of care for the affected patients.
- In March 2020, Community Care Service staff told the OIG that authorizations were ended for continuing episodes of care for some patients.

Changes in Community Care

MISSION Act Impact on Community Care Authorization Mechanisms

Prior to the MISSION Act and VHA's transition to the new Veterans Community Care Program regulations, the facility purchased ketamine treatment for patients with treatment-resistant depression using individual authorizations through the facility's traditional community care program. Individual authorizations were needed because ketamine treatment was not available at the facility or through the national contracted provider network under the facility's third-party administrator.

In spring 2019, VHA's Acting Deputy Under Secretary for Health for Operations and Management issued a series of memoranda providing guidance on transitions in mechanisms for purchasing care in the community under the MISSION Act. An April 17, 2019, memorandum outlined requirements that all care authorized via traditional community care individual authorizations after June 6, 2019, be transitioned to the Patient Centered Community Care national contract under VHA's third-party administrator or, if the required service was not available through the national contract, a VCA.[38] A subsequent memorandum issued on

[37] "Veterans Care Agreements (VCAs)," VHA Office of Community Care Fact Sheet, accessed September 9, 2019, https://www.va.gov/COMMUNITYCARE/docs/pubfiles/factsheets/VA-FS_Veteran-Care-Agreements.pdf. Veterans Care Agreements are agreements with community care providers that are intended to be used in limited circumstances where contracted services are not provided or not sufficient. The term "authorization" refers to a written or electronic document that details the covered services and gives the community care provider the authority to provide health care to the veteran and provides assurance of payment for those services.

[38] Acting Deputy Under Secretary for Health for Operations and Management VA Memorandum, *Veterans Care Agreements for Dental, Personal Care Services and Home Hospice*, April 17, 2019.

May 7, 2019, amended previous guidance to allow for the continued use of individual authorizations through September 30, 2019, to ensure that there would not be an abrupt end to clinically necessary care during the transition period. The memorandum also required facilities to amend all individual authorizations to end on September 30, 2019.[39] On May 14, 2019, further guidance was provided on how to establish a VCA in the limited instances where there was no other established mechanism to purchase care.[40]

Facility Awareness and Response to MISSION Act Changes in Community Care Purchasing Authorities

Community Care and Mental Health Service Leaders

Per OIG's review of email communications from June 2019 through July 2019, Community Care and Mental Health Service leaders were aware of the changes in purchasing authorities occurring as a result of the MISSION Act and the requirement to transition or end all traditional community care individual authorizations by September 30, 2019. Further, the communications indicated awareness that ketamine treatment would not be covered under VHA's third-party administrator contract.[41] However, the OIG found that no plan for addressing the issue was established at that time.

During interviews with the OIG, the ACOS for Community Care Service, the ACOS for Mental Health Service, and the Chief of Psychiatry indicated lack of awareness for the need to address the expiring individual authorizations for patients receiving ketamine through community care prior to September 30, 2019. The ACOS for Community Care Service acknowledged an overall awareness of purchasing authority changes and that a large volume of community care consults was affected by the changes. The high number of consults was cited as the reason this group of patients was overlooked until the day the transition occurred. The ACOS for Mental Health Service acknowledged prior communications about the pending changes to purchasing authorities, but indicated a belief that the facility Community Care Service would implement a VCA if one were required.

[39] VA Memorandum, *Revised Community Care Purchasing Authorities,* May 7, 2019.

[40] VA Memorandum, *Procedures for Establishing Veterans Care Agreements,* May 14, 2019.

[41] Correspondence from the National Director for Psychopharmacology and Somatic Treatments in the Office of Mental Health and Suicide Prevention, who also headed VHA's Community of Practice for ketamine and esketamine treatment, indicated that VA's central office was pursuing a contract modification with the relevant third party administrator to cover ketamine and esketamine in August 2019. However, at the time of this review, the third party administrator did not cover ketamine or esketamine treatment, and a VCA remained the only mechanism to authorize and pay for ketamine or esketamine treatment in the community.

On October 1, 2019, the ACOS for Community Care Service notified Mental Health Service leaders that there was no longer a mechanism to authorize care for 28 patients who were receiving ketamine treatment with the community care provider.

Chief of Staff

The facility's Chief of Staff acknowledged that the facility "should have been better prepared" for the transitions required by the MISSION Act and should have initiated work to establish a VCA with the community care provider before September 30, 2019. The Chief of Staff explained that leadership changes and loss of key staff in the facility Community Care Service, as well as the scope of work associated with the transition, affected the execution of these tasks.

Failure to Implement a VCA by October 2019

The OIG found that the facility failed to complete a VCA with the community care provider prior to the expiration of the existing individual authorizations on September 30, 2019. Absence of a VCA resulted in the community care provider treating patients for at least 18 days without a valid authorization to prevent interruption of the patients' care.

Disruption of Authorization for Community Care

Upon becoming aware of the expiring individual authorizations at the end of September 2019, the ACOS, Community Care Service entered a note in the patients' EHRs alerting the referring providers to pursue an alternate plan of care for those patients. The ACOS, Community Care Service did not seek clinical input from Mental Health Service leaders or providers regarding potential impacts of abruptly discontinuing the established care or the availability of feasible treatment alternatives prior to documenting the need to establish an alternate plan of care. The notification cited expiration of the ability to authorize care using traditional community care individual authorizations and refusal by the third-party administrator to authorize the care. Reasons for refusal were the treatment was described as "experimental," or "not considered the standard of care." [42]

On September 30, 2019, Community Care Service staff notified the community care provider that treatment was no longer authorized and advised the community care provider to cease treatment for those patients. The Chief Operating Officer for the community care provider's clinic sent an email to the facility's ACOS for Community Care Service stating they had been seeking guidance regarding the issue for "weeks" and abruptly ceasing ketamine treatment as advised would be "medically and ethically improper." In continuing correspondence to the ACOS of Community Care and the Chief of Staff, the community care provider emphasized that

[42] The terms "non-standard" and "experimental" referred to the off-label use of ketamine for treatment resistant depression, which was not covered by VHA's third party administrator contract or under reimbursable under Medicare standards.

"precipitously" ending treatment would be "potentially catastrophic" for patients because they were at "high risk for suicide and have failed to benefit from all conventional treatment modalities."

The facility's Chief of Psychiatry also registered clinical opposition on October 1, 2019, stating that the facility could not "precipitously stop these treatments" for patients with treatment-resistant depression. The response from the ACOS for Community Care Service indicated published safety implications from discontinuation of intravenous ketamine could not be identified.

Facility Initiation of a Veterans Care Agreement

When the lapse in authorization occurred on October 1, 2019, the facility did not have the capacity to provide ketamine treatment or esketamine treatment for patients with treatment-resistant depression in-house. Mental Health Service leaders and providers advocated for continuing access to ketamine treatment for these patients and requested continuing authorization of community care. The Chief of Staff directed the ACOS for Community Care Service to initiate a VCA with the community care provider to allow for continuing authorizations of treatment and ensure continuity of care. Mental Health Service leaders assisted by providing clinical justifications for the VCA. The VCA was signed by the Facility Director on October 4, 2019. The Chief of Staff responded to the community care provider on October 4, 2019, apologizing for the gap in services and informed the community care provider that a VCA was being submitted and the facility's Chief of Psychiatry would contact the community care provider to follow up.

The VCA required review and approval by VHA's Office of Community Care. The VHA Office of Community Care processed and approved the VCA on October 18, 2019, and the community care provider was notified the same day. With the VCA completed and Mental Health Service providers requesting continuation of community care, additional episodes of care for ketamine treatment in the community were authorized. There was an 18-day gap between the expiration of the individual authorizations for ketamine treatment with the community care provider on September 30, 2019, and the completion of the VCA to allow for continuing ketamine treatment in the community on October 18, 2019. Once the VCA was completed, facility Community Care Service staff authorized the episodes of care to cover treatment starting October 1, 2019.

Continuity of Care During the Gap Between Authorizations

Although the care was not officially authorized and the community care provider was advised by facility Community Care Service staff to cease treatment when authorizations expired on October 1, 2019, the community care provider determined that the clinically and ethically appropriate course of action was to continue providing ketamine treatment for these patients. Continuation of care was undertaken by the provider with the belief that the facility was working

on a resolution of the authorization issue. According to the Chief Operating Officer for the community care provider's clinic, retroactive authorizations had been used previously to cover gaps.

The OIG determined that the Community Care Service's failure to timely enact a VCA prior to October 1, 2019, disrupted the ability to authorize and pay for continuing ketamine treatment. However, actions by the community care provider ensured that no patients were denied treatment during the gap in time between the authorizations.

Recurrent Expiring Authorizations in March 2020

The OIG found that challenges with authorizing community ketamine treatment recurred when the initial episodes of care authorized through the VCA expired, which required Mental Health leaders to prematurely transition some patients' care to the facility. Typically, clinical delegated authorities approved, and Community Care Service staff authorized, ketamine for treatment-resistant depression for six-month episodes of care. Starting in February 2020, the community care provider submitted requests for authorization to continue care since the episodes of care initially authorized under the VCA in October 2019 would begin expiring in March 2020. On March 11, 2020, the community care provider contacted Community Care Service, Mental Health Service, and facility leaders expressing frustration with the inability to obtain authorizations despite repeated requests.

Following another communication from the community care provider on March 13, 2020, the facility's Chief of Psychiatry contacted the Community Care Service to address the authorizations. The facility's Chief of Psychiatry, as the clinical delegated authority, requested continuing authorization of community care for ketamine treatment for all patients receiving ongoing care from the community care provider until the facility had established its own program and had the capacity to provide the necessary treatment at the facility. While the majority of patients were granted continuing authorization for community care, seven patients were not authorized to continue community care and were transitioned to the facility.

Facility Justifications for Transitions of Care

Across OIG interviews, as well as in facility responses to inquiries from other sources, multiple reasons, including administrative and clinical factors, were identified as influencing the decision to transition patients receiving ketamine treatment through community care to the facility.

Administrative Factors

The OIG determined that administrative factors were the primary drivers behind the decision not to authorize additional episodes of community care for the seven patients despite Mental Health Service leaders advocating for a longer timeline for the transition. Reasons cited by Community Care Service leaders included

- late receipt of requests from the provider,
- use of an incorrect form and fax number to convey requests for authorization of additional services,
- internal processes, which resulted in requests being inadvertently scanned to the patient's record rather than being identified for processing by the facility's Community Care Service, and
- inability to locate some of the originating community care consults in the patients' medical records.

Patient Safety and Treatment Efficacy Concerns

During the time frame that Community Care Service staff were being asked to authorize additional episodes of care for the patients receiving ketamine treatment from the community care provider (spring 2020), the ACOS of Community Care Service began reviewing patient EHRs and raised concerns about the safety and efficacy of the treatment, citing adverse reactions during treatments that were documented in the EHR notes for some patients. The ACOS of Community Care Service consulted the facility's Chief of Performance Improvement Management service and initiated several Joint Patient Safety Reports documenting these concerns.[43] The Joint Patient Safety Reports introduced questions about treatment efficacy and patient safety as part of the dialog between Community Care and Mental Health Services as the service leaders tried to negotiate consensus on continuing care plans in the best interests of the patients.

A senior Mental Health Service leader described discussions with the ACOS of Community Care Service to explain side effects that would be considered expectable with ketamine treatment, such as sedative, dissociative, and hallucinatory symptoms, and to share a mental health clinical perspective on the balance between benefits and harm of continuing ketamine treatment considering the lack of viable effective treatment alternatives for these patients. Each Joint Patient Safety Report prompted individual review of a patient's care by a qualified clinical provider. Clinical reviews did not identify imminent patient safety concerns. The recommendation in each case was for continuation of ketamine treatment through community care.

[43] National Center for Patient Safety Defense Health Agency, "Joining Forces for Safer Care: Joint Patient Safety Reporting," *Topics in Patient Safety 17*, no. 2 (April May June 2017): 3. Joint Patient Safety Reports are electronic reports submitted by facility staff to report safety-related events and concerns. Reports are reviewed by patient safety professionals in an effort to identify and prevent patient harm.

Community Care Provider Practice and VA Guidance on the Administration of Ketamine

The community care provider's use of an intramuscular route of administration during ketamine treatments was identified as out of alignment with VA's National Protocol Guidance, which specifies the intravenous route of administration of ketamine for treatment-resistant depression.[44] On June 8, 2020, the facility provided a statement to the press identifying the community care provider's deviation from "industry standards of care" as the rationale for transitioning ketamine care back to the facility from the community care provider:

> This particular [community care] provider repeatedly deviated from industry standards of care and from what VA had authorized by VA or Medicare standards when it comes to treatment-resistant depression.
>
> As a result, VA is terminating its relationship with the provider, and about 30 VA patients who were receiving treatment there are transitioning back to in-house treatment at the VA San Diego Healthcare System. No patients were "taken off" their treatment.[45]

While intramuscular injection of ketamine was not consistent with VA's 2017 guidance, Mental Health Service leaders acknowledged being aware of the route of administration and continuing to approve treatment as prescribed by the community care provider. Prior to the administrative factors that prompted re-examination of the community care authorizations, concern about this inconsistency had been deemed insufficient to warrant discontinuation of the treatment prior to the establishment of a ketamine treatment program at the facility. Interviews and documentation reviewed by the OIG indicated that

- the October 2019 VCA between the facility and the community care provider did not specify intravenous administration of ketamine,
- prior community care referrals for ketamine treatment did not consistently specify the route of administration (intravenous or intramuscular),
- the clinical delegated authority did not consistently identify the intravenous route of administration when documenting approval of the requests for care,
- providers repeatedly documented in EHRs that patients received intramuscular ketamine therapy from the community care provider,

[44] VA Pharmacy Benefits Management Services, December 2017.

[45] While the facility's June 8, 2020, press statement indicated that the VA was terminating its relationship with the provider, the facility continued to authorize patient care with the community care provider while making plans to transition the remaining patients back to the facility.

- according to the facility's Chief of Psychiatry, the facility did not communicate to the community care provider that the VA intended for only intravenous ketamine to be provided, and
- in an October 2019 communication between the facility's Chief of Psychiatry and the Community of Practice national lead, the community care provider's use of intramuscular ketamine was noted and no concern was raised.

The OIG concluded that the provider's deviation from "industry standards of care" was not the primary determinant in the facility's decision to decline seven patients' authorizations for community care ketamine treatment in March 2020. Other patients' community care authorizations for the same treatment were approved and the facility identified administrative justifications to the OIG for the declination.

Transition of Patients from Community Care to the Facility

While Mental Health Service leaders indicated interest in transitioning patients' care to the facility, and the esketamine program had started in January 2020, the facility did not have a ketamine treatment program in place when authorizations began to expire in March 2020. Mental Health Service leaders and providers who reviewed the clinical care advocated for continuing authorization of ketamine treatment with the community care provider, and indicated an extension of the time frame for the transition to coordinate care would be in the best interest of the patients. However, Community Care Service leaders' asserted that additional episodes of care could not be authorized for the seven patients. Mental Health Service leaders initiated plans for transitioning the patients' care to the facility. The Chief of Psychiatry described that to prevent disruption in care, the facility transitioned the seven patients and offered alternative treatment with esketamine. The first transition occurred in late April 2020. When asked about the transition, a senior Mental Health Service leader reported finding it "extremely challenging."

Facility and Mental Health Service leaders noted plans to transition the remaining patients from community care to care at the facility after the facility's ketamine program became fully operational. The remaining patients received authorization for additional episodes of care through community care to provide time for development of more clinically informed transition plans.

The OIG concluded that administrative justifications for limiting additional authorizations resulted in abrupt discontinuation of community care services and created undesirable, accelerated timelines for transitions of care to the facility for the seven patients. Administrative factors in the facility Community Care Service appeared to be the primary driver behind the gap in authorizations, the decision to stop authorizing community care for ketamine treatment, and the timeline for transitioning the seven patients back to the facility for care. The OIG further concluded that Community Care Service leaders' lack of timely communication, resistance to

clinical input of mental health leaders in the disposition of these patients, and lack of proactive collaboration with stakeholders in this process contributed to challenges for care coordination.[46]

2. Substitution of Esketamine for Ketamine Treatment

The OIG substantiated that in spring 2020, the facility stopped authorizing ketamine treatment through community care for seven patients. The seven patients were then transitioned to the facility and treated with intranasal esketamine instead of ketamine. The OIG found that the seven patients had a poor response to esketamine and were subsequently changed to intravenous ketamine.

Ketamine Treatment with the Community Care Provider

Patients may develop tolerance to ketamine with prolonged use and require an increased dose in order to continue experiencing similar effects from the medication. During treatment with the community care provider, the seven patients received high doses of intramuscular ketamine. At the time the patients transitioned to the facility, the average length of time they had been in ketamine treatment with the community care provider was 30 months, with a range of 13 to 40 months.

Patients raised concerns about the transition with the community care provider who shared information with the patients about their current ketamine treatment and intranasal esketamine treatment, including

- much less of the medication is absorbed during intranasal esketamine treatment than during intramuscular or intravenous ketamine treatment,
- intranasal esketamine doses were fixed, restricting the ability to customize the dose for patients that may need higher doses to receive an optimal antidepressant effect, and
- the transient dissociative or psychedelic experiences that often occur with ketamine treatment may not occur or may be milder and shorter with intranasal esketamine treatment.

Alternative Esketamine Treatment at the Facility

The seven patients who transitioned to the facility between late April and late June 2020 were treated with intranasal esketamine. Six of the seven patients were transitioned before intravenous ketamine was available. While intranasal esketamine was FDA-approved for treatment-resistant depression, there was no direct comparison between esketamine and ketamine. The equivalency of dosing for intranasal esketamine to a patient's established maintenance dose of intramuscular

[46] The OIG used the term stakeholders to refer to Mental Health Service leaders, treating providers at the facility, the community care provider, and patients.

ketamine was not known. The facility did not have a policy that required patients to have a trial on intranasal esketamine prior to receiving intravenous ketamine; however, a facility psychiatrist reported availability of intravenous ketamine therapy at the facility remained very limited until September 2020.

Patient Outcomes After Transitioning to Esketamine

After failed episodes of treatment with esketamine ranging from 1 to 15 weeks (median of five weeks), all seven patients were changed to intravenous ketamine.

Due to concerns with the seven patients' switch from high-dose intramuscular ketamine to intravenous ketamine, the Chief of Staff suggested a plan on June 24, 2020, to the facility's Chief of Psychiatry to consult ketamine treatment experts related to the transition including whether the transition should occur in an inpatient setting. Later that day, the facility's Chief of Psychiatry emailed the Community of Practice national lead (who was also the National Director) confirming that they agreed on a plan for the remaining patients transitioning from community care to initiate esketamine and change to intravenous ketamine only after non-response. Despite concurrence with this plan, the facility's Chief of Psychiatry wrote the National Director eight days later and formally requested a subject matter expert panel's guidance to transition the remaining patients in community care. A panel was convened and provided recommendations in August 2020.

The OIG concluded that seven patients were prematurely transitioned to esketamine treatment at the facility as a result of administrative issues in the Community Care Service despite Mental Health Service leaders request to extend authorizations to avoid abrupt discontinuation of care and allow time to plan transitions of care for these clinically complex patients.

All seven patients had an unsatisfactory response to esketamine, which prompted change to intravenous ketamine treatment. If administrative concerns had not forced an accelerated time frame for the transition of care, the first seven patients transitioning back to the facility would have benefited from both the expert panel's review and detailed treatment planning, as well as the increased availability of intravenous ketamine treatment in the facility.[47]

3. Deficits in Coordination of Care and Negative Treatment Outcomes

The OIG found that poor communication negatively affected coordination of care for 28 patients and contributed to patient distress when lapses in authorizations for community care occurred. The OIG substantiated that discontinuation of community care and subsequent treatment changes

[47] In late August 2020, the subject matter expert panel forwarded recommendations for the transition of the remaining 15 patients receiving ketamine treatment through community care. The panel's recommendations included a comprehensive review of current treatment and a detailed transition treatment plan. Those plans included recommendations for 11 of the patients to transition to intravenous ketamine and four of the patients to transition to esketamine.

negatively affected the treatment outcomes for seven patients whose care was prematurely transitioned from the community care provider to the facility. While distress related to uncertainties about continuing ketamine treatment was identified as a contributory stressor, the OIG did not substantiate that discontinuation of community care resulted in a patient's death by suicide, as the community care provider continued to offer ketamine treatment to that patient.

Risks for negative patient outcomes increased as a result of

- deficits in communication and coordination of care,
- ending community care authorizations despite Mental Health Service leaders clinical input requesting to extend authorizations for care,
- the accelerated timeline for transition of care, and
- uncertainties associated with abruptly discontinuing or changing an established, effective treatment for complex, treatment-resistant patients and transitioning them to a different treatment for which equivalency was not established.

The OIG found that the facility's management of community care administrative processes failed to effectively recognize or mitigate these concerns.

Deficits in Communication and Coordination

The OIG found that facility Community Care Service's communication deficits and failure to coordinate collaboratively and proactively with clinical providers negatively affected patient treatment outcomes. The facility Community Care Service's lack of timely communication with facility Mental Health Service providers, the community care provider, and patients, contributed to delays in resolving concerns and deficits in care coordination.

Community Care Service staff are expected to communicate VHA's plan of care to the patient or caregiver, providers, and care teams, as needed, throughout the episode of care. Specifically, Community Care Service staff are expected to communicate proactively with the patient and have an open line of communication with providers managing the patient's care, including discussing the plan of care and managing transitions.[48]

When Community Care Service staff failed to complete a VCA to re-authorize care by October 1, 2019, and when episodes of care under the new VCA expired again in March 2020, the affected patients learned from the community care provider that their ketamine treatments were no longer being authorized. The community care provider's ability to offer guidance for those patients about ongoing treatment plans was limited because facility Community Care Service failed to respond timely or fully to the community care provider's requests for additional information or efforts toward resolving the authorization issues. Mental Health Service providers

[48] VHA Office of Community Care Field Guidebook, Chapter 3: How to Perform Care Coordination.

became aware of disruptions in the authorization of the patients' ketamine treatments directly from concerned patients or via the community care provider, rather than from Community Care Service staff. Mental Health Service providers would typically play a central role in discussing changes in treatment plans and coordinating transitions in care with their patients.[49] However, the lack of timely communication precluded Mental Health Service providers' ability to anticipate those changes and proactively communicate with patients to address concerns.

The facility Community Care Service staff's lack of communication with Mental Health Service leaders, treating providers, the community care provider, and patients during this process represented a failure in coordination of care and was inconsistent with a patient-centered care model.

Patient Distress Related to Anticipated Loss

The OIG found that when patients were notified about lapses in authorization, they expressed distress about an anticipated loss of care. The patients receiving care from the community care provider had been identified as candidates for ketamine treatment by Mental Health Service providers specifically because they had been through many prior unsuccessful treatment approaches, often over several years. Upon learning that continuing ketamine treatment with the community care provider would no longer be authorized, a number of the patients expressed distress about the anticipated loss of this treatment and described ketamine as the only treatment they had received that had been effective in managing their psychiatric symptoms, alleviating suicidal thoughts, or restoring their capacity to function in meaningful areas of their lives.

Distress associated with anticipated loss of the established treatment, deficits in communication, and lack of patient-centered coordination of care is illustrated by the case of Patient A.

Patient A

This patient had a history of severe, treatment-resistant depression and posttraumatic stress disorder with chronic suicidal ideation. The patient began receiving ketamine treatment in the community in 2017. In summer 2019, the treatment was approved and authorized for 52 weekly treatment sessions. Concurrent with the care received in the community, the patient received antidepressant medications and was followed in the facility outpatient mental health clinic by a facility psychiatrist.

In early fall 2019 (day 1), the patient had a follow-up appointment with the facility psychiatrist. The facility psychiatrist noted that the patient, who continued to receive ketamine treatments in the community, expressed gratitude stating, "It's keeping me alive." During the appointment, the patient denied suicidal ideation. The psychiatrist documented that "ketamine is the only

[49] VHA Handbook 1160.01, *Uniform Mental Health Services*, September 11, 2008, amended November 16, 2015.

treatment that works even partially" for the patient's symptoms. At the conclusion of the appointment the assigned psychiatrist recommended to "continue ketamine treatments as frequently as necessary."

On day 2, the patient's ketamine treatment was affected by the gap in authorization for community care.

On day 3, the patient received a ketamine treatment from the community care provider.

On day 4, the community care provider contacted the patient's spouse to advise of the issue with authorization for care, and indicated they agreed not to apprise the patient of the issue at that time due to concerns about the distress this was expected to evoke. The community care provider told the OIG team that the patient's spouse intended to contact the VA to advocate for the patient's continuing care in the community.

On day 5, the patient received a ketamine treatment from the community care provider and was scheduled to return for the next ketamine treatment on day 10.

On day 8, a facility staff psychiatrist called the patient regarding the ongoing efforts to have continuing ketamine treatments approved and left a message when the patient could not be reached directly. The message acknowledged the uncertainty about funding for the treatment through community care, but specified that they were working on it, and if community care could not be re-authorized, care would be provided at the facility.

On day 9, the patient canceled the day 10 ketamine treatment.

On day 11, the patient sent an email communication to the community care provider referencing the anticipated loss of care with the provider. The patient's email described the treatment as having been a "lifeline" and that "I depend on it for any hope of survival." The email also stated, "It seems like every time we make progress (like recently), and I dare to hope, I get crushed" and "The timing of the VA changing the referral process, which does not include approving K[etamine], feels like it is meant to be."

On day 16, the patient died by suicide.

Patient A Case Analysis

As noted above, uncertainties about continuing ketamine treatment were an identified stressor for affected patients. While this patient's ketamine treatment with the community care provider had not been discontinued, deficits in patient-centered care coordination and the patient's anticipation of ketamine treatment with the community care provider being discontinued evoked distress.

The community care provider continued to treat the patient, and no transition of care to the facility had occurred at the time of the patient's death. The OIG identified the anticipated loss of ketamine treatment with the community care provider as a recent stressor. However, it was not possible for the OIG to ascertain the extent to which the patient's distress about this anticipated

loss may have contributed to the patient's suicidality. The patient had a complex mental health condition, remained severely depressed despite treatment, had chronic suicidal ideations to varying degrees across years of treatment, and had acknowledged other recent events as heightening distress in addition to the anticipated loss of the established treatment relationship. The etiology of suicide is multifactorial and the psychological processes underlying an individual's suicidal ideations and decision to act on suicidal thoughts are complex.

Transitions of Treatment and Therapeutic Setbacks

The OIG found that the seven patients whose community care was discontinued in spring 2020 experienced therapeutic setbacks and less effective management of psychiatric symptoms following the transition.

Patient reports of decreased treatment effectiveness and indicators of poorer management of psychiatric symptoms highlighted concerns about the changes in treatment. Following discontinuation of ketamine treatment with the community care provider, patients who were transitioned to intranasal esketamine showed insufficient responses and were subsequently changed to treatment with intravenous ketamine at the facility. Additionally, some patients expressed that the intravenous ketamine treatments received at the facility did not work as well as their prior treatment with the community care provider. A Mental Health Service provider involved in the care transitions acknowledged that many of the patients experienced therapeutic setbacks with the change in treatment and opined that most were "not doing as well" since the transition of care.

Declines in management of psychiatric symptoms following the transition in care are illustrated by the case of Patient B.

Patient B

This patient, who had a history of treatment-resistant depression, posttraumatic stress disorder, and cannabis dependence, began ketamine treatment through community care in early 2018. A few weeks prior, the patient had been placed on a High Risk for Suicide Patient Record Flag (flag) by the facility's suicide prevention coordinator due to a plan to complete suicide by hanging.[50] Clinical improvements observed after community care ketamine treatment initiation prompted deactivation of the flag in spring 2018.

In early spring 2020, the patient was receiving regular weekly intramuscular ketamine treatments through community care. The patient received a ketamine treatment with the community care

[50] A High Risk for Suicide Patient Record Flag is an alert placed in a patient's EHR which communicates to VA staff that a patient is identified as being at high risk for suicide. The flag is part of VHA's national suicide prevention strategy and alerts staff interacting with the patient to consider this potential safety concern when making treatment decisions. VHA Directive 2008-036, *Use of Patient Record Flags to Identify Patients at High Risk for Suicide*, July 18, 2008.

provider in mid-spring 2020 and was unaware that the treatment was the last authorized session. A facility psychiatrist contacted the patient three days after the mid-spring visit to discuss the need to transition from ketamine treatment with the community care provider to esketamine treatment at the facility. The patient expressed disappointment, noting an "extended period of stability" and that "life was finally getting on track'" with ketamine treatment."

After returning to the facility, the patient received nine esketamine treatments over a period of approximately 30 days without significant response. The patient and the facility psychiatrist discussed "treatment options going forward," which included intravenous ketamine. The patient expressed "eager" interest in changing to that treatment option.

In late spring 2020, the patient received the first intravenous ketamine treatment at the facility. At the conclusion of the treatment, the patient expressed frustration regarding the change in treatment from the community care provider and reported no improvement in mood, asking the assigned facility psychiatrist, "why do I have to go through all of this?" The plan was to increase the dose of ketamine at the next appointment and continue weekly treatments.

Nine days after the first intravenous ketamine treatment,, the patient contacted the facility psychiatrist and reported "strong impulses" to commit suicide by hanging and an inability to "get the thoughts out of [my] head." The patient was seen in the facility's Emergency Department and subsequently admitted to the inpatient mental health unit. A flag was reactivated.

During a six-day hospitalization, the patient received intravenous ketamine treatments, including one on the day of discharge, with a plan to continue weekly intravenous ketamine treatment at the facility as an outpatient. The patient received the first of the planned intravenous ketamine treatments five days after inpatient discharge. Three days later, the patient expressed a resurgence of active suicidal thoughts and was readmitted to the inpatient mental health unit stating, "miserable, I was looking for a place to hang myself." The patient was discharged after three days and, as of fall 2020, the flag remained in place. The patient continued to be treated with weekly intravenous ketamine infusions at the facility.

Patient B Case Analysis

For several months following the transition from intramuscular ketamine treatment with the community care provider to treatment at the facility with intranasal esketamine and then intravenous ketamine, the patient experienced significant deterioration in mood and resurgence of suicidal ideations, necessitating two acute psychiatric hospitalizations and reactivation of a flag. This period of clinical deterioration stands in contrast to the preceding period of relative clinical stability when the patient's ketamine treatment was managed by the community care provider.

The OIG concluded that the changes in treatment negatively affected treatment outcome for the patient.

Coordination of Timeline for Transitions of Treatment

The OIG identified possible risks associated with the facility's timeline for transitioning the seven severe, treatment-resistant depression patients from established care in the community in spring 2020. The accelerated timeline for the transition of care occurred in opposition to clinical provider recommendations because of administrative constraints presented by Community Care Service processes.

As noted above, patients are eligible for care in the community when the clinically indicated service is not available at a VA medical facility.[51] The MISSION Act expanded eligibility for care in the community to also include select circumstances in which the patients and their clinicians agree that it is in the patient's "best medical interest" to be referred to a community care provider.[52] Eligibility for community care based on best medical interest may be justified by "potential for improved continuity of care" if the provider determines that delivery of the requested service at VHA would disrupt an established treatment plan with a community care provider who delivers "stable, consistent care to the patient during a specific episode of care."[53]

The OIG determined, based on discussions with key staff in the transition process, that the spring 2020 transition of the seven patients from ketamine treatment with the community care provider was premature based on multiple factors:

- As the facility did not yet have the capacity to provide ketamine treatment, the accelerated timeline constrained alternative treatment planning due to the limited available treatment options at the facility.
- The rationale that intranasal esketamine provided an equivalent treatment alternative was not sufficiently supported.
- Even following the facility's development of limited capacity for ketamine treatment, uncertainty remained about the equivalency of treatment available at the facility when compared with the patients' established treatment in the community.
- Clinical delegated authorities requested to continue community care, and Mental Health Service providers had not been consulted to develop clinically informed plans for the transition.
- When transitioning patients from one treatment to the other, lack of available research to guide an evidence-based plan presented significant challenges for reconciling the high

[51] Fact Sheet Veterans Community Care General Information.

[52] Fact Sheet Veterans Community Care General Information.

[53] VHA Office of Community Care Field Guidebook, Chapter 2: Eligibility, Referral, and Scheduling.

> doses of intramuscular ketamine from the community care provider with the lower dose limits for intravenous ketamine administration at the facility.

In the context of these challenges, the accelerated timeline for transitioning care constricted Mental Health Service providers' ability to develop clinically informed individualized treatment plans to try and reduce likelihood of negative responses to the treatment change.

Concerns about the premature timeline for transitioning care are illustrated by the case of Patient C.

Patient C

This patient, who had a history of major depression and chronic pain, began weekly ketamine treatment with the community care provider in spring 2016. By summer 2018, the weekly intramuscular ketamine treatments were increased to twice a week.

Concurrent with the care received in the community, the patient received antidepressant medications and was followed in the facility outpatient mental health clinic by a facility psychiatrist. In early spring (day 1) 2020, the patient had a follow-up appointment with the assigned facility psychiatrist who noted the patient's chronic depression and described the patient as having

> Failed to respond to numerous aggressive medication trials but has responded extremely well to ketamine injections (twice weekly frequency needed) with near complete resolution of depression. There is no evidence of adverse consequences of this treatment.

Two days later, in the absence of prior notification, the patient was informed by the community care provider that the clinic would no longer be able to provide the patient with ketamine treatment. In response to this information, the patient called the facility psychiatrist in "significant distress." The facility psychiatrist and the patient identified a plan to begin esketamine treatment at the facility with the assigned facility psychiatrist, adding "if possible, we might be able to start next week so as to preclude any period of worsening mood."

The patient received esketamine treatments at the facility on day 7 and day 11. On day 15, the patient sent a secure message to the assigned primary care provider requesting "approval and authorization" from the primary care provider to allow ketamine treatment with the community care provider. The patient wrote "I'm not handling this situation well and becoming more depressed…please help me out." The primary care provider alerted the assigned facility psychiatrist to the message.

On day 18, the assigned facility psychiatrist completed an assessment for the patient to receive facility intravenous ketamine treatment for depression. The assessment noted "for the past several years, [the patient] has been receiving intramuscular ketamine treatments for depression at an outside provider" with "excellent benefit."

On day 23, the patient received the first intravenous ketamine treatment at the facility and was scheduled for weekly intravenous ketamine infusions. As the patient had experienced no meaningful response to weekly treatment through day 39, it was decided to increase the frequency of intravenous ketamine to twice weekly starting on day 42.

Over the next two weeks, the patient received twice weekly intravenous ketamine treatments at the facility. At the conclusion of the treatment on day 53, the assigned facility psychiatrist documented that the patient "continues to experience a robust initial response" to the intravenous ketamine infusions "with (at least this week) some maintenance of response at 4 days between treatments." Despite the observation that the patient's response to intravenous ketamine treatments lasted approximately four days, a decision was made to shift back to a weekly treatment schedule after day 56.

After reverting to a weekly treatment schedule at the facility, the patient began privately receiving concurrent treatment by the community care provider on an almost weekly basis through summer 2020. The facility psychiatrist's EHR notes indicated that the patient had shown some "improvement in mood" in response to what was thought to be weekly treatments at the facility. During a review of the patient's EHR, the OIG found no evidence that VHA providers were aware of concurrent ketamine treatment with a community care provider.

Patient C Case Analysis

The patient was maintained on twice weekly ketamine treatments with the community care provider. Within one week of an appointment with a facility psychiatrist, where the efficacy of the treatment was noted and plans to continue ketamine treatment through community care were confirmed, the patient was notified of the discontinuation of community care and transitioned to treatment at the facility with intranasal esketamine. The facility did not have an intravenous ketamine treatment option available at that time, though the patient was later transitioned to intravenous ketamine due to poor response with esketamine treatment. The patient reported continuing lack of sufficient response after change to weekly intravenous ketamine treatments, and frequency was briefly increased to twice weekly. The patient independently re-initiated concurrent treatment with the community care provider outside of VHA's community care process after the facility reverted to weekly treatments. In fall 2020, the patient withdrew from intravenous ketamine treatment at the facility and returned to the community care provider where the patient continued to receive intramuscular ketamine at the patient's own expense.

The OIG concluded that the abrupt ending of the patient's community care authorization resulted in premature transition of care, which contributed to decreased efficacy of treatment, deficits in care coordination, and patient frustration.

Unknown Equivalency of Treatments and Doses

Clinical research has not established the equivalency or lack thereof between esketamine and ketamine, and does not provide significant guidance for an evidence-based algorithm for transitioning patients from one medication to the other. Potential differences in the potency of esketamine and ketamine exist and significant variability may occur in bioavailability dependent on the route of administration.[54] Data on the therapeutic effectiveness of different doses of each medication depending on the route of administration are not available. Interviewees informed the OIG that these uncertainties raised concerns about the suitability of substituting the fixed dose intranasal esketamine treatment available at the facility for the high-dose intramuscular ketamine treatment that patients were receiving in the community.

Uncertainties persisted for the providers when the patients who returned to the facility in spring 2020 were switched to intravenous ketamine following insufficient responses with the intranasal esketamine. Mental Health Service providers did not have clear guidelines or data on how to best transition patients from the community care provider's intramuscular ketamine treatments with doses that had been increased over time to facility intravenous ketamine treatments that were not approved at the higher doses. Extrapolating from the limited available data was further complicated as the majority of the published research on use of ketamine for treatment-resistant depression was focused on acute, short-term administrations or single doses rather than long-term maintenance treatment over a course of months or years, as was the situation with these patients.

Concerns regarding the unknown equivalency of treatments and dosing issues when transitioning from one medication to another are illustrated by the case of Patient D.

Patient D

The patient, who had a history of depression, anxiety, insomnia, and chronic back pain since the mid-1990s, was approved by Community Care Service staff to receive ketamine treatments in the community in spring 2017. Through spring 2020, the patient was regularly seen by a facility psychiatrist, who prescribed antidepressant medications, while concurrently receiving ketamine treatments with the community care provider.

At a spring 2020 follow-up appointment with the facility psychiatrist, it was noted that the patient was receiving intramuscular ketamine three times weekly with the community care provider. The patient reported "it [ketamine] buys me some breathing space, easing of the depression."

[54] Gary Price and Deven A Patel, "Drug Bioavailability," StatPearls Publishing, National Library of Medicine, May 21, 2020. Bioavailability refers to "the extent a substance or drug becomes completely available to its intended biological destination(s)." In lay terms, bioavailability refers to how much of the dose of the active drug reaches its target.

On a Thursday, in early summer, the community care provider contacted the facility psychiatrist and informed the facility psychiatrist that the patient's last approved community care ketamine treatment was scheduled for the following day. The facility psychiatrist called the patient and explained a plan in which the patient would begin to receive esketamine treatments at the facility two times a week starting the following Monday.

The next day (Friday), the patient received the last approved community care ketamine treatment at the patient's regular dose of 3.0 milligrams/kilogram (mg/kg) of ketamine in divided shots given 20 minutes apart. With a patient weight of 100 kg, a total treatment dose of 300 mg of intramuscular ketamine was administered during the clinical encounter.

On the following Monday, the patient received the first facility-provided intranasal esketamine treatment at a total dose of 56 mg provided in two divided doses of 28 mg separated by a five-minute interval. Three days later, the patient received the second facility-provided esketamine treatment at the maximal total dose of 84 mg provided in three divided doses of 28 mg separated by five-minute intervals.

Due to the lack of a therapeutic response to esketamine, the facility psychiatrist placed a non-formulary pharmacy request for approval of intravenous ketamine treatment. The patient was approved for facility treatment with intravenous ketamine with a starting dose of 0.5 mg/kg with permission to increase in succeeding treatments by 0.25 mg/kg up to 1.0 mg/kg, per protocol.

Five days after the second intranasal esketamine treatment, the patient had the first intravenous ketamine treatment at the facility in which 0.5 mg/kg of ketamine was infused over 40 minutes, one sixth of the intramuscular dose that the patient had been receiving three times per week through the community. When asked about sedation, dissociation, or mood change in response to the treatment, the patient reported "absolutely no." It is further documented by the treating facility psychiatrist that the patient

> was receiving high dose (>2 mg/kg) IM [intramuscular] ketamine up to 3x [three times] a week at a non-VA provider before transferring care to the VA and failing intranasal esketamine. Given the high doses used previously, it is not surprising tht [*sic*] 0.5 mg/kg today did not produce any response.

The plan for the next treatment included increasing the dose per the non-formulary guidelines to 0.75 mg/kg. A week later, when the patient was treated with the higher dose, the patient reported no "mood change," and the next scheduled treatment was planned to provide 1.0 mg/kg of intravenous ketamine.

Mid-summer, the patient was treated with 1.0 mg/kg of intravenous ketamine and reported no "significant mood change." The facility psychiatrist documented that since transition from intramuscular ketamine treatment with the community care provider, the patient's "mood has worsened significantly, and suicidal thoughts have increased in severity (though without intent or

plan).” The documented plan was to “skip [the patient’s] next scheduled treatment” as “the hope is that that might provide more time away from high-dose IM ketamine and allow for a decrease in tolerance.”

Figure 1 shows the progression of the patient’s treatment transition and doses.

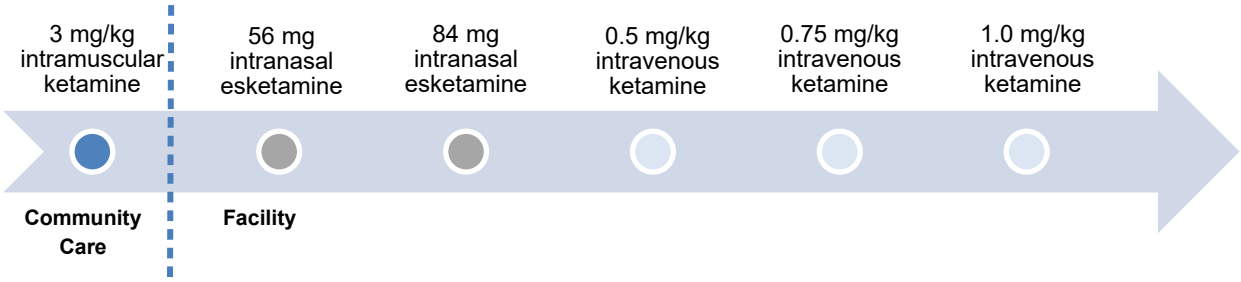

Figure 1. Patient D treatment transition and doses.
Source: OIG review of EHR.

Instead of skipping a dose, the patient privately paid “out of pocket” and received an intramuscular 3mg/kg dose of intramuscular ketamine from the community care provider. The patient reported that the interim medication dose resulted in “feeling much better for about 4 days” and that the suicidal ideation decreased after the treatment and continued until the next ketamine treatment at the facility.

At the conclusion of a facility-provided intravenous ketamine treatment, the patient reported an interest in continuing treatment “but feels [the] dosage is inadequate at this time.” As of late summer 2020, the patient had canceled all scheduled future treatments.

Patient D Case Analysis

The patient received high-dose, high-frequency intramuscular ketamine treatments through the community care provider and this treatment was reported to be beneficial in managing the patient’s depression and suicidal ideations. Upon transition to the facility, treatment was changed to esketamine, which failed to yield the same effects. The patient’s treatment plan was changed to intravenous ketamine, and that treatment was started at the standard initiating dose, to which the patient reported no response. Over subsequent treatments, the patient’s intravenous ketamine dose was titrated up twice to the maximum dose in the facility’s intravenous ketamine treatment protocol, but the patient continued to report no response. The patient returned to the community care provider once and paid out of pocket for a single session of high-dose intramuscular ketamine treatment and reported good effect from that session.

The OIG concluded that, in the context of the transition from high-dose, high-frequency ketamine treatment and likely tolerance, the patient’s lack of response to treatments at the facility

indicated non-equivalent efficacy of the alternative treatments as administered, and suggested that transition of care for such an established patient may require a different approach than the typical treatment initiation protocol for a patient new to ketamine treatment.

Plan to Transition Remaining Patients to the Facility's Ketamine Treatment Program

With both intravenous ketamine and intranasal esketamine treatment options fully implemented at the facility as of August 31, 2020, resources to manage the care needs for patients with treatment-resistant depression were available without continuing use of community care mechanisms. Facility and Mental Health Service leaders described steps taken to improve the coordination of care and transitions for patients who continued to receive intramuscular ketamine in the community.

Time Frames, Communication, and Support for Transitions

The facility planned to transition the remaining patients from the community by the end of September 2020. However, the facility modified and extended that timeline, setting target dates to transition all but one of the patients by the end of December 2020. The facility's transition plan outlined that all patients had been contacted directly by one of the facility psychiatrists from the Therapeutic Neuromodulation Program to discuss the transition.[55] In contrast to the initial seven patients, the transition plan for the remaining patients specified that the decision whether to transition to intravenous ketamine or intranasal esketamine was the patient's choice. The facility also established processes for enhanced monitoring of care during transitions through the Therapeutic Neuromodulation Program interdisciplinary team.

Expanded Capacity for Intravenous Ketamine Treatment

While the facility started offering ketamine for treatment-resistant depression in May 2020, the psychiatrist overseeing the ketamine program noted the facility had limited capacity for this service and could not accommodate the number of patients receiving this treatment through community care. Upon initial stand-up of the facility's intravenous ketamine program, all intravenous administration of ketamine for patients with treatment-resistant depression occurred in the facility's post anesthesia care unit (PACU). The resource demands limited the program capacity to six treatment slots per week.

During interviews with the OIG in August, 2020, Mental Health Service leaders indicated plans for the facility's intravenous ketamine program to open in a new dedicated clinic space,

[55] The Therapeutic Neuromodulation Program managed somatic treatment options including electroconvulsive therapy and repetitive transcranial magnetic stimulation treatments and added esketamine and ketamine treatment options as the treatments became available at the facility.

providing increased operating capacity and access to intravenous ketamine at the facility. On August 31, 2020, the facility's new Therapeutic Neuromodulation Program suite was inaugurated, providing clinic space and staffing to support the facility's intravenous ketamine, intranasal esketamine, and repetitive transcranial magnetic stimulation treatments. As of October 1, 2020, the facility had increased capacity for provision of intravenous ketamine, growing from 6 to 66 treatment slots per week, including 60 weekly slots at the new clinic, and the existing slots in the PACU, which the facility planned to reserve for complex cases.

The OIG acknowledges the significant efforts of the facility's Mental Health Service leaders and providers to develop both intravenous ketamine and intranasal esketamine treatment options to address the complex care needs of patients with treatment-resistant depression.

Modification of Dosing Limits in the Facility's Intravenous Ketamine Protocol

Mental Health Service leaders collaborated with pharmacy and anesthesia services to update the facility's intravenous ketamine protocol and raise the approved maximum dosing for treatment of depression. In accordance with VA's National Protocol Guidance for ketamine infusion for treatment-resistant depression, the facility's protocol specified the initiating dose as 0.5mg/kg infused over the course of 40 minutes. The protocol was updated to delineate that subsequent infusions may be increased to a maximum of 1.0mg/kg for patients who do not respond at the initiating dose. The Chief of Pharmacy Service also noted that if a patient failed to respond to treatments with the maximum dose allowed by the facility's protocol, the treating provider could refer the case to the facility's Ketamine Steering Committee for review and request approval for a higher dose.[56] At the time of the OIG's review, the Ketamine Steering Committee had approved one patient in the facility's ketamine treatment program for dosing exceeding the protocol's maximum dose guidance.

Consultation with National Community of Practice

As noted above, Mental Health Service leaders, with the support of facility leaders, contacted the National Director (who also headed the Community of Practice for ketamine and esketamine treatment), and requested consultation to help develop clinically informed guidelines and individualized plans for the transition of care for the remaining patients. The National Director assembled a small review team of subject matter experts (Community of Practice team) to provide consultation. That Community of Practice team reviewed patient EHRs, developed

[56] The facility's Ketamine Steering Committee, co-chaired by the Medical Director of the facility's Neuromodulation Program and the facility's Mental Health Clinical Pharmacy Specialist, was established in December 2019. The committee included representatives from Mental Health, Pharmacy, Anesthesiology, and Nursing Services.

overall guidance on considerations for transitions of care, and offered individualized recommendations on transition of care plans for the remaining patients in late August 2020.

The Community of Practice team's recommendations highlighted considerations for a patient-centered care approach, which addressed concerns identified by the OIG's review. They explicitly acknowledged the importance of engaging patients in shared decision-making about transitions of care and recognized the need to balance clinical evidence, expert recommendations, and risks with patient preferences and values. The Community of Practice team's recommendation that the facility's care team seek input from the community care provider on the proposed care transition plans underscored the importance of collaborative coordination of care, especially in the context of the complex patient care needs. The Community of Practice team also noted the importance of patients having established treatment relationships with a facility mental health provider and completion of risk assessments and safety planning prior to transitions. The Community of Practice team recommended extension of the patients' community care if these aspects of the treatment plan could not be accomplished within the remaining authorized time frame. This recommendation touched on the importance of the timeline for transitions allowing for appropriate coordination of care.

Additionally, the Community of Practice team's response reinforced the challenges presented by the limited clinical research and lack of evidence base to inform best practices for transitions between the treatment modalities, while also offering consensus guidance for the facility.

4. Concern: VHA Care Coordination Challenges for Ketamine Community Care

The OIG identified a challenge for VHA related to coordination and oversight of ketamine community care, particularly for patients receiving such care through Veterans Care Agreements. The OIG found that variance in ketamine treatment practice for treatment-resistant depression between the community care provider and the VA National Protocol Guidance raised questions about the acceptable degree of differences in ketamine practices and complicated patient care transition from the community to the facility.

Absence of Guidance to Community Care Provider

The VCA and prior individual authorizations under which ketamine community care was authorized did not reference VA's National Protocol Guidance for ketamine or specify the route of ketamine administration.[57] The community care provider was not advised of VA's National Protocol Guidance for ketamine or notified of an expectation to provide care within that

[57] The VCA that established a contract for services between VHA and a community care provider stipulated "Provider, and any providers that perform services authorized under this Agreement, shall always meet and comply with all applicable VA quality standards and requirements."

framework. When the evidence base for a treatment is limited or evolving, such as with ketamine for treatment-resistant depression, variability in accepted ranges of clinical practice may occur. Absence of clear communication in the VCA for treatment may increase the likelihood of inconsistencies between the ketamine treatment intended by the referring provider and the treatment provided in the community.

Ketamine Community Care Beneficial but Inconsistent with VA Protocol

The OIG's review of patient EHRs supports that the community care ketamine treatment was beneficial in managing the patients' conditions. Patients who were receiving care with the community care provider responded favorably to the treatments, which were adjusted or tailored over the course of treatment by the community care provider based on individual patient responses. However, the treatment provided by the community care provider was not consistent with VA's National Protocol Guidance for ketamine treatment. VA's National Protocol Guidance states that it is not intended to be overly proscriptive, and clarifies that "this guidance allows facilities the flexibility to exercise modifications to the protocol as necessary to operationalize the use of ketamine for treating treatment-resistant depression or severe suicidal ideation."[58] However, differing practices and uncertainties about treatment equivalency challenged transitioning patients back to the facility for continuing care.

Ketamine Community Care and VA Ketamine Protocol Differences Complicated Transition of Care

To be consistent with VA's National Protocol Guidance, Mental Health Service providers could not continue intramuscular ketamine as a treatment option. Facility providers' decisions were made more difficult by the lack of guidance regarding safe and effective dosing for long-term ketamine treatment. The variability in practice and need to transition treatment in a way consistent with VA's National Protocol Guidance complicated patients' transitions from high maintenance doses with the community care provider to lower doses outlined in VA guidance.

During the course of ongoing care for these patients, Mental Health Service providers and delegated authorities reviewing the community care authorizations recognized the variance in route of administration and dose range but did not raise concerns about this variance with the community care provider or identify these issues as a sufficient clinical justification for discontinuing treatment. Facility leaders determined that, in the absence of a ketamine program

[58] VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives, and Office of Mental Health Somatic Treatment Field Advisory Committee, *Ketamine Infusion for Treatment Resistant Depression and Severe Suicidal Ideation National Protocol Guidance*, December 2017.

at the facility, continuation of ketamine treatment in the community was in the best interest of the patients.

Ketamine Treatment in the Community

Discrepancies in treatment protocols between the community care provider and VA's National Protocol Guidance confounded transition of patients' care to the facility. Failure to provide clear guidance when contracting for treatment with the community care provider likely contributed to the issue. Given varying availability of ketamine and esketamine across VHA sites and growing support for these treatment options, the need for VHA to continue utilizing community care to meet demand is likely. This points to a need to ensure that non-VA ketamine treatment providers are aware of and follow VA's National Protocol Guidance. In October 2020, the Community of Practice authored guidance to the field on community care referrals for intranasal esketamine and intravenous ketamine. The guidance includes an amendment to VCAs, which ensures ketamine treatment in the community is delivered consistent with VA's National Protocol Guidance.

The OIG also recognized much knowledge could be gained from conducting further research studying the use of ketamine and esketamine for treatment-resistant depression. The lack of data on the comparative efficacy of ketamine and esketamine, dependent on route of administration and dose, and the lack of safety and efficacy data examining long-term maintenance treatment introduce uncertainties about acceptable degree of differences in clinical practices and present challenges for providers. As demand for these treatments grow, such research will become increasingly important to inform evidence-based practices.

Conclusion

The OIG substantiated that the facility ended authorization of community care for patients receiving ketamine for treatment-resistant depression on two occasions. Although no gaps in treatment occurred as a result, the OIG found that Community Care Service leaders failed to timely address expiring authorizations:

- Community Care Service leaders failed to implement a VCA by October 1, 2019, to allow for continuing authorization of care with the community care provider under the new Veterans Community Care Program regulations. This failure necessitated urgent action to ensure continuity of care for the affected patients.
- In March 2020, Community Care Service staff told the OIG that authorizations were ended for continuing episodes of care for some patients.

The OIG concluded that administrative justifications for limiting additional authorizations resulted in abrupt discontinuation of community care services and created undesirable, accelerated timelines for transitions of care to the facility for seven patients. Administrative factors in the facility Community Care Service appeared to be the primary driver behind the gap

in authorizations, the decision to stop authorizing community care for ketamine treatment, and the timeline for transitioning these seven patients back to the facility for care. The OIG further concluded that Community Care Service leaders' lack of timely communication, resistance to clinical input of mental health leaders in the disposition of these patients, and lack of proactive collaboration with stakeholders in this process contributed to challenges for care coordination.

The OIG substantiated that after the facility stopped authorizing ketamine treatment through community care for seven patients in spring 2020, those patients were transitioned to the facility and treated with intranasal esketamine instead of ketamine. The OIG found that the seven patients had a poor response to esketamine and were subsequently changed to intravenous ketamine.

The OIG found that poor communication negatively affected coordination of care for 28 patients and contributed to patient distress when lapses in authorizations for community care occurred. The OIG substantiated that discontinuation of community care and subsequent treatment changes negatively affected the treatment outcomes for seven patients whose care was prematurely transitioned from the community care provider to the facility. While distress related to uncertainties about continuing ketamine treatment were identified as a contributory stressor, the OIG did not substantiate that discontinuation of community care resulted in a patient's death by suicide, as the community care provider continued to offer ketamine treatment to that patient.

Risks for negative patient outcomes increased as a result of

- deficits in communication and coordination of care,
- ending community care authorizations despite Mental Health Service leaders' clinical input requesting to extend authorizations for care,
- the accelerated timeline for transition of care, and
- uncertainties associated with abruptly discontinuing or changing an established, effective treatment for complex, treatment-resistant patients and transitioning them to a different treatment for which equivalency was not established.

The OIG found that the facility's management of community care administrative processes failed to effectively recognize or mitigate these concerns.

With both intravenous ketamine and intranasal esketamine treatment options fully implemented at the facility as of August 31, 2020, resources to manage the care needs for patients with treatment-resistant depression were available without continuing use of community care mechanisms. Facility and Mental Health Service leaders described steps taken to improve the coordination of care and transitions for patients who had continued to receive intramuscular ketamine in the community. Key factors identified in facility plans for improved coordination of care transitions included

- extended timeframes for transitions to improve coordination of care,
- proactive communication between facility mental health providers and patients about transitions,
- shared decision-making, with patients choosing whether to transition to intravenous ketamine or intranasal esketamine,
- processes for enhanced monitoring of care during transitions through the Therapeutic Neuromodulation Program interdisciplinary team,
- expanded capacity for intravenous ketamine treatment at the facility,
- modification of the dosing limits in the facility's intravenous ketamine treatment protocol, and
- consultation with VHA's national Community of Practice for ketamine and esketamine treatment for guidance to develop clinically informed guidelines and individualized transition plans for the remaining patients.

The OIG identified a challenge for VHA related to coordination and oversight of ketamine, particularly for patients receiving such care through VCAs, which allows delivery of care to veterans outside of the third-party administrator networks. The OIG found that variance in ketamine treatment practices for treatment-resistant depression between the community care provider and the VA National Protocol Guidance raised questions about the acceptable degree of differences in ketamine practices and complicated patient care transition from the community to the facility. Failure to provide clear guidance when contracting for treatment with the community care provider likely contributed to the issue. This points to a need to improve (1) non-VA ketamine treatment providers awareness of VA's National Protocol Guidance, and (2) knowledge related to the comparative efficacy of ketamine and esketamine when used to manage treatment-resistant depression to inform evidence-based practices.

Recommendations 1–6

1. The Under Secretary for Health requires that all community care providers authorized to provide ketamine or esketamine for treatment-resistant depression receive and review VA's National Protocol Guidance on ketamine infusion and intranasal esketamine.

2. The Under Secretary for Health evaluates the need for conducting research on the use of ketamine and esketamine for treatment-resistant depression including the comparative efficacy of ketamine and esketamine, the effect of route of administration, therapeutic dose range, mechanism of action, and efficacy and safety of long-term treatment, and initiates research efforts as indicated.

3. The VA San Diego Healthcare System Director confirms that the facility's Community Care Service takes timely actions to ensure that administrative processes for care authorization do not disrupt continuity of clinical care.

4. The VA San Diego Healthcare System Director makes certain that the facility's Community Care Service processes incorporate relevant clinical service input in decisions regarding authorization, denial, or discontinuation of care.

5. The VA San Diego Healthcare System Director ensures that the facility's Community Care Service processes incorporate a consistent mechanism for communication with Veterans Health Administration and community clinical providers and patients to facilitate well-timed coordination of care.

6. The VA San Diego Healthcare System Director monitors implementation of the coordinated, clinically informed plans for continuing care when transitioning the remaining patients from ketamine treatment in the community to care at the facility.

Appendix A: Under Secretary for Health Memorandum

Department of Veterans Affairs Memorandum

Date: July 1, 2021

From: Under Secretary for Health, Office of the Under Secretary for Health (10)

Subj: Healthcare Inspection—Deficiencies in Coordination of Care for Patients with Treatment-Resistant Depression at the VA San Diego Healthcare System in California

To: Assistant Inspector General for of Healthcare Inspections (54)

1. Thank you for the opportunity to review and comment on the Office of Inspector General (OIG) draft report on care coordination for patients with treatment-resistant depression at San Diego. The Veterans Health Administration concurs with recommendations 1 and 2 and provides an action plan in the attachment.
2. Please refer to the Network Director and Medical Center Director responses for recommendations 3 thru 6.
3. Comments regarding the contents of this memorandum may be directed to the GAO OIG Accountability Liaison Office at VHA10BGOALACTION@va.gov.

(Original signed by:)

Richard A. Stone, M.D.
Acting Under Secretary for Health

Under Secretary for Health Response

Recommendation 1

The Under Secretary for Health requires that all community care providers authorized to provide ketamine or esketamine for treatment-resistant depression receive and review VA's National Protocol Guidance on ketamine infusion and intranasal esketamine.

Concur.

Target date for completion: October 2021

Under Secretary for Health Comments

When dealing with off-label use of FDA-approved medications, such as with ketamine for treatment-resistant depression, variability in accepted ranges of clinical practice do occur. VA's National Protocol Guidance states that the guidance is not intended to be overly prescriptive, and states that, "this guidance allows facilities the flexibility to exercise modifications to the protocol as necessary to operationalize the use of ketamine for treating treatment-resistant depression or severe suicidal ideation." VHA expects community care providers to exercise their medical judgement and determine treatment options for treatment-resistant depression or severe suicidal ideation that are in the best interest of our Veterans and align with VHA and clinical practice standards, such as those described in the American Psychiatric Association's Consensus Statement on the use of ketamine in the treatment of mood disorders. Currently, VHA only includes ketamine intravenous infusions as a covered medical benefit and is only referring patients to the community for ketamine infusions. This is based on the existing evidence supporting safety, efficacy, and clear dosing parameters in use of ketamine via this route of administration.

Veterans Care Agreements (VCAs) have been the commonly used vehicle for purchasing esketamine and ketamine treatment for treatment resistant depression. The Office of Community Care and Office of Mental Health and Suicide Prevention have collaborated to provide and regularly update guidance to the field on community care referrals for intranasal esketamine and intravenous ketamine since summer 2020. The guidance includes using an amendment to the VCA, which requires that community care providers meet several key criteria. These criteria are designed to ensure ketamine treatment in the community is delivered in a manner that is consistent with VA's National Protocol Guidance. Community care providers are required to sign the amendment verifying they meet all the criteria before the VCA becomes effective and the community provider is utilized to provide veteran care. Additionally, the VCA amendment provides instructions to community providers on how to access VA's National Protocol Guidance for both ketamine and esketamine on the external facing VA National Formulary

Search website available here:
https://www.va.gov/COMMUNITYCARE/providers/Service_Requirements.asp

The administration of ketamine and esketamine is a serious matter and VHA agrees it is important for community providers to have knowledge of VA's National Protocol Guidance. VHA will review current community provider education platforms to determine the best approach for ensuring the receipt and review of VA's National Protocol Guidance by community providers.

Recommendation 2

The Under Secretary for Health evaluates the need for conducting research on the use of ketamine and esketamine for treatment-resistant depression including the comparative efficacy of ketamine and esketamine, the effect of route of administration, therapeutic dose range, mechanism of action, and efficacy and safety of long-term treatment, and initiates research efforts as indicated.

Concur.

Target date for completion: October 2021

Under Secretary for Health Comments

The VHA Office of Research and Development, under the VHA Office of Health for Discovery Education and Affiliate Networks, will evaluate the need for conducting research on the use of ketamine and esketamine for treatment-resistant depression. This evaluation will need to consider what is known about the interventions and what still needs to be determined. Since the introduction of esketamine as an approved treatment by the FDA for major depression, the VHA Office of Research & Development has initiated trial planning efforts to assess research needs. Elements such as dosing, administration and adverse events have been evaluated in the foundational clinical trials leading to FDA approval; therefore, retrospective analyses could provide a robust picture of both how this has been implemented within VA, and whether specific research questions should still be addressed in any other study. Going forward, we will work to determine additional variables in considering ketamine and esketamine in clinical practice to be informed by research.

Appendix B: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 16, 2021

From: Director, Desert Pacific Healthcare Network (10N22)

Subj: Healthcare Inspection—Deficiencies in Coordination of Care for Patients with Treatment-Resistant Depression at the VA San Diego Healthcare System in California

To: Under Secretary for Health, Office of the Under Secretary for Health (10)

1. I have reviewed and concur with San Diego's actions and recommendations on the Healthcare Inspection: Deficiencies in Coordination of Care for Patients with Treatment-Resistant Depression at the VA San Diego Healthcare System in California

2. If you have any additional questions, please contact me. Thank you.

(*Original signed by*:)

Michael W. Fisher
VISN 22 Network Director (10N22)
VA Desert Pacific Healthcare Network

Appendix C: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: June 8, 2021

From: Director, San Diego Healthcare System (664/00)

Subj: Healthcare Inspection—Deficiencies in Coordination of Care for Patients with Treatment-Resistant Depression at the VA San Diego Healthcare System in California

To: Director, Desert Pacific Healthcare Network (10N22)

1. I have reviewed and concur with findings and the recommendations in the report of the Healthcare Inspection review.
2. Corrective action plans have been established with completion dates as detailed in the attached report.

(*Original signed by*:)

Robert M Smith, MD
Director

Facility Director Response

Recommendation 3

The VA San Diego Healthcare System Director confirms that the facility's Community Care Service takes timely actions to ensure that administrative processes for care authorization do not disrupt continuity of clinical care.

Concur.

Target date for completion: August 31, 2021

Director Comments

With the implementation of the MISSION Act on June 6, 2019, the VA San Diego Healthcare System Community Care Service (VASDHS CC) made significant changes to meet the needs of Veterans. Since that time, we have further increased VASDHS CC staffing and implemented standard operating procedures that will be revised as needed. We expect to have 90% of those administrative staff on board and fully trained by the end of August.

Additionally, the facility has reorganized the leadership of the VASDHS CC Service and made significant strides in redesigning and streamlining the functional organization and process for community care referrals. The facility currently matches or exceeds median Region 4 processing metrics, but is working to improve in all tracking metrics (e.g. time to schedule etc.) and uses those metrics to guide program changes.

Recommendation 4

The VA San Diego Healthcare System Director makes certain that the facility's Community Care Service processes incorporate relevant clinical service input in decisions regarding authorization, denial, or discontinuation of care.

Concur.

Target date for completion: Completed

Director Comments

All VASDHS CC consults require review and approval from Clinical Services Delegated Authorities (DA) for care in the community. The process for reviewing requests for additional services also requires clinical review and approval from DAs, but the process has changed since the transition to the CCN [community care network]. All requests for additional care or services are received from community providers and reviewed by VASDHS CC Registered Nurses (RN). When VASDHS CC RNs identify requests for additional care, these requests are sent to DAs for review. If a DA approves the request, a new authorization is then created for the patient to

continue to be treated in the community. To improve coordination with clinical services and DAs, VASDHS CC has instituted regular meetings between clinical services and CC leaders to enhance communication and care coordination.

OIG Comment

The OIG considers this recommendation open to allow time for the submission of documentation to support closure.

Recommendation 5

The VA San Diego Healthcare System Director ensures that the facility's Community Care Service processes incorporate a consistent mechanism for communication with Veterans Health Administration and community clinical providers and patients to facilitate well-timed coordination of care.

Concur.

Target date for completion: August 31, 2021

Director Comments

To ensure that community providers and patients can communicate with VASDHS CC Service, a VASDHS CC call center was established (858-623-1879). After the transition to the CCN, the CC call center options were expanded to include an option to discuss claims concerns and an option for community providers to request to join the CCN. Community providers can also contact the VASDHS CC Service by faxing requests to one of our dedicated fax lines, which are reviewed daily. The VASDHS CC Service is in the process of adding text messaging capabilities to enhance our ability to communicate with patients regarding their community authorizations. Community providers can also request access to Healthshare Referral Manager (HSRM) to streamline communication with the VASDHS CC Service. HSRM was not an available resource to community providers until July 2020. Once community providers have access to HSRM, they receive automatic email notifications when authorizations are ready for their review, which eliminates the need for faxing. Community providers can also communicate directly with local Community Care Services through HSRM.

Recommendation 6

The VA San Diego Healthcare System Director monitors implementation of the coordinated, clinically informed plans for continuing care when transitioning the remaining patients from ketamine treatment in the community to care at the facility.

Concur.

Target date for completion: Completed April 15, 2021

Director Comments

VASDHS initiated its internal ketamine for Treatment Resistant Depression (TRD) program in March 2020 in order to assure compliance with VHA treatment guidelines for use of ketamine. All 26 patients receiving parenteral ketamine for TRD in the community were offered VASDHS ketamine treatment over a period of 13 months (March 2020 to April 2021). Of these patients, 16 patients continue to receive ketamine at VASDHS. Eight patients are no longer receiving ketamine for various reasons and continue to be treated with other regimens. Two patients have chosen to return to the community provider and are paying for treatment themselves.

OIG Comment

Based on information provided, the OIG considers this recommendation closed.

Glossary

To return to point of origin, press and hold alt+left arrow

community of practice. A "group of people who share a common concern, a set of problems, or an interest in a topic and who come together to fulfill both individual and group goals. Communities of practice often focus on sharing best practices and creating new knowledge to advance a domain of professional practice."[59]

dissociative. Characterized by feelings of detachment from reality, including the physical environment and self.[60]

hallucinogenic. Experiencing sensory perceptions, such as "seeing images, hearing sounds, and feeling sensations that seem real but are not."[61]

intramuscular. "Situated in, occurring in, or administered by entering a muscle," such as administered by an injection into the muscle.[62]

intranasal. "Lying within or administered by way of the nasal structures," such as administered by a nasal spray.[63]

intravenous. "Situated, performed, or occurring within or entering by way of a vein," such as administered by an infusion into the vein.[64]

off-label. Prescription of an FDA-approved drug for a condition that it is not approved to treat, or at a different dose or via a different route of administration than that approved by the FDA.[65]

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[59] Alberta Regional Professional Development Consortium, *Creating Communities of Practice*, accessed October 30, 2020, http://www.communityofpractice.ca/background/what-is-a-community-of-practice/.

[60] National Institutes of Health, *How do Dissociative Drugs work?,* accessed October 30, 2020, https://www.drugabuse.gov/publications/research-reports/hallucinogens-dissociative-drugs/what-are-effects-common-dissociative-drugs-brain-body.

[61] National Institutes of Health, *What are Hallucinogens and Dissociative Drugs?* accessed October 30, 2020, https://www.drugabuse.gov/publications/research-reports/hallucinogens-dissociative-drugs/what-are-hallucinogens.

[62] Merriam-Webster Medical Dictionary, *intramuscular*, accessed November 30, 2020, https://www.merriam-webster.com/dictionary/intramuscular.

[63] Merriam-Webster Medical Dictionary, *intranasal*, accessed November 30, 2020, https://www.merriam-webster.com/dictionary/intranasal.

[64] Merriam-Webster Medical Dictionary, *intravenous*, accessed November 30, 2020, https://www.merriam-webster.com/dictionary/intravenous#medicalDictionary.

[65] U.S. Food and Drug Administration, "*Understanding Unapproved Use of Approved Drugs "Off Label"*", accessed September 29, 2020, https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.

post anesthesia care unit. A hospital unit where patients are temporarily admitted following surgical procedures that is designed to provide care and monitoring for patients recovering from anesthesia.[66]

repetitive transcranial magnetic stimulation. A "noninvasive procedure that uses magnetic fields to stimulate nerve cells in the brain to improve symptoms of depression." Transcranial magnetic stimulation is "typically used when other depression treatments [have not] been effective."[67]

[66] Renaissance School of Medicine, Stoney Brook University, Post Anesthesia Care Unit (PACU), accessed October 30, 2020, https://renaissance.stonybrookmedicine.edu/anesthesiology/patient/pacu.

[67] Mayo Clinic, *Transcranial magnetic stimulation*, accessed September 28, 2020, https://www.mayoclinic.org/tests-procedures/transcranial-magnetic-stimulation/about/pac-20384625.

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