DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Death of a Patient, Deficiencies in Domiciliary Safety and Security, and Inadequate Contractual Agreement at the VA Northeast Ohio Healthcare System in Cleveland

HEALTHCARE INSPECTION | REPORT 19-07091-159 | MAY 28, 2020

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Executive Summary

The VA Office of Inspector General (OIG) conducted an inspection at the VA Northeast Ohio Healthcare System (facility) Domiciliary Residential Rehabilitation Treatment Program (domiciliary) in Cleveland to determine the validity of allegations regarding deficiencies in the care of a patient there who died after an Emergency Department visit, as well as safety, security, and staffing at the domiciliary. The OIG also received a request from Senator Sherrod Brown to evaluate whether Volunteers of America (VOA), who provided the facility's domiciliary services as part of a contractual agreement, met contract requirements for food service, staffing, and cleanliness.[1]

The OIG did not substantiate that Emergency Department staff failed to properly assess the patient. In 2019, the patient was transferred from a facility inpatient unit where the patient was treated for substance use disorder to the facility's 122-bed domiciliary located in a building adjacent to the facility.[2] Approximately three weeks after the transfer, the patient was sent to the facility's Emergency Department for excessive drowsiness, a possible side effect of medications (including methadone), that were being adjusted to manage the substance use disorder.

The patient did not appear distressed to the Emergency Department physician. Other than an elevated blood pressure reading, the patient's vital signs were normal. The patient's medication regimen was confirmed with the Opioid Treatment Program pharmacist. When the patient denied feeling drowsy and declined further evaluation, the Emergency Department physician discharged the patient without changes to any medications. The next morning, the patient was found unresponsive by the patient's domiciliary roommate and could not be resuscitated.

The medical examiner was not able to conclusively determine whether the patient's postmortem medication levels were at therapeutic or toxic levels. While the medical examiner opined that the patient likely died from a cardiac-related event or secondary to respiratory depression, the autopsy findings did not result in a clear determination of the mechanism of death. The manner of death was ruled as accidental and cause of death as an acute intoxication by the combined effects of prescribed medications.

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[1] Senator Brown also requested an evaluation of the domiciliary's safety and security. As noted on the Volunteers of America® website, VOA is a nonprofit human service organization that offers housing and health care to individuals throughout the United States. VOA has approximately 16,000 staff and 60,000 volunteers, and supports and empowers groups, including veterans, homeless individuals and families, persons with disabilities, and persons recovering from addictions. https://www.voa.org/about-us. (The website was accessed on July 18, 2019.)

[2] VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)*, December 22, 2010. In 1995, VA established a mental health residential level of care to provide structure and support for patients in need of mental health and substance use disorder treatment. In 2005, all residential treatment programs, including domicilaries, fully integrated under the Mental Health Residential Rehabilitation Treatment Programs.

Although there was not a conclusive determination that a cardiac event contributed to the patient's death, the OIG found that no provider ordered an electrocardiogram prior to methadone initiation as would have been expected.[3]

The nurse practitioner who was responsible for ordering the electrocardiogram and notifying the Opioid Treatment Program physician if there were any concerns, was on leave at the time the medication was started, and no other staff ordered the electrocardiogram. The Opioid Treatment Program physician informed the OIG that methadone initiation would proceed absent notification of test abnormalities from the nurse practitioner. For this patient, the Opioid Treatment Program physician reported being unaware that the test had not been done. As an abnormality notification was not received, the Opioid Treatment Program physician went forward with the plan to start the new medication. Without a current electrocardiogram, providers may have failed to identify an existent cardiac abnormality that might have been worsened by methadone and caused cardiac arrest.

The OIG found that facility leaders took the following actions as required: (1) submitted an issue brief to executive Veterans Health Administration leaders, and (2) conducted a root cause analysis. The facility's chaplain offered domiciliary patients support, and open discussion groups were held for the staff. Facility leaders did not make an institutional disclosure to the patient's next of kin. Although the facility identified staff's failure to obtain an electrocardiogram, the OIG concluded that facility leaders focused on other possible causes for the patient's death and did not consider an institutional disclosure at the time. The OIG determined that given the failure to obtain an electrocardiogram, facility leaders should consider an institutional disclosure.

The OIG substantiated that VOA staff improperly completed health and safety round sheets during the OIG team's unannounced site visit and therefore did not ensure adequate safety and security of the domiciliary, as required by the Veterans Health Administration (VHA). Other monitoring checks, including bed checks, patient room and contraband inspections, and patient and visitor monitoring requirements, appeared to be completed as required. However, VOA managers informed the OIG team while documentation was reviewed, the accuracy of the documentation was not verified. The Assistant Nurse Manager noted that they used the "honor system" and managers looked for VOA staff's notes on the rounds sheets to suggest that they were actually inspecting the areas as scheduled.

[3] VHA Pharmacy Benefits Management Services recommends that a baseline electrocardiogram be obtained within three months prior to methadone treatment initiation for patients with cardiac risk factors, and a baseline electrocardiogram within the prior 12 months for patients without cardiac risk factors. The patient had an electrocardiogram that showed no irregularities 17 months prior to methadone induction.

The OIG concluded that the absence of a monitoring system to ensure that VOA staff completed documentation of safety checks properly compromised confidence in the validity of the documentation.

The OIG found that the physical security of the domiciliary building and grounds was in compliance with VHA requirements.[4] Facility police did not have jurisdiction at the domiciliary but coordinated with local police as needed for law enforcement. The VOA's domiciliary emergency plan provided emergency procedural information consistent with police jurisdiction.

The OIG substantiated that the domiciliary had a minimum of two nurses on duty and a maximum capacity of 122 patients. However, the OIG did not substantiate that domiciliary nurse staffing was unsafe because there was a minimum of two nurses on every shift along with VOA resident monitors. The OIG found that VOA resident monitors were scheduled to be present during all shifts to monitor safety and security for a six-month period that included several weeks before and after the death of the patient discussed in this report.

VHA's minimum core staffing requirements for mental health residential rehabilitation treatment programs and the facility's nurse staffing methodology were reviewed. Based on staff rosters provided by facility and VOA leaders, the OIG found that staffing exceeded recommended nurse staffing levels. The OIG team reviewed nursing schedules for the two-week period when the subject patient died and the two-week period immediately prior to the unannounced site visit. During those two periods, 90 percent of the shifts had three or more nursing staff present and there were no times when fewer than two nurses were on duty. The day of the patient's death, at least three nurses were on duty from midnight until 8:00 p.m., and at least two nurses from 8:00 pm until midnight. In addition to nursing, the OIG found the domiciliary also met or exceeded minimum core staffing requirements for other clinical staff.

The OIG determined that VOA substantially met its contractual obligations related to food services, non-clinical staffing, and cleanliness. However, the OIG noted an open recommendation from a 2012 OIG report related to the initial 10–year term Residential Services Agreement executed in 2009 between VHA and Veterans Development, LLC, (Vet Dev), the entity that agreed to finance, construct, own, and operate the 122–bed domiciliary building

[4] VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)*, December 22, 2010. This handbook was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1162.02, *Mental Health Residential Rehabilitation Treatment Program,* July 15, 2019, which contains the same or similar language related to domiciliary building entrance and egress doors with a single point of keyless access and closed circuit television video monitoring.

adjacent to the facility.[5] The Residential Services Agreement did not clearly define clinical and non-clinical services that would be provided by Vet Dev. Similarly, a separate agreement that Vet Dev executed with VOA (Services Provider Contract) to provide the domiciliary services for the facility did not clarify this matter.[6]

VHA policy issued in December 2010 limited community organizations (such as VOA) to providing non-clinical services and required that VHA staff perform all clinical services.[7]

Despite a recommendation by the OIG in 2012 to clarify existing contracts to specify the services VOA is required to perform at the domiciliary, the OIG found that, in 2019, VA simply extended the initial patchwork of ambiguous contracts for 10 years. The OIG determined that these contracts grouped clinical and non-clinical domiciliary services together and did not clearly define the obligations of the contracting parties; instead, a separate informal spreadsheet was created by the site monitor well after the contracts were executed that outlined the expectations of the services to be provided by VA and VOA employees, which has no force or effect of law. The lack of clear definitions of obligations may have contributed to unilateral actions by VA or VOA without proper authorization.[8]

The OIG made two recommendations to the VA Office of Asset Enterprise Management Director related to current services contracts including modifications as necessary that would clearly define the parties' rights and responsibilities.

The OIG made three recommendations to the Facility Director related to institutional disclosure, completion of electrocardiograms with initiation of methadone, and implementation of a monitoring process to ensure the integrity of documented safety checks.

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[5] Louis Stokes Cleveland Department of Veterans Affairs Medical Center, Wade Park Domiciliary Transitional Housing, *2018 Vulnerability Assessment Report, 2018*. The domiciliary building includes approximately 77,000 usable square footage. The recommendation remained open due to the lengthy legal procedures associated with the property ownership and sale; and the complex contractual relationships between VA, the services provider, and the building owner.

[6] The Services Provider Contract specified that VOA was "not responsible for any clinical services." The Services Provider Contract however, required VOA to provide "rehabilitative care," including "psychological, vocational, educational, or social" services to meet veterans' rehabilitative care needs. VOA was also responsible for "all facets" of domiciliary services, including staffing, assessment of veterans, case management, rehabilitative services, nutrition, and quality of life, as specified in Exhibit C. Exhibit C did not specify domiciliary services, only inspection procedures for the domiciliary. No other exhibit to the Services Provider Contract specified the non-clinical services VOA was required to perform.

[7] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The 2019 directive does not articulate the same limitation regarding clinical services.

[8] In 2011, Brecksville VA Medical Center closed and the domiciliary moved to the Wade Park, Cleveland campus. VA Office of Inspector General, *Review of the Enhanced Use Lease between the Department of Veterans Affairs and Veterans Development, LLC*, Report No. 12-00375-290, September 28, 2012. An enhanced use lease is an agreement between the VA and a third-party lessee, under the authority contained in United States Code, VHA Handbook 7454, *Enhanced-Use Leasing Post Transaction*, June 29, 2012. This handbook was not scheduled for recertification.

Comments

The Executive Director, VA Office of Asset Enterprise Management Director, and the Veterans Integrated Service Network and Facility Directors concurred with the recommendations and provided acceptable action plans (see appendixes C, D, and E). The OIG will follow up on the planned actions until they are completed.

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Contents

Abbreviations

CGA	CGA LSVA Residential, LLC
FTE	full-time employee equivalent
OIG	Office of Inspector General
VHA	Veterans Health Administration
Vet Dev	Residential Services Agreement with Veterans Development, LLC
Vet Dev Dom	Veterans Development Domiciliary, LLC
VISN	Veterans Integrated Service Network
VOA	Volunteers of America

Introduction

The VA Office of Inspector General (OIG) conducted an inspection at the VA Northeast Ohio Healthcare System (facility) Domiciliary Residential Rehabilitation Treatment Program (domiciliary) to determine the validity of allegations regarding deficiencies in the care of a patient there who died after an Emergency Department visit, as well as safety, security, and staffing at the domiciliary. The OIG also received a request from Senator Sherrod Brown to evaluate whether Volunteers of America (VOA), who provided the facility's domiciliary services as part of a contractual agreement, met contract requirements for food service, staffing, and cleanliness.[9]

Facility Background

The facility, part of Veteran Integrated Service Network 10, is located in Cleveland, Ohio.[10] The facility includes a medical center and 13 community-based outpatient clinics.[11] From October 1, 2017, through September 30, 2018, the facility served 111,234 patients and had a total of 674 hospital operating beds, including 296 inpatient, 180 mental health residential rehabilitation treatment, 173 community living center, and 25 compensated work therapy transitional residence.

Domiciliary

Congress first established domiciliary care programs in the 1860s to provide services to "economically-disadvantaged" veterans. Domiciliary programs evolved into integral clinical treatment programs within the Veterans Health Administration (VHA) mental health continuum

[9] Senator Brown also requested an evaluation of the domiciliary's safety and security. As noted on the Volunteers of America® website, VOA is a nonprofit human service organization that offers housing and healthcare to individuals throughout the United States. VOA has approximately 16,000 staff and 60,000 volunteers, and supports and empowers groups, including veterans, homeless individuals and families, persons with disabilities, and persons recovering from addictions. https://www.voa.org/about-us. (The website was accessed on July 18, 2019.)

[10] VA Office of Inspector General, *Review of the Enhanced Use Lease between the Department of Veterans Affairs and Veterans Development, LLC,* Report No. 12-00375-290, September 28, 2012. VHA Handbook 7454, *Enhanced-Use Leasing Post Transaction*, June 29, 2012. In 1961, VA opened the Brecksville VA Medical Center, in Brecksville, Ohio. In 1964, the Wade Park VA Medical Center, Cleveland, Ohio, was opened. In 1971, the two medical centers merged and became known as the Cleveland VA Medical Center with two divisions, Brecksville and Wade Park. Wade Park VA Medical Center was renamed the Louis Stokes Cleveland VA Medical Center in 1999. In 2011, Brecksville VA Medical Center closed and the domiciliary moved to the Wade Park, Cleveland campus. During 2018–2019, the Louis Stokes Cleveland VA Medical Center and community-based outpatient clinics became VA Northeast Ohio Healthcare System.

[11] VA Northeast Ohio Healthcare System, *2018 Annual Report*. The community based outpatient clinics are located throughout Ohio. https://www.cleveland.va.gov/about/AnnualReportFY18.pdf. (The website was accessed on November 11, 2019.)

of care. In 1995, VA established a mental health residential level of care to provide structure and support for patients in need of mental health and substance use disorder treatment. In 2005, all residential treatment programs, including domiciliary, fully integrated under the Mental Health Residential Rehabilitation Treatment Programs and in 2010, VHA established procedural and reporting requirements.[12]

Facility leaders reported that the facility's 180 residential rehabilitation treatment beds included 122 domiciliary beds.[13] The domiciliary is located in a building adjacent to the facility and provides housing and services for veterans including those who are homeless or diagnosed with post-traumatic stress and substance use disorders. The acute residential rehabilitation treatment program is located in another facility building. In October 2009, VA executed an initial 10–year term Residential Services Agreement with Veterans Development, LLC, (Vet Dev) in which Vet Dev agreed to finance, construct, own, and operate a 122–bed domiciliary building adjacent to the facility.[14] The Residential Services Agreement specified that Vet Dev provide domiciliary services including assessment, counseling, psychosocial rehabilitative care, nutritional services, housing, and building management duties.[15] As of September 2017, CGA Residential TIC I-III, gained ownership of the domiciliary and in February 2018, transferred all rights and responsibilities to CGA LSVA Residential, LLC (CGA), an affiliate of CGA Residential TIC I-III. See appendix A for additional information about the Residential Services Agreement and other contractual arrangements.

Allegations and Concerns

In 2019, a complainant submitted allegations to the OIG. The Office of Healthcare Inspections reviewed the complaint and approximately a month later, opened a hotline inspection. Shortly thereafter, Senator Sherrod Brown requested a review of the domiciliary's safety and security procedures and other contract requirements with VOA.

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[12] VHA Handbook 1162.02, *Mental Health Residential Rehabilitation Treatment Program (MH RRTP)*, December 22, 2010. Mental Health Residential Rehabilitation Treatment Programs include domiciliary residential rehabilitation treatment programs, domiciliary care for homeless veterans, general domiciliary programs, domiciliary substance abuse programs, and domiciliary post-traumatic stress disorder programs. This handbook was in effect at the time of the events discussed in this report until it was rescinded and replaced by VHA Directive 1162.02, *Mental Health Residential Rehabilitation Treatment Program,* July 15, 2019, which contains the same or similar language related to reporting requirements.

[13] VHA Directive 1002, *Bed Management Solution (BMS) for Tracking Beds and Patient Movement Within and Across VHA Facilities*, November 28, 2017. This VHA directive is scheduled for recertification on or before the last working day of November 2022.

[14] Louis Stokes Cleveland Department of Veterans Affairs Medical Center, Wade Park Domiciliary Transitional Housing, *2018 Vulnerability Assessment Report, 2018*. The domiciliary building includes approximately 77,000 usable square footage.

[15] Wade Park Residential Services Agreement By and Between The United States Department of Veterans Affairs and Veterans Development, LLC, October 1, 2009.

The inspection addressed the following allegations and additional OIG-identified concerns:

- Allegation 1—Emergency Department staff did not properly assess the patient.
    - Related Concern—Did facility leaders follow up appropriately after the patient's death?
- Allegation 2—Facility managers did not ensure adequate safety and security of the domiciliary, including VHA and VOA staff completion of health and safety rounds as required by VHA.
- Allegation 3—Domiciliary staffing consisted of two to three nurses for a maximum of 122 veterans and was unsafe.
    - Related Concern—Is VOA meeting other contractual requirements for staffing, food service, and cleanliness in the domiciliary?

Prior OIG Reports

In 2012, the OIG found that the VA inappropriately used an enhanced-use lease to lease the then Brecksville campus to Vet Dev.[16] The OIG found that a services agreement added to the enhanced-use lease violated VHA requirements for domiciliary care because the services agreement was for healthcare services and not space, and VA could only outsource housing or related non-clinical support services.

As of May 17, 2019, one recommendation relevant to this inspection remained open:

> Immediately determine what services VOA is actually performing and which services VA employees are performing and what services, if any, VA needs from VOA. Consideration should be given to simply leasing the existing space, with VA employees providing all the services, or relocating the domiciliary.[17]

In a 2017 report, the OIG found that domiciliary employees did not perform and document contraband inspections, rounds of all public spaces, resident room inspections for unsecured

[16] In 2011, Brecksville VA Medical Center closed and the domiciliary moved to the Wade Park, Cleveland campus. VA Office of Inspector General, *Review of the Enhanced Use Lease between the Department of Veterans Affairs and Veterans Development, LLC*, Report No. 12-00375-290, September 28, 2012. VHA Handbook 7454, *Enhanced-Use Leasing Post Transaction*, June 29, 2012. An enhanced-use lease is an agreement between the VA and a third-party lessee, under the authority contained in United States Code. This handbook was not scheduled for recertification.

[17] The recommendation remained open due to the lengthy legal procedures associated with the property ownership and sale; and the complex contractual relationships between VA, the services provider, and building owner.

medications, and hourly safety and security rounds. On February 13, 2019, the OIG closed all recommendations upon receipt of documentation that reflected compliance with actions taken.[18]

Scope and Methodology

In 2019, the OIG team conducted an unannounced site visit to inspect the completion and documentation of domiciliary health and safety rounds, and cleanliness. An announced site visit was conducted approximately one month later, which included staff interviews, and inspections of the Emergency Department, and the domiciliary dining area and kitchen. Facility leaders and staff, the VOA domiciliary program manager and staff, representatives and property managers of the CGA, Executive and Deputy Directors of the VA Office of Asset Enterprise Management, and the two county medical examiner physicians involved in the patient's autopsy were interviewed.[19]

The OIG reviewed the patient's electronic health record and autopsy report, as well as facility internal review documents related to the patient's care. Other pertinent documents that were reviewed included VHA handbooks, directives, and other guidance, facility policies, meeting minutes, nursing schedules, nurse staffing methodology, and relevant organizational charts. The OIG also reviewed VOA documentation for rounding and safety inspections, and domiciliary contract documents.

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, §7, 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 leadership on patient care issues. Findings and recommendations do not define a standard of care or establish legal liability.

[18] VA Office of Inspector General, *Clinical Assessment Program Review of the Louis Stokes Cleveland VA Medical Center, Cleveland, Ohio,* Report No. 16-00553-135, March 13, 2017.

[19] CGA Capital, also called CGA LSVA Residential, LLC, is a privately held company and a single location business in Timonium, Maryland. CGA LSVA Residential, LLC, is the "Owner" identified in the Residential Services Agreement with the VA.

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.

Patient Case Summary

The patient was in their 30s at the time of death in the domiciliary.[20] The patient first used opioid pain medications after a 2011 surgery related to an injury incurred during military service overseas. Following the surgery, the patient began abusing opioid pain medications. In 2012, following discharge from a non-VA residential program, the patient met with a facility social worker and described anxiety, insomnia, and irritability. The social worker diagnosed the patient with opioid dependence, generalized anxiety disorder, and rule out post-traumatic stress disorder.

In the seven years prior to death, the patient had more than 35 inpatient admissions related to substance use disorders. Thirty-one of the admissions occurred at VHA facilities, including six admissions to the facility domiciliary. Of the six domiciliary treatment admissions, the patient completed two; was administratively discharged three times for failure to adhere to program rules; and died during the last admission. The patient's longest reported period of sobriety was from the end of 2017 to late 2018, which included a two-month incarceration and a 90-day residential treatment program. The patient's treatment history included Suboxone® and methadone (prescribed daily doses up to 100 milligrams).

In 2018, the patient began using heroin and fentanyl, and taking non-prescribed benzodiazepines. The patient was treated twice for heroin overdose at a non-VA hospital. A few weeks later, the patient requested residential substance use treatment at the facility and was admitted to the facility medical inpatient unit. A provider noted in the patient's electronic health record the previous substance use disorders and withdrawal seizures, by history. Three days after admission, the patient started Suboxone®, as recommended by a psychiatrist. That same day, a nurse practitioner entered domiciliary admission orders and assigned the patient's medication management level as semi-independent with inpatient medications, and nursing staff were to administer controlled substances. When the patient was transferred to the domiciliary two days later (day 1), an assistant nurse manager assigned the patient an independent medication self-administration level and the patient signed a safe medication agreement. In the domiciliary, the psychiatrist prescribed the patient's medications including Suboxone®, mirtazapine for post-traumatic stress disorder symptoms, gabapentin for protracted withdrawal symptoms, and hydroxyzine as needed for anxiety.

On day 6, in response to the patient's expressed preference for methadone, the psychiatrist increased the Suboxone® to help with the patient's cravings. On day 15, the interdisciplinary treatment team noted that the patient appeared "more constructively engaged in treatment compared to prior treatment episodes." On day 16, the Opioid Treatment Program physician

[20] The OIG uses a singular form of they in this instance for the purpose of patient privacy.

agreed to taper the patient's Suboxone® dose with a plan to start 20 milligrams of methadone four days later.

On day 20, the patient signed an informed consent and received a first morning dose of methadone. Five hours later, the patient appeared drowsy and left a group therapy session. The next two mornings, the patient received methadone and appeared drowsy and tired in group therapy later on those two mornings. On day 23, the patient received methadone and a few hours later, the patient requested a methadone dose increase due to symptoms of cravings, runny nose, and hot/cold flashes. The Opioid Treatment Program pharmacist recommended an increased daily methadone dose beginning day 24, and the Opioid Treatment Program physician wrote the order. The patient received the first increased dose of methadone on day 24, and appeared drowsy in group therapy that started 15 minutes later.

On day 25, a few hours after the patient took the increased methadone dosage, VOA staff found the patient asleep in the domiciliary dining area and escorted the patient to see a nurse. The nurse noted the patient was unable to participate in a conversation due to the severity of drowsiness. The nurse obtained a urine alcohol and drug test sample, paged the physician on duty, and called the nursing supervisor.[21] The nursing supervisor instructed the nurse to call 911. The ambulance arrived to transport the patient to the facility's Emergency Department and the domiciliary nurse provided a report to the Emergency Department nurse.

In the Emergency Department, the triage nurse documented the patient's vital signs as normal except for an elevated blood pressure reading. The pharmacist contacted the Opioid Treatment Program pharmacist and verified the patient's initial and increased methadone doses. The Emergency Department physician documented that the patient was ambulating around the Emergency Department without difficulty and did not appear "sleepy." The patient denied feeling drowsy and declined further Emergency Department evaluation. The Emergency Department physician discharged the patient from the Emergency Department without changes to the patient's medications. The patient walked back to the domiciliary without an escort.

That evening, a nurse documented that VOA staff escorted the patient to the nursing station after the patient reported getting into a verbal argument with another patient. The patient reported a high anxiety level, refused vital sign assessment, and calmed down after talking with the nurse. After approximately 30 minutes, the patient left the nursing station and VOA staff reportedly observed the patient going to the patient's room.

The next morning, on day 26, staff documented that the patient was last seen at baseline at 5:00 a.m. At 8:55 a.m., the patient's roommate notified nursing staff that the patient was unresponsive. Nursing staff found the patient in bed without a pulse. Staff initiated cardiopulmonary resuscitation and administered Narcan® six times without response.

[21] The patient's urine drug screen was positive only for methadone.

Emergency medical services arrived within 15 minutes and the patient was pronounced dead shortly thereafter. The medical examiner's office ruled the manner of death as accidental and cause of death as an acute intoxication by the combined effects of methadone, buprenorphine, gabapentin, and mirtazapine.

Inspection Results

1. Emergency Department Care

The OIG did not substantiate that Emergency Department staff failed to properly assess the patient. The triage nurse's care and disposition of the patient was appropriate and consistent with facility policy.[22] The patient declined further medical evaluation and the Emergency Department physician considered the patient to have medical decision-making capacity, so the physician discharged the patient back to the domiciliary.

On day 25 of the domiciliary admission, the patient was drowsy, and the domiciliary nurse arranged for an ambulance to transport the patient to the facility's Emergency Department. Upon arrival at the Emergency Department, the patient told the Emergency Department triage nurse the "DOM [domiciliary] is wrong." The triage nurse documented the patient's vital signs as normal except for an elevated blood pressure reading.

Triage nursing staff assigned the patient a "3" on the Emergency Severity Index since the patient had no symptoms of a cardiac event, stroke or infection, and denied thoughts of suicide over the past two weeks. The Ambulatory Care Chief Nurse reported that the patient was placed on Fast Track to be evaluated by a provider, consistent with facility policy.[23] The OIG determined that the triage nurse's care of the patient was appropriate.

Although the patient was likely not harmed by omission of a repeat blood pressure assessment, the OIG would have expected Emergency Department staff to reassess the patient's blood pressure given the elevated reading.[24] The Emergency Department physician documented that the patient was brought to the Emergency Department due to the domiciliary nurse's concern about the patient's methadone use. The Emergency Department pharmacist confirmed that the patient's methadone dosage was increased three days earlier.

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[22] Louis Stokes Cleveland VA Medical Center (541), Emergency Department Policy and Procedure, *ED-093, Nurse Triage*, July 24, 2018.

[23] VHA Directive 1101.05(2), *Emergency Medicine,* September 2, 2016, amended March 7, 2017. VHA defines Fast Track as a designated area within the Emergency Department where lower acuity patients can be seen. This VHA directive is scheduled for recertification on or before the last working day of September 2021. Louis Stokes Cleveland VA Medical Center Emergency Department Policy and Procedure, *ED-093 Nurse Triage*, July 24, 2018.

[24] After the Emergency Department discharge and upon return to the domiciliary, the patient declined a domiciliary nurse's request to check vital signs.

VHA patients have the right to accept or refuse medical treatment or procedure. "All treatments and procedures require the prior, voluntary informed consent of the patient, or if the patient lacks decision-making capacity, the patient's authorized surrogate." Patients are presumed to have decision-making capacity to provide informed consent unless a practitioner documents a clinical assessment that determines a patient's lack of decision-making capacity.[25] The physician documented that the patient did not report feeling drowsy, was ambulating without difficulty, and was not distressed. The physician noted that the patient had three negative urine drug screens in the prior two weeks. The physician told the OIG that the patient was awake, alert, walking, answered questions appropriately, and did not want further medical treatment.

Based on these factors, the physician determined that the patient had capacity to make decisions about treatment, and discharged the patient since the patient declined further medical care. The OIG concluded that the physician used a medically acceptable rationale for discharging the patient that included consideration of the patient's presentation, capacity to provide informed consent, and preferences.

Potential Explanations for the Patient's Cause of Death

On day 19 of the domiciliary admission, the patient stopped taking Suboxone®. The next day, the patient was prescribed methadone, gabapentin, and mirtazapine, which can collectively cause sedation, central nervous system depression, and respiratory depression.[26] Methadone taken in conjunction with mirtazapine can increase the likelihood of cardiac arrhythmia.[27] Starting on day 24, the Opioid Treatment Program physician increased the patient's methadone to reduce cravings. That same day, the patient received one-week-supply prescriptions for gabapentin and mirtazapine. Inventory of the patient's medications after death suggested that the patient had taken more than the prescribed dose of gabapentin and the expected dose of mirtazapine.

Postmortem blood concentrations of medications can be difficult to interpret due to multiple factors. Drug levels in the body may change due to resuscitation attempts, the interval between death and examination, positioning of the body, and refrigeration of the body prior to autopsy. For example, methadone levels may more than double in postmortem concentration. Additionally, metabolism of some drugs continues after the heart stops and drugs will

[25] VHA Handbook 1004.01(2), *Informed Consent for Clinical Treatments and Procedures*, August 14, 2009, amended September 20, 2017, and April 4, 2019. The major components of decision-making capacity are the patient's ability to understand and appreciate the nature and expected consequence of each health care decision, and the patient's ability to formulate a judgement and communicate a clear decision regarding health care.

[26] Prescribers' Digital Reference, *Methadone Hydrochloride - Drug Summary.* https://www.pdr.net/drug-summary/Methadone-Hydrochloride-Oral-Solution-methadone-hydrochloride-3322#13. (The website was accessed on November 25, 2019.)

[27] Prescribers' Digital Reference, *Mirtazapine – Drug Summary*. https://www.pdr.net/drug-summary/Mirtazapine-mirtazapine-3335.8320#13, 2019. (The website was accessed on November 25, 2019.)

redistribute between tissues and blood during the postmortem period, further impacting blood concentration levels.[28]

According to the medical examiner who conducted the patient's autopsy, the postmortem gabapentin concentrations were consistent with expected levels and gabapentin was unlikely to have been the primary cause of fatality. The patient's postmortem buprenorphine (a component of Suboxone®) screen was positive, but the amount was too small to be quantified. The medical examiner explained that the patient's methadone level fell in the substantial overlap between therapeutic and toxic levels during postmortem examination.[29] As such, the medical examiner was not able to conclusively determine whether the patient's methadone level (consistent with both high therapeutic and mid-toxic levels) was secondary to postmortem changes, reflective of methadone poisoning with an increased dosage, or due to taking supplemental, non-prescribed methadone.

The medical examiner emphasized the unpredictable nature of methadone and that a therapeutic dose for one person may be toxic for another person due to the overlap between therapeutic and toxic levels. Additionally, therapeutic methadone levels can lead to sudden death by cardiac arrhythmia or respiratory depression.[30] The medical examiner opined that the patient most likely died from a cardiac-related event or secondary to respiratory depression, but the autopsy findings did not result in a clear determination of the mechanism of death.

The OIG found that the patient was taking multiple medications with combined effects of sedation as well as central nervous system and respiratory depression.[31] After initiation of methadone, multiple clinicians noted that the patient was drowsy and tired; a nurse documented the patient was falling asleep during a conversation, indicating sedative effects. The OIG determined that the patient's death was unforeseeable and unpreventable and concurred with the medical examiner's opinion that the patient's death was caused by an accidental overdose from the combined impact of the patient's medications.

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[28] Roger Byard and Danielle Butzbach, "Issues in the interpretation of postmortem toxicology," *Forensic Science, Medicine, and Pathology*, (2012) 8:205-207.

[29] The patient's postmortem methadone level was measured as 0.672 milligrams per liter. The medical examiner's laboratory therapeutic reference milligrams per liter level range was 0.03-0.75 and the toxic range was 0.024-1.0.

[30] Sumeet Chugh, Carmen Socoteanu, Kyndaron Reinier, Justin Waltz, Jonathan Jui, Karen Gunson, "A Community-Based Evaluation of Sudden Death Associated with Therapeutic Levels of Methadone," *The American Journal of Medicine*, 121, no. 1, January 2008: 66-71.

[31] Prescribers' Digital Reference, *Methadone Hydrochloride - Drug Summary.* https://www.pdr.net/drug-summary/Methadone-Hydrochloride-Oral-Solution-methadone-hydrochloride-3322#13. (The website was accessed on November 22, 2019.)

Failure to Obtain an Electrocardiogram Prior to Methadone Initiation

VHA Pharmacy Benefits Management Services recommends that a baseline electrocardiogram be obtained within three months prior to methadone treatment initiation for patients with cardiac risk factors and a baseline electrocardiogram within the prior 12 months for patients without cardiac risk factors.[32] The patient had an electrocardiogram that showed no irregularities 17 months before the patient's methadone induction.

The OIG team was informed by Opioid Treatment Program staff that the nurse practitioner was responsible for ordering an electrocardiogram within a week of when a patient starts methadone treatment. However, the nurse practitioner was on leave at the time of the patient's evaluation and approval for methadone treatment, resulting in the electrocardiogram not being completed. The Opioid Treatment Program physician thought the test had been done. In an interview with the OIG, the Opioid Treatment Program physician reported being unaware that the test had not been done and in the absence of abnormality notification, went forward with the plan to start the new medication. The Patient Safety Manager informed the OIG that the facility had noted that the patient did not have an electrocardiogram as would be expected. The nurse practitioner informed the OIG that the Opioid Treatment Program implemented software that requires the provider to document and communicate a patient's electrocardiogram results to the pharmacist. Additionally, since the patient's death, Opioid Treatment Program staff implemented a methadone pre-screening checklist to ensure an electrocardiogram test is completed prior to medication initiation. Facility managers reported 100 percent compliance for a three month period after the checklist was initiated.

Although there was not a determination that a cardiac event contributed to the patient's death, the OIG found that no provider ordered an electrocardiogram prior to methadone initiation as would have been expected. Without a current electrocardiogram, providers may have failed to identify an existent cardiac abnormality that might have been worsened by methadone and caused cardiac arrest.

[32] VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives, *Oral Methadone Dosing Recommendations for the Treatment of Chronic Pain*, July 2016.

Related Concern: Response Following the Patient's Death

The OIG found that facility managers and leaders reported the patient's death as required but did not make an institutional disclosure.[33] Facility leaders responded appropriately to domiciliary patient and staff needs following the patient's death.

Reporting

VHA requires facility leaders to submit an issue brief within two business days of an adverse event such as an unexpected occurrence involving death, or a serious physical or psychological injury.[34] Facility leaders submitted an issue brief to executive VHA leaders the day after the patient's death. Facility leaders also completed a root cause analysis as required.[35] VHA allows medical center leaders to make the determination of whether or not to report negative clinical events to The Joint Commission.[36] The Chief, Quality Management, told the OIG that facility leaders did not submit a report because The Joint Commission had alerted them that a complaint was submitted regarding the patient's death and therefore, that was considered notification.

Disclosure

Facility leaders did not make an institutional disclosure to the patient's next of kin. Although the facility identified staff's failure to obtain an electrocardiogram, the OIG concluded that facility leaders focused on other possible causes for the patient's death and did not consider an institutional disclosure at the time. The OIG determined that given the failure to obtain an electrocardiogram, facility leaders should consider an institutional disclosure.

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[33] VHA Directive 1004.08, *Disclosure of Adverse Events to Patients,* October 31, 2018. This VHA directive is scheduled for recertification on or before the last working day of October 2023. An adverse event may warrant an institutional disclosure, which is a formal process for facility leaders and clinicians to inform the patient or patient's personal representative that an adverse event occurred and includes specific information about the patient's rights and recourse.

[34] Deputy Secretary for Health for Operation and Management, *10N Guide to VHA Issue Briefs*, updated March 2018. VHA requires written documentation to provide specific, and factual information to leadership within the organization regarding a situation/event/issue.

[35] VHA Handbook 1050.01, *VHA National Patient Safety Improvement Handbook*, March 4, 2011. This handbook was scheduled for recertification on or before the last working date of March 2016 and has not been recertified.

[36] The Joint Commission, *About the Joint Commission*, *2019*. The Joint Commission is an independent, not-for-profit organization, that accredits and certifies over 22,000 health care organizations and programs in the United States. https://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx. (The website was accessed on September 25, 2019.) VHA Directive 1100.16, *Accreditation of Medical Facility and Ambulatory Programs*, May 9, 2017; VHA Handbook 1050.01.

Follow-Up Support for Patients and Staff

The Domiciliary Chief told the OIG that after the patient died, facility and VOA leaders, and a chaplain met with domiciliary patients to offer support. The Domiciliary Chief further indicated that patients shared their feelings about the patient's death and that staff encouraged patients to speak with them as needed. One of the domiciliary psychologists told the OIG team that staff held open discussion groups to provide patients opportunities to discuss their feelings and concerns. After the patient's death, the Domiciliary Chief provided staff with contact information for the Employee Assistance Program and encouraged them to use the program as needed.[37]

2. Safety and Security

The OIG substantiated that VOA staff improperly completed health and safety round sheets during the OIG team's unannounced site visit and therefore did not ensure adequate safety and security of the domiciliary, as required by VHA. Although facility leaders reported taking immediate action, the OIG concluded that the integrity of the VOA staff documentation remained uncertain because managers only reviewed documentation to determine completion and did not monitor the accuracy of the documentation.

The OIG found that bed checks, patient room and contraband inspections, and patient and visitor monitoring requirements appeared to be completed as required. However, the absence of a monitoring system to ensure that VOA staff completed the documentation properly compromised confidence in the validity of the documentation. The OIG found that the physical security of the domiciliary building and grounds was in compliance with VHA requirements.[38] Facility police did not have jurisdiction at the domiciliary but coordinated with local police as needed for law enforcement. The OIG found that VOA's domiciliary emergency plan provided emergency procedural information consistent with police jurisdiction.

Health and Safety Rounds

Domiciliaries operating in collaboration with community organizations must follow VHA procedural requirements.[39] VHA requires domiciliary staff to complete and document health and

[37] Office of Personnel Management, *Frequently Asked Questions.* The Employee Assistance Program "is a voluntary work-based program that offers employees free services including assessments, short-term counseling, and referrals to employees with personal and/or work-related problems." https://www.opm.gov/faqs/QA.aspx?fid=4313c618-a96e-4c8e-b078-1f76912a10d9&pid=2c2b1e5b-6ff1-4940-b478-34039a1e1174. (The website was accessed on September 5, 2019.)

[38] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to domiciliary building entrance and egress doors with a single point of keyless access, and closed circuit television video monitoring.

[39] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to community organizations following VHA procedures.

safety rounds of resident rooms and public spaces every two hours to ensure patient, staff, and visitor safety.[40] During site visits and interviews with facility staff, OIG learned that the VOA resident monitors were assigned to one of three resident room floors to cover 24 hours, seven days a week, and document hourly health and safety rounds.[41]

During the 2019 unannounced site visit, the OIG found that for four of six shifts, VOA staff documented health and safety rounds completion prior to the expected inspection time. VOA staff's proper performance of health and safety rounds is critical to ensuring the well-being of residents and overall security of the domiciliary. While on site, the OIG informed the Facility Director of the deficiency. The Quality Manager told the OIG that the Facility Director immediately informed staff of OIG's finding. The next day, the Facility Director informed facility leaders including the Chief of Staff and the Associate Director of Patient Care Services. The Facility Director made an unannounced visit on a weekend, and did not find that VOA staff had pre-completed the rounds sheets. During a site visit the following month, the OIG found that VOA staff completed health and safety rounds sheets prior to the expected inspection times for the three shifts observed.

According to the VOA Program Director, the VOA assistant program director reviewed health and safety rounds sheets after each shift to ensure completion. The Domiciliary Assistant Chief Nurse reported that VA domiciliary managers reviewed the health and safety rounds sheets in morning report during the week and on Mondays to cover the weekends. The Assistant Nurse Manager noted that they used the "honor system" and managers looked for VOA staff's notes on the rounds sheets to suggest that they were actually inspecting the areas as scheduled.

Bed Checks

VHA requires domiciliary staff to perform resident bed checks at approximately 11:00 p.m. and 6:00 a.m. to verify the physical presence of each resident.[42] At the time of the patient's death, facility policy required bed checks at approximately midnight and 3:00 a.m.[43] Closed circuit television video footage showed that a nurse and VOA staff member completed bed checks of

[40]VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019.The two policies contain the same or similar language related to public spaces and health and safety rounds.

[41] Volunteers of America, *Monitoring and Rounds,* March 2019. VOA's resident monitors are milieu staff responsible for safety and security of the domiciliary. For the purposes of this report, the Health and Safety Rounds-Veterans Domiciliary forms will be referred to as health and safety rounds sheets.

[42] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to bed checks.

[43] Medical Center Policy 118-006, *Monitoring of Residents and Environmental Safety and Security in the Residential Rehabilitation Treatment Program*, September 17, 2018. This policy was rescinded and replaced by Medical Center Policy 118-006, *Monitoring of Residents and Environmental Safety and Security in the Residential Rehabilitation Treatment Program,* February 28, 2019. The 2019 policy contains same or similar language related to checks with the addition of a third 6:00 a.m. bed check.

the patient's room at 12:16 a.m. and 3:16 a.m. In response to the patient's death, the Domiciliary Chief reported adding a third 6:00 a.m. bed check.[44] During the unannounced 2019 site visit, the OIG team shadowed one shift of bed checks and observed staff compliance with VOA policy. The OIG found that VOA and facility staff initialed bed checks for 12:00 a.m., 3:00 a.m., and 6:00 a.m. daily throughout the unannounced site visit.

Patient Room and Contraband Inspections

VHA requires regular and random inspections of common areas and at least 10 percent of patient rooms to detect contraband and unsecured medications.[45] While on site, the OIG team observed a resident monitor's demonstration of room inspection procedures and found the inspection to be thorough. The OIG team reviewed five days of patient room inspection documentation post-site visit, and found that VOA staff documented inspections of patients' rooms daily. The VOA Director told the OIG that community safety specialists are responsible to inspect patients' belongings at admission and when a patient returns from an off-campus pass.

Patient and Visitor Monitoring

VHA requires domiciliary staff to monitor the whereabouts of patients for purposes of safety and security.[46] All patients and visitors were required to sign-in and sign-out using designated log books at the reception desk.[47] The OIG found nine patient sign-in and sign-out log sheets fully completed during the unannounced site visit.[48] The OIG team also observed patients routinely signing the logs upon entrance and exit from the building. Each of three visitor sign-in log sheets for the previous day was reviewed and found that each sign-in sheet was fully completed. The Domiciliary Chief told the OIG that at 9:00 p.m. each day, staff reconciled the patient sign-in logs to determine if there were any signed-out patients who had not returned. If a patient was missing, facility policy required staff to contact the police service, nursing supervisor, and the psychiatric provider who determined the patient's risk level based on history and current clinical situation. If a patient was determined to be at "acute high risk," staff enacted the facility's missing patient policy.[49]

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[44] Medical Center Policy 118-006, September 17, 2018; Medical Center Policy 118-006, February 28, 2019. The 2019 policy contains language for an additional presence check.

[45] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to contraband inspection and medication security.

[46] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to the monitoring of patients' whereabouts.

[47] Veterans Domiciliary at Wade Park Veteran Handbook, revised October 2018.

[48] The sheets included columns for date, last name, first name, time out, time in, and destination/purpose.

[49] VA Northeast Ohio Healthcare System Medical Center Policy 118-006, *Monitoring of Residents and Environmental Safety and Security in the Residential Rehabilitation Treatment Program,* September 17, 2018.

Physical Security

VHA requires the securing of all domiciliary building entrance and egress doors with a single point of keyless access and closed circuit television video monitoring.[50] The OIG team observed that the domiciliary building entrance and egress security was in compliance with requirements. Private security guards monitored the domiciliary's alarm systems and closed circuit television video of the building's interior and exterior. Both the facility and the private security company tested the panic alarms during October 1, 2017, through September 30, 2018, to ensure they were operational. The property manager told the OIG team that facility police monitored the domiciliary panic alarms and contacted local police as needed. Additionally, CGA employed evening patrols for the perimeter of the domiciliary building.

The OIG found functional closed circuit television security cameras throughout the building including at the front entrance of the domiciliary. As required by VHA, signage was posted to alert individuals that they were being video-recorded.[51] During both site visits, OIG observed that VOA staff monitored closed circuit television. The closed circuit television video cameras were operational at the time of the OIG site visits.

The OIG also found that the domiciliary maintained a physical environment to support female patients' rights to dignity, respect, and safety, including separate sleeping arrangements and secure bathrooms, as required by VHA.[52]

Police Jurisdiction and Emergency Plan

In 2012, VA Office of General Counsel determined that facility police did not have jurisdiction at the domiciliary because the domiciliary was not located on VA-owned or leased property. Facility police may not patrol the domiciliary but are authorized to coordinate police response with local law enforcement agencies; conduct internal investigations, physical security surveys, and vulnerability assessments; and provide security education.[53]

The VOA domiciliary emergency plan dated October 1, 2018, was reviewed by the facility's Occupational Health & Safety Department. The plan directed staff to call 911 and facility police.[54] Under the current services agreement, CGA was required to ensure adequate

[50] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to domiciliary building entrance and egress doors with a single point of keyless access, and closed circuit television video monitoring.

[51] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to closed circuit television video recording signage.

[52] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to reporting requirements.

[53] Louis Stokes Cleveland VA Medical Center Medical Center Policy 007-009, *Security Management Plan*, August 11, 2017.

[54] Veterans Domiciliary at Wade Park Emergency Procedures Plan, October 1, 2018.

domiciliary emergency services. A CGA managing partner reported that the University Circle Police Department and the Cleveland Police Department provided the domiciliary emergency services, and facility police were notified of emergencies. Local police departments conducted random patrols on the property during and after business hours. According to facility police and a county law enforcement agency, monthly canine patrols of the domiciliary were conducted. In 2019, facility police conducted situational awareness training at the domiciliary.

The OIG team reviewed facility managers' domiciliary rounds for a 13-month period including the time of the patient's death for safety and security issues. Identified safety and security deficiencies were corrected either on the same day of rounding or within 28 days of the documented deficiency.

3. Domiciliary Staffing

The OIG substantiated that the domiciliary had a minimum of two nurses on duty and a maximum capacity of 122 patients. However, the OIG did not substantiate that domiciliary nurse staffing was unsafe because there was a minimum of two nurses on every shift along with VOA resident monitors. The OIG found that VOA resident monitors were scheduled to be present during all shifts to monitor safety and security for a six-month period that included several weeks before and after the death of the patient discussed in this report.

In 2010, VHA established minimum core staffing requirements for mental health residential rehabilitation treatment programs that dictated 3.1 full-time employee equivalent (FTE) nurses for a domiciliary with 100 to 125 patients. The nurse manager determines the number of registered nurses, licensed practical nurses, and nursing assistants needed to meet the core staffing requirement. In 2017, VHA developed a nurse staffing methodology for mental health residential rehabilitation treatment programs and provided tools to determine nurse staffing needs based on program complexity, average daily census, and number of admissions and discharges.

The January 2016 through March 2016 facility nurse staffing methodology indicated that the domiciliary required 6.3 FTE registered nurses and 7.8 FTE licensed practical nurses. The domiciliary did not employ nursing assistants and instead, 24.9 FTE VOA resident monitors provided coverage. At that time, the facility staffing methodology data identified a deficit of 2.3 FTE registered nurses and met or exceeded the licensed practical nurse and nursing assistant or resident monitor recommendations.

Based on staff rosters provided by facility and VOA leaders in 2019, the OIG found that staffing exceeded the recommended nurse staffing levels with seven registered nurses, 10.5 licensed practical nurses, and 27 resident monitors. The OIG team reviewed nursing schedules for the two-week period when the subject patient died and for the two-week period immediately prior to the unannounced site visit. During those periods, 90 percent of the shifts had three or more nursing staff present and there were never fewer than two nurses on duty. The day of the

patient's death, at least three nurses were on duty from midnight until 8:00 p.m. and at least two nurses from 8:00 p.m. until midnight. In addition to nursing, OIG found the domiciliary also met or exceeded minimum core staffing requirements for other clinical staff. Specific staffing numbers are listed in appendix B.

An employee must be physically present at all times on each domiciliary floor [55] The VOA Program Director told the OIG that for each shift, a resident monitor was located on each floor, and a receptionist and a community safety specialist were at the front desk/building entry point. The VOA Program Director also told the OIG that when a VOA staff member calls off work, another VOA staff member, the program director, or assistant director fills in for the shift. During both OIG site visits, the team observed VOA staff present on each floor as well as at the front entry desk and security office area with closed circuit television monitors.

Related Concern: VOA Contract Requirements

Despite a 2012 recommendation by OIG to clarify existing contracts to specify the services VOA was required to perform at the domiciliary, the OIG found that VA simply extended the initial patchwork of ambiguous contracts for 10 years. The OIG determined that these contracts grouped clinical and non-clinical domiciliary services together and did not clearly define the obligations of CGA, VHA, and VOA; instead, a separate informal spreadsheet was created by the site monitor well after the contracts were executed that outlined the expectations of the services to be provided by VA and VOA employees, which has no force or effect of law. The lack of clear definitions of obligations may have contributed to unilateral actions by VA or VOA without proper authorization.[56]

The OIG found that VOA substantially met the contractually identified expectations for non-clinical staffing, food service, and cleanliness in the domiciliary.

Contractual Basis for VOA Services

As of May 2019, the 2012 OIG recommendation to determine what services VOA performed and to consider whether to lease the space with VA employees providing all the services or relocate the domiciliary remained open.[57] In August 2019, the local site monitor reported that a new

[55] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to staff physical presence.

[56] VA Office of Inspector General, Report No. 12-00375-290; VHA Handbook 7454.

[57] VA Office of Inspector General, Report No. 12-00375-290; VHA Handbook 7454.

Residential Services Agreement was drafted but that a signed agreement was not completed.[58] As of October 2019, CGA was reviewing the proposed Residential Services Agreement. See appendix A for more details regarding the background and contractual basis for VOA services.

Since the domiciliary opened in 2009, VHA providers have performed all clinical services for patients while VOA staff performed non-clinical services. Beginning in December 2010, this strict division of labor was embodied in VHA policy, which limited community organizations, such as VOA, to providing non-clinical services and required that VHA staff perform all clinical services.[59] The OIG determined that the 2010 policy cast doubt on the continuing legal adequacy of the 2009 Residential Services Agreement, which failed to specify the non-clinical services VOA was authorized to perform. Exhibit D to the Residential Services Agreement purported to require VOA to perform an array of clinical services, including rehabilitative services such as psychosocial assessments, treatment planning, and therapy. The OIG found that this ambiguity of contract language persists; therefore, it would be difficult for VA to use the Residential Services Agreement to determine what services VOA is being paid for, or to enforce its contractual rights against VOA.

CGA has primary responsibility for ensuring that the non-clinical services specified in the Residential Services Agreement Exhibits D and G were provided according to VHA standards.[60] CGA representatives reported delegating these responsibilities to various companies through subcontracts approved by VA. Since CGA and its subcontractors were not authorized by VHA policy to provide clinical services, the OIG determined they had no responsibility for hiring, training, or monitoring clinical staff at the domiciliary.

The OIG found that facility leaders did not conduct annual evaluations of VOA for quality of the environment of care, contracted staff performance, and other specific elements in the contract performance indicators as required by VHA at the time of the inspection. However, as of July 15, 2019, VHA no longer required an annual evaluation for community organizations.[61]

[58] VA Handbook 7454. The local site monitor is a VA employee who does not have authority to execute amendments to the Enhanced Use Lease or exhibits but is responsible for significant business aspects of the lease including facilitating communication between VA and the lessee, overseeing operational activities, managing compliance issues, and conducting periodic inspections.

[59] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The 2019 directive does not articulate the same limitation regarding clinical services.

[60] Residential Services Agreement, Exhibit G, October 23, 2009, detailed the facility management requirements for services, utilities, and maintenance; VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019.

[61] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The 2019 VHA no longer requires an annual performance evaluation for community organizations.

Food Service

Per the Residential Services Agreement, VOA was responsible for food service at the domiciliary.[62] A May 2018 Commission on Accreditation of Rehabilitation Facilities inspection resulted in no recommendations and offered a suggestion to expand dietary offerings and address special dietary needs and options. In March 2019, The Joint Commission identified two deficiencies in the domiciliary related to improperly stored food items. Facility managers implemented a corrective action plan.

In 2019, the OIG team toured the kitchen and dining area during the breakfast service. The resident refrigerator had posted instructions on dating and labeling food. The team observed refrigerator logs with current date entries and daily checks. The dining area contained postings of a menu that included alternate diabetic, renal, or vegetarian meals as well as a reminder for patients to inform servers of special diet needs. Patients described general satisfaction with the food service.

The VOA Program Director provided the domiciliary with a kitchen manager, two full-time cooks, four assistant cooks, and a dietician. The Program Director stated VOA contracted with an outside vendor for purchased food. The kitchen manager and dietitian ensured meals met dietary standards. The dietician additionally ensured compliance with state and federal sanitation health and personal hygiene standards, and conducted monthly in-service trainings for kitchen staff.

The OIG reviewed facility managers' domiciliary rounds for a 13-month period for compliance with food management and kitchen area cleanliness. All documented food service deficiencies, such as a dirty microwave and incomplete refrigerator documentation, were corrected in an average of eight days. Consistent with the OIG's finding that VOA staff completed health and safety rounds documentation improperly, facility staff conducted an inspection on a day in 2019 and found the refrigerator temperature and dry good storage logs signed off for the following day.

Cleanliness

Mental health residential rehabilitation treatment program environments must be kept clean with routine and timely maintenance.[63] The VOA Program Director told the OIG that CGA contracted with a private company for domiciliary cleaning. During both of the OIG site visits, the domiciliary was neat and clean, and the building and furnishings appeared well maintained. The CGA property manager told the OIG that a new cleaning company was contracted in 2019 due to dissatisfaction with the prior cleaning company. Additionally, VOA employed a full-time housekeeper responsible

[62] Dining was offered Monday through Sunday at 7:00 a.m., 11:30 a.m., and 5:00 p.m.

[63] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to environmental cleanliness.

for cleaning resident rooms upon discharge, the common area, and other domiciliary areas as necessary.

Conclusion

The OIG did not substantiate that Emergency Department staff failed to properly assess the patient. The OIG determined that the triage nurse's care and disposition of the patient was appropriate and consistent with facility policy.[64] The patient declined further medical evaluation and the Emergency Department physician considered the patient to have medical decision-making capacity, so the physician discharged the patient back to the domiciliary.

The patient was taking multiple medications with combined effects of sedation as well as central nervous system and respiratory depression.[65] The OIG determined that the patient's death was unforeseeable and unpreventable and concurred with the medical examiner's opinion that the patient's death was caused by an accidental overdose from the combined impact of the patient's medications.

VHA Pharmacy Benefits Management Services recommends that a baseline electrocardiogram be obtained within three months prior to methadone treatment initiation for patients with cardiac risk factors and a baseline electrocardiogram within the prior 12 months for patients without cardiac risk factors.[66] An electrocardiogram was not completed within the designated time frame for this patient; the provider thought the test had been done. Although there was not a conclusive determination that a cardiac event contributed to the patient's death, the OIG found that no provider ordered an electrocardiogram prior to methadone initiation as would have been expected. Without a current electrocardiogram, providers may have failed to identify an existent cardiac abnormality that might have been worsened by methadone and caused cardiac arrest.

Facility managers and leaders reported the patient's death as required but did not make an institutional disclosure. Although the facility identified staff's failure to obtain an electrocardiogram, the OIG concluded that facility leaders focused on other possible causes for the patient's death and did not consider an institutional disclosure at the time. Given the failure to obtain an electrocardiogram, facility leaders should consider an institutional disclosure. Facility leaders responded appropriately to domiciliary patient and staff needs following the patient's death.

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[64] Louis Stokes Cleveland VA Medical Center Emergency Department Policy and Procedure, *ED-093 Nurse Triage*, July 24, 2018.

[65] Prescribers' Digital Reference, M*ethadone Hydrochloride - Drug Summary, 2019.* https://www.pdr.net/drug-summary/Methadone-Hydrochloride-Oral-Solution-methadone-hydrochloride-3322#13. (The website was accessed on November 22, 2019.)

[66] VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives, *Oral Methadone Dosing Recommendations for the Treatment of Chronic Pain*, July 2016.

The OIG substantiated that VOA staff improperly completed health and safety round sheets during the OIG team's unannounced site visit and therefore adequate safety and security of the domiciliary was not ensured, as required by VHA. The Assistant Nurse Manager noted that they used the "honor system" and managers looked for VOA staff's notes on the rounds sheets to suggest that they were actually inspecting the areas as scheduled. Although facility leaders reported taking immediate action, the OIG concluded that the integrity of the VOA staff documentation remained uncertain because managers only reviewed documentation to determine completion but did not monitor the accuracy of the documentation.

Bed checks, patient room and contraband inspections, and patient and visitor monitoring requirements appeared to be completed as required. However, the absence of a monitoring system to ensure that VOA staff completed the documentation properly compromised confidence in the validity of the documentation. Physical security of the domiciliary building and grounds was in compliance with VHA requirements.[67] Facility police did not have jurisdiction at the domiciliary but coordinated with local police and the Cleveland Police Department as needed for law enforcement. The VOA's domiciliary emergency plan provided emergency procedural information consistent with police jurisdiction.

The OIG substantiated that the domiciliary had a minimum of two nurses on duty and a maximum capacity of 122 patients. However, the OIG did not substantiate that domiciliary nurse staffing was unsafe because there were a minimum of two nurses on every shift along with VOA resident monitors. VOA resident monitors were scheduled to be present during all shifts to monitor safety and security for a six-month period that included several weeks before and after the death of the patient discussed in this report.

The OIG found that the non-clinical services required from VOA were not specified and as discussed in appendix A, the Residential Services Agreement did not include references to the Services Provider Contract between CGA LSVA Residential, LLC and VOA.

The OIG found that VOA substantially met the contractually identified expectations for non-clinical staffing, food service, and cleanliness in the domiciliary.

VHA policy issued in December 2010 limited community organizations (such as VOA) to providing non-clinical services and required that VHA staff perform all clinical services.[68]

Despite a recommendation by OIG in 2012 to clarify existing contracts to specify the services VOA is required to perform at the domiciliary, the OIG found that, in 2019, VA simply extended for 10 years the initial patchwork of ambiguous contracts. The OIG determined that these

[67] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to domiciliary building entrance and egress doors with a single point of keyless access, and closed circuit television video monitoring.

[68] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The 2019 directive does not articulate the same limitation regarding clinical services.

contracts grouped clinical and non-clinical domiciliary services together and did not clearly define the obligations of the contracting parties; instead, a separate informal spreadsheet was created by the site monitor well after the contracts were executed that outlined the expectations of the services to be provided by VA and VOA employees, which has no force or effect of law. The lack of clear definitions of obligations may have contributed to unilateral actions by VA or VOA without proper authorization.[69]

Recommendations 1–5

1. The VA Northeast Ohio Healthcare System Director conducts a full review of the patient's care, including electrocardiograms and methadone initiation, and considers whether an institutional disclosure is warranted.

2. The VA Northeast Ohio Healthcare System Director ensures that electrocardiograms are completed prior to and during methadone treatment in accordance with Veterans Health Administration Pharmacy Benefits Management Services recommendations.

3. The VA Northeast Ohio Healthcare System Director ensures that domiciliary leaders implement a process to monitor the integrity of Volunteers of America staff documentation including health and safety rounding sheets and additional documentation directly pertaining to patients' health, safety, and security.

4. The VA Office of Asset Enterprise Management Director ensures that the Residential Services Agreement includes references to the Services Provider Contract between CGA LSVA Residential, LLC and Volunteers of America.

5. The VA Office of Asset Enterprise Management Director, in consultation with the VA Office of General Counsel, determines if the Residential Services Agreement and the new term agreement needs to be reformed, or whether new contracts should be executed that clearly define the rights and responsibilities of all parties with respect to domiciliary services.

[69] VA Office of Inspector General, Report No. 12-00375-290; VHA Handbook 7454.

Appendix A: Residential Services Agreement and Services Provider Contract

Residential Services Agreement

In October 2009, VA executed an initial 10-year term Residential Services Agreement with Vet Dev in which Vet Dev agreed to finance, construct, own, and operate a 122-bed domiciliary building adjacent to the facility. Through this agreement, Vet Dev agreed to provide rooms and services for veterans. The Residential Services Agreement specified that Vet Dev provide domiciliary services including assessment, counseling, psychosocial rehabilitative care, nutritional services, housing, and building management duties. VA reserved the right to request Vet Dev make changes to the domiciliary services, and the Residential Services Agreement to be formally amended to reflect agreed upon changes. Vet Dev reserved the right to subcontract with other companies to perform its obligations under the Residential Services Agreement, subject to prior approval by VA.[70]

Services Provider Contract

Under the Residential Services Agreement, Vet Dev assigned its interests as Owner to an affiliated company, Veterans Development Domiciliary, LLC (Vet Dev Dom). By separate agreement, Vet Dev Dom executed a Services Provider Contract with VOA to provide the domiciliary services for the facility. As required by the Residential Services Agreement, Vet Dev Dom named VA as a third-party beneficiary in the Services Provider Contract to ensure that VA could enforce the Services Provider Contract directly with both VOA and Vet Dev Dom. Vet Dev Dom was prohibited from replacing the services provider, or changing the terms of the Services Provider Contract without VA's approval. If VOA failed to adequately perform its obligations, VA (through Vet Dev Dom) could serve a notice of dissatisfaction. If VOA received notices of dissatisfaction in two consecutive quarters or four in any three-year period, Vet Dev Dom was required to terminate the Services Provider Contract, absent written consent from VA to retain VOA as the Services Provider. If the Services Provider Contract with VOA was terminated, Vet Dev Dom was required to ensure that veterans received the domiciliary services set forth in the Services Provider Contract.

The Residential Services Agreement Exhibit D specified that VOA was "not responsible for any clinical services." The Services Provider Contract however, required VOA to provide "rehabilitative care," including "psychological, vocational, educational, or social" services to meet veterans' rehabilitative care needs. VOA was also responsible for all facets of domiciliary

[70] Wade Park Residential Services Agreement By and Between The United States Department of Veterans Affairs and Veterans Development, LLC, October 1, 2009.

services, including staffing, assessment of veterans, case management, rehabilitative services, nutrition, and quality of life, as specified in Exhibit C. Exhibit C did not specify domiciliary services, only inspection procedures for the domiciliary. No other exhibit to the Services Provider Contract specified the non-clinical services VOA was required to perform.

Supplementary Services Agreement

In January 2011, the Facility Director executed a Supplementary Services Agreement with the President/Chief Executive Officer of VOA of Greater Ohio. The Supplementary Services Agreement purported to be an amendment to the Residential Services Agreement. Under the Supplementary Services Agreement, domiciliary services were to be provided through a partnership between VOA and facility staff. The agreement required (1) facility staff to provide all clinical services, such as multidisciplinary assessments, treatment planning, case management, and discharge planning, and (2) VOA staff to perform "supportive services" including services in support of clinical care, transportation, and assistance with access to housing, employment, and benefits. VOA staff were also required to assist and supplement the 24-hour, 7-days a week milieu coverage provided by VA staff. Facility and VOA staff were required to collaboratively develop treatment and discharge plans.

Residential Services Agreement New Term Agreement

On September 20, 2017, Vet Dev Dom transferred the domiciliary building and surrounding land to three companies, as tenants in common, collectively known as CGA Residential TIC I-III. On February 14, 2018, VA consented to the assignment of all rights and responsibilities under the Residential Services Agreement by Vet Dev Dom to CGA LSVA Residential, LLC (CGA), an affiliate of CGA Residential TIC I-III. The same day, VA executed a Residential Services Agreement New Term Agreement with CGA, which substituted CGA as owner of the domiciliary building and land, and created a new 10-year agreement, beginning on May 3, 2021, for CGA to provide domiciliary services under the same terms as the original Residential Services Agreement.

Appendix B: May 2019 Nurse and Core Staffing

Table B.1. VHA Domiciliary Staffing Recommendations and Actual Facility Staffing

Nursing and Core Staffing Positions	Recommended Nursing and Required Core Staffing FTE	Actual Facility Domiciliary FTE
Registered Nurse	6.3	7
Licensed Practical Nurse	7.8	10.5
Nursing Assistant/Resident Monitor (24/7 Staff)	24.9	26
Domiciliary Chief	1.0	1.0
Assistant Chief/Clinical Manager	1.0	1.0
Medical Provider	1.6	2.6
Psychiatrist	1.3	3.3
Psychologist	2.6	5.4
Social Worker	5.0	7.0
Peer Technician	1.3	1.8
Recreation Therapist	1.0	1.5
Dietician	1.0	2.0
Pharmacist	1.0	1.0

Sources: VHA Handbook 1162.02, Domiciliary Organizational Chart, Domiciliary Nurse Staffing Methodology Presentation, and Domiciliary VOA Staff Roster[71]

[71] VHA Handbook 1162.02, December 22, 2010; VHA Directive 1162.02, July 15, 2019. The two policies contain the same or similar language related to core staffing except for an additional requirement of a 1.5 FTE admissions coordinator and 1.5 FTE recreation therapist in the 2019 directive.

Appendix C: VA Office of Asset Enterprise Management Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 30, 2020

From: Executive Director, VA Office of Asset Enterprise Management

Subj: Healthcare Inspection—Death of a Patient, Deficiencies in Domiciliary Safety and Security, and Inadequate Contractual Agreement at the VA Northeast Ohio Healthcare System in Cleveland

To: Director, Mental Health Programs
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. In response to Healthcare Inspection—Death of a Patient, Deficiencies in Domiciliary Safety and Security, and Inadequate Contractual Agreement at the VA Northeast Ohio Healthcare System in Cleveland, the Office of Asset Enterprise Management (OAEM) is providing the response and comments toward implementation of OIG's Recommendation #4 and #5.

2. If you have any questions, please call me at (202) 461-7778 or email me at Brett.Simms@va.gov.

(Original signed by:)

C. Brett Simms,
Executive Director, Office of Asset Enterprise Management

VA Office of Asset Enterprise Management Director Response

Recommendation 4

The VA Office of Asset Enterprise Management Director ensures that the Residential Services Agreement includes references to the Services Provider Contract between CGA LSVA Residential, LLC and Volunteers of America.

Concur.

Target date for completion: May 2020

Director Comments

VA Office of Asset Enterprise Management will incorporate a reference to the fact that CGA relies on a third-party services provider and has a separate contractual agreement for services. Adding anything overly specific to Volunteers of America would limit the flexibility of CGA, with whom we share a contractual obligation, to change services providers if desired in the future.

Recommendation 5

The VA Office of Asset Enterprise Management Director, in consultation with the VA Office of General Counsel, determines if the Residential Services Agreement and the new term agreement needs to be reformed, or whether new contracts should be executed that clearly define the rights and responsibilities of all parties with respect to domiciliary services.

Concur.

Target date for completion: May 2020

Director Comments

VA Office of Asset Enterprise Management has determined that an update to the Residential Services Agreement is required. In February 2018, with VA's consent, Veterans Development sold the Wade Park office, residential services, and parking facilities to CGA Capital (CGA). At the time of the sale to CGA, VA made minor updates to all three service agreements, including executing new term agreements. However, additional updates are needed to address the services component of the Residential Services Agreement. VA has completed the revised Residential Services Agreement that clearly outlines the services that are being performed by VA and CGA/services provider. It will be executed once price negotiations are completed.

Appendix D: VISN Director Memorandum

Department of Veterans Affairs Memorandum

Date: April 2, 2020

From: Director, VISN 10--VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

Subj: Healthcare Inspection—Death of a Patient, Deficiencies in Domiciliary Safety and Security, and Inadequate Contractual Agreement at the VA Northeast Ohio Healthcare System in Cleveland

To: Director, Mental Health Programs, (54MH00)
Director, GAO/OIG Accountability Liaison Office (VHA 10EG GOAL Action)

1. I have reviewed the draft report of the Healthcare Inspection – Death of a Patient, Deficiencies in Domiciliary Safety and Security, and Inadequate Contractual Agreement of the VA Northeast Ohio Healthcare System, Cleveland.
2. I concur with the responses and action plans submitted by the Cleveland VA Medical Center Director.
3. Thank you for the opportunity to respond to this report.

(Original signed by:)

RimaAnn O. Nelson
Network Director, VISN 10 (10N10)

Appendix E: Facility Director Memorandum

Department of Veterans Affairs Memorandum

Date: March 27, 2020

From: Director, VA Northeast Ohio Healthcare System (541/00)

Subj: Healthcare Inspection—Death of a Patient, Deficiencies in Domiciliary Safety and Security, and Inadequate Contractual Agreement at the VA Northeast Ohio Healthcare System in Cleveland

To: Director, VISN 10--VA Healthcare System Serving Ohio, Indiana and Michigan (10N10)

1. I have reviewed and concur with Recommendations 1-3 as outlined in the Healthcare Inspection-Death of a Patient, Deficiencies in Domiciliary Safety and Security, and Inadequate Contractual Agreement at the VA Northeast Ohio Healthcare System in Cleveland report.

2. If you have any questions or concerns, please contact Kristen Guadalupe, PhD, RN, Chief, Quality Management at (216) 791-3800.

(Original signed by:)

Jill K. Dietrich, JD, MBA, FACHE
Director/CEO

Facility Director Response

Recommendation 1

The VA Northeast Ohio Healthcare System Director conducts a full review of the patient's care, including electrocardiograms and methadone initiation, and considers whether an institutional disclosure is warranted.

Concur.

Target date for completion: May 31, 2020

Director Comments

The Chief of Staff will conduct a full review of the patient's care including electrocardiograms and methadone initiation. A decision about whether an institutional disclosure is warranted will be made by the Chief of Staff in conjunction with the Risk Manager in accordance with VHA Directive 1004.08, Disclosure of Adverse Events to Patients, October 31, 2018.

Recommendation 2

The VA Northeast Ohio Healthcare System Director ensures that electrocardiograms are completed prior to and during methadone treatment in accordance with Veterans Health Administration Pharmacy Benefits Management Services recommendations.

Concur.

Target date for completion: November 30, 2020

Director Comments

The Veterans Addiction Recovery Center (VARC) Opioid Treatment Program Electrocardiogram Protocol was reviewed by the Chief, VARC to ensure alignment with the VHA Pharmacy Benefits Management Service recommendations for electrocardiograms when prescribing methadone. An audit of compliance with electrocardiograms prior to methadone induction, annually, and as clinically indicated will be completed by Quality Management staff with the Chief, Psychiatry Service. The Chief, Quality Management will report audit results to the Executive Leadership Board until 90 percent compliance is maintained for 3 consecutive months.

Recommendation 3

The VA Northeast Ohio Healthcare System Director ensures that domiciliary leaders implement a process to monitor the integrity of Volunteers of America staff documentation

including health and safety rounding sheets and additional documentation directly pertaining to patients' health, safety, and security.

Concur.

Target date for completion: November 30, 2020

Director Comments

Executive VA leadership met with Volunteers of America (VOA) Domiciliary leadership on July 10, 2019 to discuss concerns with VOA staff documentation of health and safety rounds. The discussion resulted in retraining VOA staff to validate understanding of VHA requirements. The VA Domiciliary Nurse Manager or Assistant Nurse Manager complete a daily review of the VOA health and safety rounding sheets during morning report. The VA Domiciliary Chief and Quality Management staff conduct random, unannounced checks to monitor the integrity of VOA staff documentation pertaining to patients' health, safety, and security. The Chief, Quality Management will report audit results to the Executive Leadership Board until 90 percent compliance is maintained for 3 consecutive months.

Glossary

acute intoxication. A temporary condition following the administration of alcohol or other psychoactive substance, resulting in changes in function and responses.[72]

anxiety. Excessive fear (the emotional response to imminent threat), anxiety (the emotional response to anticipation of future threat), and behavioral avoidance responses. An anxiety disorder differs from developmentally appropriate fears and anxieties by their severity and duration beyond six months.[73]

benzodiazepines. A class of medications prescribed to treat symptoms of anxiety and sleep disorders. Patients using these medications are at risk for physiological dependence (including withdrawal symptoms) and addiction.[74]

cardiac arrhythmia. An abnormal or irregular heartbeat.[75]

cardiopulmonary resuscitation. A technique used to reestablish normal breathing after cardiac arrest.[76]

controlled substances. The Controlled Substances Act places all substances which are regulated under federal law into one of five schedules depending on the substances medical use, potential for abuse, and safety or dependence liability.[77]

electrocardiogram. A noninvasive test that detects irregularities in heart rhythm by using sensors to record the electrical activity of the heart.[78]

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[72] World Health Organization, *Acute Intoxication.* https://www.who.int/substance_abuse/terminology/acute_intox/en/. (The website was accessed on September 4, 2019.)

[73] American Psychiatric Association, Psychiatry online, Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition, *Anxiety*. https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm05, 2019. (The website was accessed on August 16, 2019.)

[74] Merck Manuals Professional edition, *Anxiolytics and Sedatives*. https://www.merckmanuals.com/professional/special-subjects/recreational-drugs-and-intoxicants/anxiolytics-and-sedatives. (The website was accessed on November 20, 2019.)

[75] Cleveland Clinic, *Arrhythmia*. https://my.clevelandclinic.org/health/diseases/16749-arrhythmia, 2019. (The website was accessed on November 25, 2019.)

[76] Merriam-Webster Dictionary, *Cardiopulmonary Resuscitation.* https://www.merriam-webster.com/dictionary/cardiopulmonary%20resuscitation. (The website was accessed on September 3, 2019.)

[77] U.S. Department of Justice. Drug Enforcement Administration, *Controlled Substance Schedules*. https://www.deadiversion.usdoj.gov/schedules/. (The website was accessed on September 30, 2019.) United States Drug Enforcement Administration, *The Controlled Substances Act,* https://www.dea.gov/controlled-substances-act. (The website was accessed on September 30, 2019.)

[78] Mayo Clinic, *Electrocardiogram (ECG or EKG).* https://www.mayoclinic.org/tests-procedures/ekg/about/pac-20384983. (The website was accessed on September 5, 2019.)

Emergency Severity Index. A triage algorithm used in emergency departments that classifies patients into five groups based on acuity and disposition resource needs.[79]

fentanyl. A synthetic opioid 50-100 times more potent than morphine that is prescribed to treat severe and post-surgical pain; and sometimes used illegally.[80]

generalized anxiety disorder. An anxiety disorder lasting longer than six months marked by excessive worry in multiple domains of an individual's life that the person finds difficult to control. The worry is accompanied by physical symptoms of anxiety including restlessness, insomnia, fatigue, and muscle tension.[81]

heroin. An illegal, highly addictive opioid that targets brain areas that respond to painful and pleasurable stimuli, that has long term negative effects on health, and may lead to death by overdose.[82]

insomnia. An atypical and extended inability to get sufficient sleep.[83]

methadone. A medication used for pain management as well as for the treatment of opioid use disorder (the use of opioids in larger amounts or longer than intended, recurrent use despite development of interpersonal, physical, or psychological problems related to the drug, needing increasing amounts of the drug to achieve similar effects, and/or withdrawal symptoms).[84]

Narcan®. A prescription medicine used to treat either an overdose or possible overdose of opioid drugs.[85]

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[79] Agency for Healthcare Research and Quality is a department of Health and Human Services, *Emergency Severity Index (ESI)*. https://www.ahrq.gov/professionals/systems/hospital/esi/index.html. (The website was accessed on September 5, 2019.)

[80] National Institute on Drug Abuse, *Brief description of fentanyl*. https://www.drugabuse.gov/drugs-abuse/fentanyl. (The website was accessed on September 13, 2019.)

[81] American Psychiatric Association, Psychiatry online, Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition, https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm05. (The website was accessed on October 21, 2019.)

[82] National Institute on Drug Abuse, *Drug Facts: What is Heroin?* https://www.drugabuse.gov/publications/drugfacts/heroin. (The website was accessed on September 13, 2019.)

[83] Merriam-Webster Dictionary, *Definition of insomnia.* https://www.merriam-webster.com/dictionary/insomnia. (The website was accessed on September 3, 2019.)

[84] Mayo Clinic, *Methadone*. https://www.mayoclinic.org/drugs-supplements/methadone-oral-route/description/drg-20075806. (The website was accessed on September 3, 2019.) American Psychiatric Association, Psychiatry online, Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition. https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm16. (The website was accessed on May 2, 2019.)

[85] Mayo Clinic, *Mayo Clinic Minute: Opioid Overdose Drug.* https://newsnetwork.mayoclinic.org/discussion/mayo-clinic-minute-opioid-overdose-drug/. (The website was accessed on September 25, 2019.)

opioid dependence. Physiological opioid dependence is defined by the development of withdrawal symptoms after the sudden cessation from excessive and prolonged use of opioid drugs, including heroin.[86]

postmortem. Happening after death.[87]

post-traumatic stress disorder. A trauma-related disorder that evolves after a person is exposed to serious injury, potential death, or sexual violence. PTSD is diagnosed after experiencing symptoms for more than one month including recurrent intrusive symptoms associated with the event, avoidance of any potential reminders of the event, negative changes in mood and thought processes, and increased reactivity.[88]

safe medication management levels—semi-independent and independent. VHA Mental Health Residential Rehabilitation Treatment Program healthcare providers assess each patient's level of independence for medication self-management as either dependent (staff administers and supervises all medications), semi-independent (veteran has partial responsibility for security, storage, and administration of medication), or independent (complete responsibility).VHA requires staff to store and administer all controlled substances, including Suboxone®.[89]

Suboxone®. A medication that is a combination of buprenorphine/naloxone used in the treatment of opioid use disorder.[90]

[86] American Psychiatric Association, Psychiatry online, Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition. https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm16. (The website was accessed on May 2, 2019.)

[87] Merriam-Webster Dictionary, *Definition of postmortem.* https://www.merriam-webster.com/dictionary/postmortem. (The website was accessed on October 27, 2019.)

[88] American Psychiatric Association, Psychiatry online, Diagnostic and Statistical Manual of Mental Disorders-Fifth Edition, *Trauma- and Stressor-Related Disorders.* https://dsm.psychiatryonline.org/doi/full/10.1176/appi.books.9780890425596.dsm07, 2019. (The website was accessed on October 21, 2019.)

[89] VHA Directive 1162.02.

[90]Prescribers' Digital Reference, *Suboxone Drug Summary.* https://www.pdr.net/drug-summary/Suboxone-buprenorphine-naloxone-1292.82072019. (The website was accessed on October 21, 2019.)

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