



DEPARTMENT OF VETERANS AFFAIRS  
**OFFICE OF INSPECTOR GENERAL**

*Office of Healthcare Inspections*

VETERANS HEALTH ADMINISTRATION

Alleged Clinical and  
Administrative Concerns  
Involving a Wound Care  
Provider in Veterans  
Integrated Service  
Network 21



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## Executive Summary

The VA Office of Inspector General (OIG) conducted a rapid response healthcare inspection to evaluate clinical and administrative concerns involving a wound care provider (provider) at a Health Care System (system) in Veterans Integrated Service Network 21.

On June 6, 2018, the OIG received numerous allegations from a confidential complainant alleging that the provider's deficient practices placed patients at risk for poor outcomes; the provider mismanaged clinic time and associated resources; and system leaders had not been fully responsive to quality of care, resource utilization, and ethical concerns as it related to the provider.

While the OIG substantiated that the provider did not order stat venous ultrasounds on three patients with suspected deep vein thrombosis (DVT—a clot or thrombus that forms in a vein), the OIG team did not find that this failure violated Veterans Health Administration (VHA) or other clinical or professional guidelines. However, the provider did not document clinical assessment of pretest probability of patient risk for DVT, as recommended by guidelines to direct additional testing and treatment. Two of the patients, who received their ultrasounds 84 and 41 days, respectively, after the initial orders, subsequently tested positive for DVT.

The OIG was unable to determine whether the provider consistently adhered to good infection control practices. The provider was counseled regarding the use of personal protective equipment (gowns and gloves) and disposal of soiled items for incidents occurring in late 2017 and early 2018; however, the OIG did not find evidence of deficient infection control practices at the time of its site visit and inspection.

The OIG was unable to determine whether the provider had used high-cost items unnecessarily in the past. The provider was counseled to use certain wound care items more efficiently; however, the OIG team could not reasonably evaluate whether the provider was using high-cost wound care items unnecessarily at the time of its site visit and inspection due to the complexity of patients' needs, treatment history, preferences, and support systems. The OIG team found that the provider documented individual care plans that reflected patients' specific needs and circumstances.

While the OIG substantiated that supplies had been removed from the system's secure storage device used for medical supplies without proper accounting of the items, the OIG could not attribute this failure to a specific user or users.

The OIG substantiated that the provider completed a patient consult via telephone rather than seeing the patient, but the team did not substantiate the implied inappropriateness of this action. The OIG determined that the telephone consult for this patient was reasonable under the circumstances. While some patients were scheduled at frequent intervals, the OIG team did not

find this scheduling practice constituted mismanagement of clinic access or that it was intended to “pad” the clinic. The provider ordered daily home health visits for some patients, but the OIG did not find that these visits were improper given the complexity of the patients’ wound care and psychosocial issues.

The OIG did not substantiate that the provider failed to follow the system’s diabetic foot ulcer algorithm, placing patients at risk for infection, sepsis, and death. While the provider occasionally responded to wound consults for inpatients, the team did not substantiate that this was an inappropriate practice that placed patients at risk. The OIG did not substantiate that the provider failed to properly evaluate a patient who experienced a cardiopulmonary arrest in the wound clinic in 2016. Further, the OIG did not substantiate that system leaders failed to hold the provider accountable for alleged quality deficits or improper actions. The OIG concluded that system leaders followed up on concerns outlined in this report.

The OIG was unable to determine whether the provider arrived late and left early nearly every day from 2011–2017. Direct observation or contemporaneous documentation by a person or persons who witnessed the alleged behavior would be the only mechanism to evaluate events that occurred in the remote past. The OIG was unable to determine that the provider improperly accepted a gift from a patient’s spouse in conflict with government ethics rules. The provider denied the allegation and reported purchasing the item in question.

The OIG did not substantiate that system leaders failed to hold the provider accountable for alleged quality deficits or improper actions. System leaders conducted reviews and took appropriate actions, as needed.

The OIG team’s review of more than 2,000 encounters revealed that the provider’s documentation of examination findings, clinical impressions, diagnostic testing, risk factors, treatment planning, and patient education met VHA requirements. However, the OIG recommended that the System Director ensure completion of evaluations of the two patients with suspected DVT discussed in this report to determine whether opportunities for more timely diagnosis of DVT existed and take appropriate action if indicated.

## Comments

The Veterans Integrated Service Network and System Directors concurred with the recommendation and provided acceptable action plans. (See Appendixes B and C, pages 17–19 for the Directors’ comments.) The OIG considers the recommendation open and will follow up on the planned action until it is completed.



JOHN D. DAIGH, JR., M.D.  
Assistant Inspector General  
for Healthcare Inspections

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## Abbreviations

DVT	deep vein thrombosis
ED	Emergency Department
EHR	electronic health record
OIG	Office of Inspector General
PAVE	Prevention of Amputation in Veterans Everywhere
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VISN	Veterans Integrated Service Network



## Introduction

### Purpose

The VA Office of Inspector General (OIG) conducted a rapid response healthcare inspection to evaluate clinical and administrative concerns involving a wound care provider (provider) at a Health Care System (system) in Veterans Integrated Service Network (VISN) 21. The purpose of the inspection was to assess the merit of the complaints and determine if system leaders responded to concerns brought to their attention.

### Background

#### Chronic Wounds and Their Care

[Chronic wounds](#) are defined as wounds that have failed to proceed through an orderly and timely reparative process over a period of three months. The most commonly encountered chronic wound is the lower extremity ulcer; this type of wound is generally [vascular or diabetic](#) in nature and accounts for up to 98 percent of all lower extremity wounds.<sup>1</sup>

Early and accurate wound diagnosis is key to determining the appropriate treatment for chronic wounds. Once the correct diagnosis is made, patient factors including nutrition, diabetes management, obesity, smoking habits, infection, and incontinence need to be addressed to ensure treatment choices are successful.<sup>2</sup> Chronic wound treatment in a clinic setting generally includes debridement of the wound and the use of special topical products and bandages (“dressings”).<sup>3</sup> Once treatment is started, regular assessment and care plan adjustment is needed to determine wound healing progress. Long-term follow-up to address the risk for recurrence of the wound is critical.<sup>4</sup>

#### Deep Vein Thrombosis of the Lower Extremity

A [deep vein thrombosis](#) (DVT) of the lower extremity occurs when a thrombus or blood clot forms in one or more deep veins of the lower extremities. A patient with a DVT may present with symptoms such as leg swelling, pain, redness, and warmth. Complications of a DVT may include chronic leg swelling, leg pain, and leg ulcers. A serious complication of a DVT is a

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<sup>1</sup> Werdin, Frank et al. *Evidenced-based Management Strategies for Treatment of Chronic Wounds*. Eplasty, June 4, 2009.

<sup>2</sup> Gupta, Subhas et. al. *Management of Chronic Wounds: Diagnosis, Preparation, Treatment and Follow-up*. Wounds, September 2017.

<sup>3</sup> Debridement is a process of removing damaged, dead, or infected tissue from a wound.

<sup>4</sup> Gupta, Subhas et. al. September 2017.

pulmonary embolism, which occurs when the thrombus from the deep leg vein is dislodged, travels to the lung, and blocks a blood vessel in the lung. This can cause shortness of breath, chest pain, and death.

By using information from the clinical history and examination, a pre-test probability assessment of lower extremity DVT guides the diagnostic work-up based on risk categories. The diagnostic studies include [ultrasound](#), blood tests ([D-dimer](#)), [venography](#), or [computed tomography \(CT\) scans](#).

## Wound Care-Related Clinics

According to the system, appropriate referrals to the wound clinic(s) at issue were for patients with chronic, non-healing wounds of greater than 30 days including pressure ulcers, and [ischemic](#), [neuropathic](#), [diabetic](#), and [venous ulcers](#).

At the time of the OIG team's onsite visit, the provider and a nurse practitioner, both of whom possessed specialized wound care certifications, ran wound care clinics with the support of a licensed practical nurse or a health technician.<sup>5</sup> Three days per week, the provider ran the Prevention of Amputation in Veterans Everywhere (PAVE) clinic, and the other two days, ran non-PAVE wound clinics.<sup>6</sup> The nurse practitioner also ran clinics five days per week for patients with wounds and/or [ostomies](#). Generally, patients were scheduled for 40-minute appointments in the wound clinics. The provider and the nurse practitioner told the OIG team they each scheduled about 10 patients per day and their patient panels were of similar size and complexity.

## Allegations

On June 6, 2018, the OIG received numerous allegations from a confidential complainant related to the provider's clinical practices, clinic and resource management, and system leaders' responsiveness to reported concerns. Specific allegations are listed below.

1. The provider placed patients at risk for poor outcomes by
  - Failing to order stat (without delay) venous ultrasounds for patients with suspected DVT<sub>s</sub>

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<sup>5</sup> A nurse practitioner is a nurse with a graduate degree in advanced practice nursing. Nurse practitioners provide a broad range of health care services and may work in clinics without physician supervision or with physicians as a joint health care team. VHA Directive 1131, *Management of Infectious Diseases and Infection Prevention and Control Programs*, November 7, 2017. The OIG noted that the provider was supervised by the Chief of Medicine and the nurse practitioner was supervised by the Chief of Surgery.

<sup>6</sup> PAVE is designed to meet the needs of patients at risk for limb amputation and prevent a second amputation of those that have already suffered an amputation. VHA Directive 1410, *Prevention of Amputation in Veterans Everywhere (PAVE) Program*, March 31, 2017.

- Not adhering to good infection control practices,
- Not following the system's algorithm designating Podiatry as the Service responsible for treating patients with diabetic foot ulcers (the particular concerns were that the provider saw hospitalized patients with diabetic foot ulcers, which was confusing [to inpatient staff] and placed patients at risk),
- Inadequately evaluating a patient who suffered a [cardiopulmonary arrest](#) in the clinic, and
- Not evaluating a patient in person but, rather, completing the consult over the phone.

Additionally, the OIG learned of 12 patients who reportedly experienced poor care or adverse outcomes as a result of the provider's actions and practices listed above. The OIG reviewed these cases (and other items) in the context of quality of care delivered.

2. The provider mismanaged clinic time and associated resources by

- Scheduling patients for frequent follow-up when their wounds no longer required such follow-up intervals,
- Removing wound care supplies from the automated supply dispensing system without documenting and accounting for those items, and using high-cost wound care products unnecessarily,
- Ordering daily home health visits when the wound did not require it, and
- Arriving 30–60 minutes late and leaving 30–60 minutes early from clinic nearly every day from 2011–2017.

3. System leaders had not been fully responsive to quality of care, resource utilization, and ethical concerns (the provider accepted a gift of a seat cushion from a patient's spouse) and had not held the provider accountable for alleged quality deficits or improper actions.

## Scope and Methodology

The OIG initiated the review in July 2018 and conducted a site visit. The review timeframe was from October 1, 2016, through July 26, 2018.

The OIG team interviewed the System Director, Chief of Staff, Chief of Surgery, Chief of Medicine, Chief of Podiatry, the provider, wound clinic nurse practitioner and staff, and other employees with knowledge of the issues. OIG staff observed the physical layout of the wound clinics.

The OIG team reviewed pertinent system policies and Veterans Health Administration (VHA) directives and handbooks. Additionally, the team reviewed system quality and internal management reports, the provider and wound clinic nurse practitioner's privileging data, clinic schedules, and efficiency and no-show data, patient advocate reports, and other documents relevant to the allegations. The OIG team also reviewed electronic health record (EHR) documentation associated with over 2,000 wound clinic encounters, applying specified documentation criteria as outlined in VHA Handbook 1907.01.<sup>7</sup> The selected encounters involved patients who were seen by the provider more than five times from October 1, 2016, through June 30, 2018, and had specified diagnoses.<sup>8</sup> Additionally, the team referred patient encounters to the OIG medical consultant that were concerning for the management of the identified wound.

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 event or action took place when there is insufficient evidence.

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.

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<sup>7</sup> VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

<sup>8</sup> The diagnoses used for the EHR reviews were arterial insufficiency, venous insufficiency, diabetic foot/leg ulcer, and pressure ulcer.

## Patient Case Summaries

### Patient A

Patient A was in his/her late 60s when seen in consultation by the provider in early 2016 for lower extremity wounds that had been present since 1996.<sup>9</sup> Patient A had diabetes, hypertension, obesity, and hyperlipidemia. The provider ordered an ultrasound to evaluate the lower extremities for a DVT.<sup>10</sup> Twelve days later, the ultrasound of the lower extremities was completed and did not show a DVT. Patient A continued to receive care with the provider with improvement in the wounds.

### Patient B

Patient B was in his/her early 70s and seen by the provider in mid-2017 for leg ulcers of six-weeks duration. The provider noted [lymphedema](#) and ordered venous and arterial ultrasounds to further evaluate Patient B. Seventy days later, Patient B reported improvement of the ulcers. The provider noted that the imaging studies had been scheduled for the next available study date, and documented that scheduling was complicated by transportation issues. Patient B had the venous ultrasound 84 days after the tests were ordered.<sup>11</sup> The ultrasound was positive for bilateral lower extremity DVTs. Patient B was subsequently sent to the Emergency Department (ED), evaluated, and started on [anticoagulant](#) (blood thinning) medications. Patient B was discharged home from the ED and followed as an outpatient in the Anticoagulant Clinic.

### Patient C

Patient C was in his/her early 70s when seen by the provider in the PAVE Clinic in spring 2018 for lymphedema and lower extremity leg ulcers. The provider documented that Patient C would need to undergo ultrasound imaging including arterial and venous studies. The provider advised a six-week follow-up and noted that Patient C could be seen sooner if the imaging studies were done sooner. Forty-one days after the studies were ordered, Patient C had a venous ultrasound that was positive for acute DVT. Patient C was seen in the ED, admitted for anticoagulation therapy, and discharged the following day without complications.

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<sup>9</sup> The OIG uses gender neutral language to protect patients' privacy.

<sup>10</sup> The ultrasound was not ordered with a stat urgency.

<sup>11</sup> The provider told Patient B on three occasions over approximately an eight-week period that the imaging study should be scheduled.

## Inspection Results

### Issue 1: Provider's Clinical Practices

#### Stat Venous Ultrasounds

While the OIG substantiated that the provider did not order stat venous ultrasounds on three patients with suspected DVT, the team did not find that this failure violated VHA or other clinical or professional guidelines.<sup>12</sup> However, the provider did not document clinical assessment of pretest probability of patient risk for DVT, which is suggested in guidelines.<sup>13</sup> This clinical assessment would have guided additional testing such as D-dimer<sup>14</sup> or ultrasound of the proximal veins, which could impact the decision about the need for more sensitive imaging studies or additional consultation.

A DVT occurs when a clot or thrombus forms in a vein. Patients A, B, and C were being assessed for DVT because of lower extremity swelling. The ultrasounds were not ordered with a stat urgency and not completed for 12 to 84 days. While both Patients B and C were diagnosed with DVTs, the OIG team could not state when the DVTs occurred, whether earlier studies would have afforded earlier treatment, or whether the delays in diagnosing and treating the DVTs had long-term complications. If, however, Patients B and C had DVTs at the time the provider saw them, and the provider failed to adequately assess the condition and refer for treatment, the patients were placed at risk for possible complications, including pulmonary embolism and death.

The Chief of Medicine, who was a critical care physician, confirmed that if there is a clinical suspicion for a DVT, a stat ultrasound would be an appropriate diagnostic test.

During the EHR review, the OIG found an additional three patients for whom the provider ordered ultrasound imaging to evaluate for DVT. One ultrasound was ordered stat and was completed immediately; the other two were ordered ASAP (as soon as possible) and completed in 7 and 14 days, respectively. None of these patients were diagnosed with a DVT.

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<sup>12</sup> The medical abbreviation “stat” means immediately. [Merriam-Webster dictionary website](https://www.merriam-webster.com/dictionary/stat) (<https://www.merriam-webster.com/dictionary/stat>).

<sup>13</sup> Shannon Bates et al. *Diagnosis of DVT*. Chest, 141, Issue 2 (February 2012): 351-418.

<sup>14</sup> D-dimer is a naturally-occurring, clot-dissolving substance. Most patients with a blood clot will have an elevated D-dimer level; while an elevated D-dimer is not conclusive of a DVT, it can be used as an indicator of the need for further testing. <https://www.mayoclinic.org/diseases-conditions/thrombophlebitis/diagnosis-treatment/drc-20354613>. (The website was accessed August 22, 2018.)

## Infection Control

The OIG was unable to determine whether the provider consistently adhered to good infection control practices. The team determined that the provider was counseled regarding the use of personal protective equipment (gowns and gloves) and disposal of soiled items for incidents occurring in late 2017 and early 2018; however, the OIG did not find evidence of deficient infection control practices when conducting the site visit/inspection.<sup>15</sup>

The system's Infection Control Manager told the OIG team that Infection Control Program staff did not monitor chronic wound infections; therefore, there was no reasonable way for the OIG team to evaluate whether the provider's infection control practices resulted in increased and unexpected infections that could not be explained by bacterial colonization in the patients' existing wounds.<sup>16</sup> The Chiefs of Surgery and Medicine reported they had no knowledge of problems with new infections in the provider's clinics.

The OIG team confirmed that the provider completed infection prevention control training annually as required for the past three years.

## Diabetic Foot Ulcer Algorithm and Inpatient Consults

The OIG did not substantiate that the provider failed to follow an "algorithm" designating Podiatry as the Service responsible for treating patients with diabetic foot ulcers. Specifically, the algorithm provided to OIG inspectors was an unsigned, undated document that had not been approved through a formal committee process. Therefore, the OIG team concluded that the document was intended to provide guidance rather than represent a firm requirement.

The complaint alleged that, contrary to the algorithm, the provider saw inpatients with diabetic foot ulcers, and that this practice confused inpatient staff and placed patients at risk as hospitalized patients should have been seen by on-call Podiatry staff. The OIG team reviewed the 26 inpatient wound consults entered from January 1 through June 30, 2018.<sup>17</sup> Most of the inpatient consults that the provider completed were for wounds other than diabetic foot ulcers. The few inpatients who did have diabetic foot ulcers were followed in one of the provider's wound clinics. The OIG team did not identify quality or timeliness concerns, nor did the team find documented evidence of confusion as to the appropriate wound consultant.

Regarding outpatients, the system's formal protocol stated that appropriate referrals to the wound clinic are for patients with chronic, non-healing wounds of greater than 30 days including

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<sup>15</sup> Standard infection control practices include hand washing, use of personal protective equipment, for example, gloves, gowns, and proper disposal of waste. The OIG team did not independently verify these events as they took place in the past.

<sup>16</sup> Colonization is defined as the presence of proliferating bacteria without a host response (observable symptoms or immune reaction).

<sup>17</sup> One of the consults, which was for foot and ankle evaluation, was discontinued and referred to Podiatry Service.

diabetic ulcers. Further, the Chief of Podiatry Service told the OIG team that Podiatry Service staff refer patients with diabetic foot ulcers to the wound clinic when patients were stable and in need of chronic wound care.

The provider told OIG team members of following diabetic foot ulcer guidelines. The OIG team found that the provider's documentation of wound assessment and treatment was thorough, and consistent with VHA documentation guidelines.

## **Cardiopulmonary Arrest**

The OIG did not substantiate that the provider failed to properly evaluate a patient who experienced a cardiopulmonary arrest in the wound clinic in 2016.

The OIG team's review of the patient's EHR determined that in mid-2016, a patient in his/her early 70s with a chronic neurological disorder was sent from a community nursing home to the wound clinic for evaluation of a sacral ulcer. The provider documented that the patient was unable to provide a history. The provider requested an ED evaluation and treatment of the necrotic sacral wound and recommended surgical debridement. While the provider was out of the room contacting the ED, the patient developed difficulty breathing and a [Code Blue](#) was called. Cardiopulmonary resuscitation was initiated; however, the patient expired.

The OIG team found that the care the provider rendered to the patient was limited to wound assessment and dressing placement. The provider appropriately attempted to refer the patient to the ED for further care. As the patient medically deteriorated after the provider left the room, the OIG did not find deficiencies in the provider's care or decision-making in this instance. The OIG team noted, however, that the vital signs listed for the encounter at issue were from a previous visit.<sup>18</sup> The Chief of Medicine told the OIG team that a review of the event, which referenced the lack of "current vital signs," did not identify discrepancies or deviation from protocol.

## **Telephone Consult**

The OIG substantiated that the provider completed a consult on a patient via telephone rather than seeing the patient in person. However, the team did not find that to be an inappropriate action.

The patient, who had a previous left above-the-knee amputation, was referred to the wound clinic and PAVE clinic in early 2018. Thirteen days later, the provider contacted the patient who agreed to an appointment in the PAVE clinic at the end of the month. This patient, who was at risk for poor wound healing, was seen in the ED at the end of the month after injuring a toe, and

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<sup>18</sup> The licensed practical nurse (LPN) responsible for taking vital signs reported difficulty in securing accurate readings and documented "[u]nable to obtain vital signs." There was no documented evidence that the LPN communicated this information to the provider.

did not come and did not cancel (no-showed) a PAVE Clinic appointment on the same day. Although the patient also no-showed for a scheduled appointment to the PAVE Clinic the next month, the provider reviewed the EHR and called the patient on the phone. The provider provided wound care education and told the patient to reschedule an appointment with the clinic. While the provider did not mention the patient's ED visit in the consult note, the OIG team did not find this to be concerning. The team concluded that the provider made appropriate contact with the patient, discussed ongoing care, and made an effort to get an appointment scheduled for follow-up. The patient was subsequently seen by the Vascular Surgery team four months later and no surgical therapy was recommended.

## **Overall Quality and Comprehensiveness**

The OIG reviewed the care delivered to the 12 patients specifically mentioned in the allegations or during the inspection. Five of the cases are discussed in the Patient Case Summaries, Cardiopulmonary Arrest, and Telephone Consult sections of this report. The OIG team's review of the remaining seven cases did not identify quality of care or patient safety concerns.

The team also evaluated overall quality of care and comprehensiveness by reviewing over 2,000 encounters involving patients who received chronic wound care services by the provider during the period October 1, 2016, through June 30, 2018, (study period). The OIG team focused on patients with conditions involving diabetic foot and leg ulcers, and pressure, arterial, and venous ulcers, as these conditions are often difficult to treat. Because the progression of wound healing in patients with chronic wounds is unpredictable, and requires frequent reassessments and periodic changes to the choice of wound healing products and protocols, the OIG team focused its review on patients with five or more clinic encounters during the study period. The OIG team's review found that the provider's documentation of examination findings, clinical impressions, diagnostic testing, risk factors, treatment planning, and patient education met VHA requirements.

## **Issue 2: Clinic and Resource Management**

### **Clinic Utilization**

The OIG did not substantiate that the provider scheduled patients for too-frequent follow-up, irrespective of the conditions of their wounds. There is no specific follow-up schedule that can be applied because multiple factors must be considered when determining a follow-up plan, including the patient's healing history, treatment compliance, and in-home support.

While the OIG team substantiated that the provider scheduled some patients at frequent intervals, the team did not find that this scheduling practice constituted mismanagement of clinic access or that it was intended to "pad" the clinic. In this context, "padding" refers to scheduling patients who do not require significant clinical attention or resources or scheduling patients where it is known they will "no-show," thus reducing the provider's workload. Based on EHR reviews, the

OIG team concluded that the provider's actions reflected an individualized approach to each patient's care. For example, if a patient only had transportation on a Tuesday, then the provider would overbook the patient for an appointment on Tuesday.

The provider's clinic efficiency data for a month in 2018 reflected that clinics were frequently scheduled at or near capacity (about 10 appointments) with occasional overbooked appointments and 22 "no-shows." Nine patients were scheduled more than twice during the month, which could represent the subset of patients who were well-known to the provider and could appear to be scheduled more often than necessary to pad the clinic. In reviewing the multiple appointment and no-show encounter data, the OIG team did not identify patterns that would suggest the provider was scheduling these patients with pre-knowledge that they would either require minimal clinical attention or would no-show and were intentionally being scheduled to pad the clinic.

The OIG team learned that the provider had a reputation for seeing patients in follow-up more frequently than would be expected "for a particular disease process." The Chief of Surgery told the OIG team that "[s]eeing patients more frequently is better than seeing patients more rarely." The Chief of Medicine described the provider's practice as "high touch" but said that "over-attention" was not a problem if productivity and efficiency were in order. The OIG team generally agreed with this reasoning and found that consults to the wound and PAVE Clinics were acted upon timely. As of fall 2018, the provider scheduled patients within five to six days of the preferred appointment date.

## **Wound Care Supplies and High-Cost Items**

### *Wound Care Supplies*

The OIG substantiated that supplies had not been properly logged when removed from the Pyxis Supply Station™<sup>19</sup> system (Pyxis). However, while Pyxis logs the identity of the user, it relies on the user to accurately document which supplies, and how many items, were removed. Therefore, it would be difficult to determine who removed supplies if that person did not document that they had removed supplies.

Pyxis is used at the system as a secure storage device for medical supplies, including wound care supplies in the PAVE and wound care clinics. The Pyxis requires users to electronically document when supplies are removed; supplies are then replenished based on a periodic automatic replacement (par) level designation. Logistics is responsible for tracking par levels of expendable supplies, such as bandages, and restocking those items as needed.

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<sup>19</sup> The Pyxis Supply Station™ system is a secure storage device that documents supply usage in real time. <http://www.bd.com/en-us/offerings/capabilities/medication-and-supply-management/medication-and-supply-management-technologies/pyxis-supply-technologies/pyxis-supplystation-system>. (This website was accessed on August 30, 2018.)

Previously, providers were permitted to issue 7–10 days of supplies from the Pyxis to patients. This was used as an interim measure while Pharmacy Service processed and mailed prescribed items. Providers should have documented the amount removed to assure accurate tracking.

The OIG team was told about a patient who reportedly received supplies that exceeded a reasonable amount, but the team found the decision to provide additional supplies was reasonable under the circumstances. The OIG team confirmed the patient’s previous homelessness, tenuous housing and support situation, and history of marginal compliance in managing wound care needs was well-documented in the provider’s notes. The provider confirmed giving the patient additional supplies, and the OIG team determined that the provider’s decision to do so was reasonable. However, the provider should have recorded the supplies appropriately in Pyxis.

The Chief of Medicine told the OIG team that a fact-finding review was conducted related to supplies but did not identify significant concerns. Nevertheless, the Chief of Medicine and the provider both confirmed that the provider was counseled about the use of, and accounting for, wound supplies. At the time of OIG team’s site visit, the timeliness of Pharmacy processing and shipping had apparently improved, and procedures were in place to direct patients to the Pharmacy for their supplies.

### *High-Cost Items*

The OIG team was unable to determine whether the provider had used high-cost items unnecessarily in the past. Although the OIG team determined that the Chief of Medicine had counseled the provider about the need to use certain wound care items more efficiently, the OIG team could not reasonably evaluate whether the provider was using high-cost wound care items unnecessarily at the time of the site visit, due to the complexity of patients’ needs, treatment history, preferences, and support systems.<sup>20</sup> The OIG team found that the provider documented individual care plans that reflected patients’ specific needs and circumstances.

The provider reported not using bioengineered tissue wound dressings, a highly specialized and expensive type of wound dressing.

### **Home Health Visits**

The OIG substantiated that the provider ordered daily home health visits for some patients but did not substantiate that these visits were improper given the complexity of the patients’ wound care and psychosocial issues.

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<sup>20</sup> The Chief of Medicine’s testimony did not specify when the provider was found to use high-cost products and the subsequent date of the counseling.

Skilled home care staff provide services to homebound patients with the intent of improving or maintaining patients' health and quality of life in their own community.<sup>21</sup> For long-term care patients (for example, those with chronic problems, including chronic and palliative wounds), the purpose of skilled home care is to

- Offer families an alternative to nursing home placement,
- Minimize the amount of follow-up by Ambulatory Care Clinics,
- Prevent premature admissions to long-term care institutions, and
- Maintain optimal physical, cognitive, and psychosocial functioning.

The system's Medical Center Memorandum that addresses skilled home care did not specify a minimum or maximum frequency of visits.

The provider ordered home health visits for 75 patients, with a total of 91 consults, during a nine-month period in 2017–2018:

- 19 consults were for daily visits
- 27 consults were for three times per week visits
- 11 consults were for twice weekly visits

The remaining 34 consults had varying frequencies due to the condition of the patient's wound, or had been cancelled or the service declined by the patient.

The OIG team reviewed the EHRs of the 19 patients with daily skilled home health orders. The team found that patients met eligibility criteria for home care. Many of the provider's patients were homebound and unable to provide their own wound care. Further, for patients with chronic wounds that may or may not heal, medical treatment can last for months or years. The provider documented individual care plans that reflected patients' specific needs and circumstances.

## **Time and Attendance Practices**

The OIG was unable to determine whether the provider arrived 30–60 minutes late and left 30-60 minutes early nearly every day from 2011–2017.<sup>22</sup> The wound and PAVE clinic medical support assistants who scheduled patients told the OIG team that the provider did not come in late or cancel patients [because of tardiness]. Further, patient advocate data for the period June 1, 2017, through March 31, 2018, did not reflect complaints related to the provider's care or availability.

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<sup>21</sup> A patient is homebound if leaving the home is not recommended because of the patient's condition; leaving home takes a considerable and taxing effort; or the patient's condition keeps him/her from leaving home without help such as the use of a wheelchair, a walker, special transportation; or needing help from another person.

<sup>22</sup> Direct observation or contemporaneous documentation by a person or persons who witnessed the alleged behavior would be the only mechanism to evaluate events that occurred in the remote past.

In response to a concern about the provider's attendance, the Chief of Medicine told the OIG team that time and attendance issues were discussed with the provider. The Chief of Medicine also reported conducting a two-week audit of the provider's attendance and tour in 2018. The Chief of Medicine found no discrepancies during the audit but acknowledged the potential "observer effect" on the findings.<sup>23</sup> The Chief of Medicine told the OIG team that the provider is expected to request leave through the Medical Service, but a verification process was not in place as to when providers log on and log off.

### **Issue 3: Leaders' Responsiveness to Concerns**

The OIG did not substantiate that system leaders failed to hold the provider accountable for alleged quality deficits or improper actions. The Chief of Medicine is the provider's direct supervisor and is generally responsible for follow-up related to deficient conditions and performance issues. The Chief of Medicine initiated internal and external reviews to evaluate quality of care concerns and the Code Blue event, completed time and attendance studies, and evaluated the provider's clinic efficiency. Further, the provider was verbally counseled about infection control practices in late 2017 and early 2018.

The OIG was unable to determine that the provider improperly accepted a chair cushion valued at approximately \$80 from a patient's spouse in conflict with government ethics rules.<sup>24</sup> The provider reported purchasing the cushion. In addition, the provider verbalized, unprompted, the correct way to manage gifts from patients and families.

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<sup>23</sup> Observer effect, also known as the Hawthorne effect, is a change in an individual's behavior in response to their awareness of being observed.

<sup>24</sup> Government ethics rules generally prohibit gifts from prohibited sources or those given due to an employee's official position valued at \$20 or more per occasion and a total of \$50 from one source annually. Title 5 Code of Federal Regulations (CFR) Part 2635.

## Conclusion

The OIG substantiated that the provider did not order stat venous ultrasounds on three patients with suspected DVT. While this failure did not appear to violate VHA or other clinical or professional guidelines, the provider did not document clinical assessment of pretest probability of patient risk for DVT, which would have guided additional testing and treatment. Two of the patients (Patients B and C) subsequently tested positive for DVT. In general, though, the OIG team found that the provider's documentation of examination findings, clinical impressions, diagnostic testing, risk factors, individualized treatment planning, and patient education met VHA requirements.

The OIG was unable to determine whether the provider consistently adhered to good infection control practices or had used high-cost products unnecessarily. The provider had been counseled about personal protective equipment, and proper disposal of waste in late 2017 and early 2018, and about the more efficient use of certain wound care items; however, the OIG did not find evidence of deficient infection control practices or improper use of wound care items at the time of its inspection.

While the OIG substantiated that supplies had been removed from the Pyxis without proper accounting of the items, the OIG could not attribute this failure to a specific user or users.

The OIG did not substantiate or was unable to make a determination about the remaining allegations related to the provider's clinical or administrative practices. The OIG team determined that system leaders followed up on concerns outlined in this report.

## Recommendation

The System Director ensures completion of evaluations of Patients B and C to determine whether opportunities for more timely diagnosis of deep vein thrombosis existed, and takes action if indicated.

## Appendix A: Glossary

**Anticoagulants** are medications that decrease the blood's ability to clot. Decreased clotting keeps fewer harmful blood clots from forming and blocking blood vessels.

<https://www.texasheart.org/heart-health/heart-information-center/topics/anticoagulants/>

**Arterial Insufficiency Ulcer** refers to poor blood circulation to the lower leg and foot. The arteries fail to deliver oxygen and nutrients to the leg and foot resulting in tissue breakdown.

<http://vascularcenterwf.com/conditions/venous-leg-ulcer/>

**Cardiopulmonary Arrest** is the abrupt loss of heart function in a person who may or may not have been diagnosed with heart disease.

<https://www.heart.org/en/health-topics/cardiac-arrest>

**Chronic Wounds** develop when any acute wounds fail to heal in the expected time frame for that type of wound. This might be a couple of weeks or up to six weeks.

<https://www.woundcarecenters.org/article/wound-types/chronic-wounds>

**Code Blue** is a term used to announce an emergency situation in a hospital or institution when a patient is in cardiopulmonary arrest.

<https://www.medicinenet.com/script/main/art.asp?articlekey=59953>

**Computerized Tomography (CT) Scan** combines a series of x-ray images taken from different angles around the body and uses computer processing to create cross-sectional images (slices) of the bones, blood vessels, and soft tissues inside the body. CT scan images provide more-detailed information than plain x-rays.

<https://www.mayoclinic.org/tests-procedures/ct-scan/about/pac-20393675>

**Debridement** is the removal of lacerated, devitalized, or contaminated tissue.

<https://www.merriam-webster.com/dictionary/debridement>

**Deep Vein Thrombosis (DVT)** occurs when a blood clot (thrombus) forms in one or more of the deep veins in the body, usually in the legs. Deep vein thrombosis can cause leg pain or swelling, but also can occur with no symptoms.

<https://www.mayoclinic.org/diseases-conditions/deep-vein-thrombosis/symptoms-causes/syc-20352557>

**Diabetic Foot/Leg Ulcer** is a breakdown in the skin that may extend to involve the subcutaneous tissues or to the level of muscle or bone.

<http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/endocrinology/prevention-on-treatment-diabetic-leg-and-foot-ulcers/>

**Hyperlipidemia** is a term that refers to any of several acquired or genetic disorders that result in high level of lipids circulating in the blood.

<https://vascular.org/patient-resources/vascular-conditions/hyperlipidemia>

**Ischemic Ulcer (wound)** can occur when there is poor blood flow in the legs or feet. These types of wounds can be slow to heal.

<https://medlineplus.gov/ency/patientinstructions/000742.htm>

**Lymphedema** refers to swelling due to blockage or damage of the lymphatic system and generally occurs in the arms or legs.

<https://www.mayoclinic.org/diseases-conditions/lymphedema/symptoms-causes/syc-20374682>

**Ostomy**, or stoma, is a surgically created opening between the intestines. The most common type of ostomy connects the small intestines or the large intestine.

<https://www.fascers.org/patients/disease-condition/ostomy-0>

**Pressure Ulcers** are injuries to skin and underlying tissue resulting from prolonged pressure on the skin.

<https://www.mayoclinic.org/diseases-conditions/bed-sores/symptoms-causes/syc-20355893>

**Ultrasound** is a type of imaging that uses high-frequency sound waves to look at organs and structures inside the body. Health care professionals use it to view the heart, blood vessels, kidneys, liver, and other organs.

<https://medlineplus.gov/ultrasound.html>

**Vascular Ulcers** are open wounds occurring around the ankle or lower leg that may not heal for weeks or months.

<http://www.upmc.com/services/heart-vascular/conditions-treatments/venous-ulcers>

**Venography** is a procedure where a dye is injected into a large vein in the foot or ankle. An X-ray creates an image of the veins in the legs to look for clots.

<https://medlineplus.gov/ency/article/003773.htm>

**Venous Insufficiency Ulcers** are open wounds that may occur with long-term, untreated venous insufficiency. Ulcerations develop in areas where blood collects and pools, as swelling there interferes with the movement of oxygen and nutrients through tissues.

<https://www.bcm.edu/healthcare/care-centers/vascular-surgery/conditions/venous-insufficiency-venous-ulcers>

## Appendix B: VISN 21 Director Comments

### Department of Veterans Affairs Memorandum

Date: December 19, 2018

From: Director, Sierra Pacific Network (10N21)

Subj: Healthcare Inspection—Alleged Clinical and Administrative Concerns Involving a Wound Care Provider in Veterans Integrated Service Network 21

To: Director, Rapid Response Team (54RR)  
Director, Management Review Service (VHA 10E1D MRS Action)

1. I have reviewed the draft report and concur with the findings and recommendation. The System has provided their response and I concur with the action being taken to review the two cases to determine opportunities for improvement.
2. Should you have any questions please contact my office.

*(Original signed by:)*

John A. Brandecker, MBA, MPH

## Appendix C: System Director Comments

### Department of Veterans Affairs Memorandum

Date: December 20, 2018

From: Director, Health Care System

Subj: Healthcare Inspection—Alleged Clinical and Administrative Concerns Involving a Wound Care Provider in Veterans Integrated Service Network 21

To: Director, Sierra Pacific Network (10N21)

1. We appreciate the opportunity to review the draft report and recommendation for the Rapid Response Healthcare inspection.
2. Please find the attached response for the recommendation included in the report. We have completed, or in the process of completing, actions to resolve these issues.

*(Original signed by:)*

System Director

## **Comments to OIG's Report**

### **Recommendation 1**

The System Director ensures completion of evaluations of Patients B and C to determine whether opportunities for more timely diagnosis of deep vein thrombosis existed, and takes action if indicated.

Concur.

Target date for completion: February 1, 2019

### **Director Comments**

On 12/13/18, the two referenced cases were referred for an evaluation of the care provided to the Veterans to identify any opportunities for improvement in diagnosing deep vein thrombosis more timely. Appropriate actions will be taken based upon the outcome of the review.

## OIG Contact and Staff Acknowledgments

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**Contact** For more information about this report, please contact the Office of Inspector General at (202) 461-4720.

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**Inspection Team** Eileen Keenan, MSN, RN, Team Leader  
Gail Bozzelli, RN  
Virginia Booth, MSN  
Victoria Coates, LICSW, MBA  
Donna Giroux, RN, CPHQ  
Patrice Marcarelli, MD  
Larry Selzler, MSPT  
Monika Spinks, BSN, RN

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**Other Contributors** Katharine Brown, JD  
Shirley Carlile, BA  
Sheyla Desir, MSN, RN  
Nicholas DiTondo, BA  
Kathy Gudgell, JD, RN  
Jason Reyes, BA  
Natalie Sadow, MBA

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