

DEPARTMENT OF VETERANS AFFAIRS

OFFICE OF INSPECTOR GENERAL

Office of Healthcare Inspections

VETERANS HEALTH ADMINISTRATION

Falsification of Blood Pressure Readings at the Danville Community Based Outpatient Clinic

Salem, Virginia



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Executive Summary

The VA Office of Inspector General (OIG) identified that a primary care provider (provider) appeared to have falsely documented patients' blood pressure readings at the Danville Community Based Outpatient Clinic (CBOC) of the Salem VA Medical Center (facility), Virginia. The Danville CBOC is a contracted clinic that is staffed and operated by Valor Healthcare, Inc. (Valor Healthcare). Specifically, the OIG found the provider documented blood pressure rechecks of 139/89 more than 150 times across more than 150 patients from January 1, 2018, through June 26, 2018. On June 28, the OIG notified the facility's Chief of Staff (COS) of the repetitive blood pressure readings documented by the provider and recommended that a comprehensive data pull and analysis be done to evaluate the extent of the 139/89 entries. A rapid response inspection was initiated in early July 2018 to assess the scope and impact of what appeared to be false blood pressure readings, facility leaders' responsiveness to the concerns, and factors contributing to the deficient conditions.

More than 500 patient encounters were reviewed for the period October 1, 2016, through June 30, 2018. Over 300 encounters involved patients with a diagnosis of either hypertension, diabetes, or atherosclerotic cardiovascular disease, making them at higher risk for poor outcomes, including heart attack or stroke. The provider documented a repeat blood pressure of 139/89 more than 30 percent of the time. As these patients had different disease burdens, health statuses, and treatment plans, blood pressure readings of 139/89 occurring at the frequency noted was highly unlikely.¹

The OIG determined that the provider had not only falsified repeat blood pressure readings, but also failed to provide hypertension management to at least 53 patients with initially elevated blood pressure readings. An OIG physician found limited evidence of interventions, treatment plan adjustments, medication changes, or close follow-up.

The OIG found the provider's explanation for the falsification of blood pressure readings, which was largely because of a lapse in remembering ("forgot") the actual readings, to be implausible. The provider reportedly spoke with other CBOC employees about being "lazy" and that the 139/89 reading improved the hypertension metrics scores.

The OIG further found the COS's initial response to the issue of the provider's falsified documentation to be inadequate and troubling. Despite being told of the concerns on June 28 by the OIG, it was not until the OIG contacted the COS a second time on August 16 that the facility began an in-depth review of the provider's documentation practices and management of patients with hypertension. The COS and Chief of Primary Care claimed that they did not do so for several reasons, including the OIG did not provide the supporting data and the facility did not

¹ A blood pressure reading of 140/90 or higher would require additional documentation or intervention.

know how to obtain the data. However, during the approximately seven weeks between the OIG's initial notification and the follow-up contact, neither the COS nor the Chief of Primary Care contacted the OIG for clarification or assistance with the data methodology, nor did they ask administrative staff, the Quality Manager, or the Veterans Integrated Service Network (VISN) for data assistance. Further, the facility did not notify the VISN of the issue, complete an Issue Brief, or notify leaders of the company providing contract healthcare services at the Danville CBOC.

Multiple factors allowed the provider's falsification of blood pressure readings to continue unabated. The OIG learned that at least one former member of Valor Healthcare, in a leadership position within the Danville CBOC, was allegedly told as early as 2016 of the provider's tendency to falsify repeat blood pressure readings. Although the OIG was unable to locate and interview this individual, several current Valor Healthcare employees acknowledged having been told about the falsified blood pressure documentation as early as 2017. However, none of these employees shared their concerns with staff in a position to take corrective action at either the facility or Valor Healthcare.

The facility did not have processes in place to validate performance measure data. Per Veterans Health Administration (VHA) guidance, Primary Care Management Module (PCMM) coordinators are supposed to validate the accuracy of the data impacting VHA Support Service Center performance monitor reports. However, the facility PCMM coordinator did not routinely take steps to validate the underlying data, which could have uncovered the provider's falsified blood pressure documentation practices.²

Neither the facility nor Valor Healthcare were meeting select aspects of the contract. The contract stated that "the [facility] COR [Contracting Officer's Representative] shall be the VA official responsible for verifying contract compliance." However, the COR had not received, nor asked for, quality-related performance reports from Valor Healthcare since starting the position in approximately June 2017. Further, Valor Healthcare did not submit to the facility COR the results of quality improvement activities involving VA patients as required.

In August 2018, the OIG learned that the provider's employment with Valor Healthcare was terminated.

The OIG made five recommendations to the Facility Director related to patient care follow-up, data integrity, policy and procedure development, leadership responsiveness, and COR training.

² It was not facility practice to routinely check this type of information and facility leaders did not request that the PCMM do so.

Comments

The Veterans Integrated Service Network and System Directors concurred with the recommendations and provided acceptable action plans. (See Appendixes B and C, pages 19–23 for the Directors' comments.) The OIG considers the recommendations open and will follow up on the planned action until it is completed.

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Abbreviations

ASCVD atherosclerotic cardiovascular disease

BP blood pressure

CBOC community based outpatient clinic
COR Contracting Officer's Representative

COS chief of staff

DBP diastolic blood pressure EHR electronic health record

FPPE focused professional practice evaluation

FY fiscal year

LPN licensed practical nurse mm Hg millimeters of mercury

OIG Office of Inspector General PACT patient aligned care team

PCMM primary care management module

QM quality management

RN registered nurse

SBP systolic blood pressure

VHA Veterans Health Administration

VISN Veterans Integrated Service Network

VSSC VHA Support Service Center



Introduction

Purpose

The VA Office of Inspector General (OIG) identified that a primary care provider (provider) appeared to have falsely documented patients' blood pressure (BP) readings at the Danville, Community Based Outpatient Clinic (CBOC) of the Salem VA Medical Center (facility), Virginia. The purpose of the rapid response inspection was to assess the scope and impact of what appeared to be false blood pressure readings, facility leaders' responsiveness to the concerns, and factors contributing to the deficient conditions.

Background

The facility is a general medicine and surgery facility located in Salem, Virginia, that includes CBOCs located in Danville, Tazewell, Lynchburg, Staunton, and Wytheville, Virginia. The facility is part of Veterans Integrated Service Network (VISN) 6, and in fiscal year (FY) 2018, operated 242 beds and served 37,252 patients.

Community Based Outpatient Clinics

All CBOCs "operate under the supervision and guidance of a single VA hospital or medical center." The parent VA facility "maintains administrative responsibility for its CBOC(s), specifically with respect to maintaining quality of care." CBOCs are operated by VA and/or contracted staff and fall into three major categories:

- VA-owned—staffed by VA personnel and the facility space is owned by VA
- Leased—the facility space is leased but staffed by VA personnel
- Contracted—the facility space is not owned or leased by VA and staff are not VA personnel

The Danville CBOC is a contracted clinic that is staffed and operated by Valor Healthcare, Inc. (Valor Healthcare).⁴ At the time of the OIG's review, there were four patient aligned care teams

³ Congressional Research Service, Veterans Health Administration: Community-Based Outpatient Clinics, February 22, 2010.

⁴ "Valor Healthcare operates more than 30 VA Community Based Outpatient Clinics (CBOCs) in the United States as a contractor for the U.S. Department of Veterans Affairs." https://www.valorhealthcare.com/. (The website was accessed on October 16, 2018.)

(PACTs).⁵ One PACT consisted of the provider with a <u>registered nurse (RN)</u> and <u>licensed practical nurse (LPN)</u>. Another PACT was led by a physician and supported by an RN and an LPN. The remaining 2 PACTs were led by nurse practitioners, each supported by an RN and LPN. Valor Healthcare contract staff also provided mental health services for veterans at the Danville CBOC. In FY 2018, the Danville CBOC completed 24,868 outpatient encounters for approximately 5,440 veterans.

Primary Care

"Primary care is the provision of integrated, accessible health care services" and includes "diagnosis and management of acute and chronic biopsychosocial conditions, health promotion, disease prevention, [and] overall care management," among other services. Patients depend on their primary care providers to provide timely health care and to minimize future health issues through medical advice and intervention. Integral to the formulation of the patient's plan of care is the provider's clinical decision-making and assessment of the patient's risks for certain conditions. For example, a strong family history of heart disease may affect the patient's care plan for cardiovascular screenings. Important goals in patient care are to prevent disease, manage conditions, and provide the highest level of care in the safest way possible. To that end, the primary care provider must understand future conditions that can develop if inadequate disease management occurs.

All providers must maintain accurate, timely, relevant, and complete electronic health records (EHRs), which contain sufficient recorded information to serve as a basis to plan patient care, support diagnoses and treatment, and measure outcomes.⁷

High Blood Pressure Management

High <u>blood pressure</u>, also known as hypertension, is a condition that occurs when the force of blood pushing against the walls of the blood vessels is consistently too high. Systolic blood pressure (SBP) indicates how much pressure the blood is exerting against the walls of the blood vessels when the heart beats. Diastolic blood pressure (DBP) indicates how much pressure the blood is exerting against the walls of the blood vessels while the heart is resting between beats. Blood pressure is recorded as SBP/DBP millimeters of mercury (mm Hg). Normal blood

⁵ VHA Handbook 1101.10(1), *Patient Aligned Care Team (PACT) Handbook*, February 5, 2014, last modified May 26, 2017. The PACT is "a team of health care professionals that provides comprehensive primary care in partnership with the patient (and the patient's personal support person(s)) and manages and coordinates comprehensive health care services consistent with agreed upon goals of care."

⁶ VHA Handbook 1101.10(1).

⁷ VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015.

⁸ Approximately 78 million adults have hypertension in the United States.

pressure is defined as less than (<)120/<80 mm Hg; 9 elevated BP 120–129/<80 mm Hg; and pre-hypertension as 130–139 mm Hg SBP or 80–89 mm Hg DBP.

Hypertension, diagnosed when the blood pressure is consistently 140/90 or higher, is usually asymptomatic; therefore, routine screening is important to identify the condition. To control and manage hypertension, clinical providers may recommend lifestyle changes such as improved diet, regular exercise, or smoking cessation. The use of blood pressure-lowering medications may be recommended for some patients. When hypertension is not controlled, or the patient is in a hypertensive.crisis, patients are at risk for heart attack, stroke, peripheral artery diseases, kidney disease, and congestive heart failure. Hypertension treatment requires lowering blood pressures to an acceptable endpoint to lessen the chance of future cardiovascular and other negative events.

Accurate measurement and recording of blood pressures is essential. According to a 2017 American College of Cardiology/American Heart Association task force:

Because individual BP [blood pressure] measurements tend to vary in an unpredictable or random fashion, a single reading is inadequate for clinical decision-making. An average of 2 to 3 BP measurements obtained on 2 to 3 separate occasions will minimize random error and provide a more accurate basis for estimation of BP ¹⁰

During interviews, the OIG team learned that at the Danville CBOC, typical practice involved an LPN or RN taking the patient's blood pressure at the beginning of each primary care appointment and documenting the reading in the EHR. While clinic practices varied depending on circumstances, the nursing staff were generally tasked with rechecking blood pressures that were initially elevated and notifying the providers.

Clinical Reminders

VA's Clinical Reminder System, a component of the EHR, assists with clinical decision-making and can alert providers to perform certain tests or other evaluations that will enhance the quality of care for specific conditions. Clinical reminders allow providers to easily view patient-specific information and the date specific patient tests or evaluations were performed, and to track and document when care has been delivered. Providers respond to the reminders by placing relevant

⁹ According to the Mayo Clinic, average blood pressure goals can vary depending on age and disease burden.

¹⁰ Paul K. Whelton, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines.

orders or recording clinical activities in the patients' EHRs. He provider documents a diagnosis of hypertension in the EHR problem list, the hypertension-related clinical reminder is added to the list of reminders for that patient. The clinical reminder for a blood pressure of ≥140/90 asks the provider what they would like to do—change medications, order laboratory tests, or make additional referrals. The provider can choose to ignore or acknowledge the reminder. A normal blood pressure value on recheck would "turn off" the reminder for that visit or until another elevated blood pressure was documented.

OIG Concerns

In December 2017, the OIG learned of a Kentucky CBOC primary care provider falsifying blood pressure readings in an apparent effort to "turn off" a hypertension-related clinical reminder that would otherwise prompt further action or intervention. The OIG evaluated that case and published *Falsification of Blood Pressure Readings at the Berea Community Based Outpatient Clinic, Lexington, Kentucky*. ¹³ As a result of that review, the OIG conducted a nationwide search for providers documenting the same blood pressure more than 150 times across more than 150 patients from January 1, 2018, through June 26, 2018. This nationwide search identified that a Danville CBOC provider documented 139/89 at an unlikely frequency.

The OIG performed an initial EHR review of 40 patient encounters identified from the above search where a repeat blood pressure reading was documented as 139/89. The OIG determined that for each patient with a diagnosis of hypertension, the provider repeatedly documented 139/89, and the provider failed to manage hypertension in high-risk¹⁴ patients. Therefore, the OIG initiated a healthcare review to better evaluate the scope of, and contributing factors to, the provider's practice of repeatedly documenting 139/89 blood pressure readings for multiple patients.

¹¹VHA Handbook 1907.01, *Health Information Management and Health Records*, March 19, 2015. A clinical reminder is a documentation tool "that acts as a template for documenting appropriate actions taken related to a given clinical reminder. The documentation of responses to a reminder, including progress note text, entry of orders, entry of vital signs, or entry of other data elements is part of the patient health record."

¹² VHA Handbook 1907.01. An outpatient care provider must initiate and maintain a summary or problem list that includes specific items such as known significant diagnoses, conditions, allergies to foods or drugs, and current medications.

¹³ VA OIG, Falsification of Blood Pressure Readings at the Berea Community Based Outpatient Clinic, Lexington, Kentucky, Report 18-01963-284, September 20, 2018. https://www.va.gov/oig/pubs/VAOIG-18-01963-284.pdf.

¹⁴ For the purposes of this report, a high-risk patient is defined as having hypertension alone or with other co-existing conditions.

Scope and Methodology

The OIG initiated the review in July 2018, and conducted a site visit August 28–30, 2018. The review included selected data and documents from October 1, 2016, through June 30, 2018.

The OIG interviewed the Facility Director, Chief of Staff (COS), Chief of Primary Care, Chief of Quality Management (QM) and QM staff, the Contracting Officer's Representative (COR), and others knowledgeable about the issues. During the site visit, the OIG interviewed the provider whose documentation practices were in question, Valor Healthcare leaders (who were accompanied by their legal counsel), and several other Valor Healthcare CBOC employees with potential knowledge of the issues. Attempts to contact several former Valor Healthcare employees assigned to the Danville CBOC were unsuccessful.

The OIG reviewed relevant facility policies and Veterans Health Administration (VHA) directives and handbooks, the contract for services between VA and Valor Healthcare, and provider performance metric data. Additionally, while onsite, the OIG team reviewed facility quality and internal management reports, privileging data for all the Danville CBOC providers, and other documents relevant to the reported concerns.

The OIG performed EHR reviews involving more than 500 primary care encounters of patients on the provider's panel for the period October 1, 2016, through June 30, 2018. Because the potential for adverse clinical outcomes¹⁵ is greater in certain high-risk groups, the OIG focused its review on encounters for patients that included diagnoses of primary or secondary hypertension, diabetes, or atherosclerotic cardiovascular disease (ASCVD) (review population). For comparison purposes, the OIG also reviewed patient encounters using the same criteria for the other primary care providers assigned to the Danville CBOC.

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

¹⁵ Within the context of this report, the OIG considered an adverse clinical outcome to be death, a change in the course of treatment or diagnosis, or a significant change in the patient's level of care.

¹⁶ The OIG chose to focus the review on these chronic conditions because of their high prevalence within the veteran population and because of the availability of nationally recognized guidelines for treating these conditions. Primary or secondary diagnoses were identified using selected International Classification of Diseases, Tenth Edition (ICD 10) codes that went into effect October 1, 2015.

Inspection Results

Issue 1: Falsification of Blood Pressure Readings and the Clinical Impact on Patients

Based on EHR reviews of more than 500 primary care encounters, the OIG determined that the provider documented a repeat blood pressure of 139/89 in the presence of an initially elevated reading at a frequency that was inconsistent with the patient's diagnosis or medical history. Although the OIG did not identify patients with adverse outcomes as a result of this documentation practice, the team did identify inadequate management of patients with hypertension that placed them at potential risk due to improper management and follow-up of the disease process. This section of the report focuses on

- The extent of blood pressure falsification, which in the context of this report refers to the provider's documentation of made-up or misrepresented blood pressure readings;
- The impact of the blood pressure falsification on the management of hypertension in high-risk patients; and
- The provider's explanation for the falsified documentation.

Extent of False Blood Pressure Documentation

Of the provider's more than 500 completed primary care encounters from October 1, 2016, to June 30, 2018, the OIG identified 355 patients with either a diagnosis of hypertension, diabetes or ASCVD. The OIG found that in 114 of the applicable encounters, the provider documented a repeat blood pressure of 139/89. As these patients had different disease burdens, health statuses, and treatment plans, blood pressure readings of 139/89 occurring at the frequency noted was highly unlikely.

Impact of Inaccurate Blood Pressure Readings and Hypertension Management on Patients

The provider not only falsified repeat blood pressure readings, but for patients with initially elevated blood pressure readings, also failed to provide hypertension management to reduce the risk of a heart attack or stroke.

The primary care provider has the knowledge to offer the best course of action to reach blood pressure goals by providing the necessary guidance through care planning for the patient. The care plan developed by a provider to treat a patient's blood pressure should be specific and include how and when follow-up should occur. Follow-up and repeat blood pressure measurements serve as critical data points to determine success or failure in achieving target

numbers. Without appropriate plans for follow-up care, patients could continue with high blood pressure, thereby increasing risk for an ASCVD event.

An OIG physician reviewed 53 patient encounters during which the patient had either an initially elevated blood pressure reading (as documented by nursing personnel) and/or other diagnosis such as diabetes or ASCVD where closer monitoring by the provider would be indicated. The OIG physician determined the following:

- Twenty-nine patients with historically high blood pressures had limited to no intervention or close follow-up.
- In the majority of primary care visits, no changes were made to blood pressure management plans despite patients having repeated patterns of high blood pressures in the past.
- In cases where changes were made to patients' blood pressure medications, the interventions were inadequate as subsequent clinic visits revealed persistently elevated blood pressure readings.
- A consistent pattern was present of the provider documenting "[t]he patient's blood pressure is usually adequately controlled. No medication changes are indicated at this time," and a one-year follow-up plan.
- When patients' care plans indicated a need for a follow-up appointment to review home blood pressure logs or to have a nurse recheck the blood pressure, those appointments were not consistently made.

Overall, an OIG physician found that for patients with or without risk factors, the provider did not adequately manage their hypertension. The OIG did not identify similar issues when reviewing patient care encounters for the other primary care providers assigned to the Danville CBOC.

Provider's Explanation of Actions

The provider, a long-tenured employee of Valor Healthcare, had worked at the Danville CBOC since 2011. When asked about the practice of consistently documenting repeat blood pressures of 139/89, the provider told the OIG that either during or at the end of the patient visit, the provider personally repeated the blood pressures for patients with initially elevated readings. If the repeat blood pressures were "normal," the provider would document 139/89 regardless of the actual blood pressure readings. The provider did not write down the actual blood pressure readings and by the time an entry was able to be made into the EHR, the provider had often forgotten the

¹⁷ The provider considered a "normal" blood pressure as less than 140/90.

actual readings. The 139/89 was used because this was the "highest normal number." The provider also told the OIG that this documentation practice did not compromise patient care.

During interviews with other CBOC primary care providers, the OIG learned that the provider was open about these documentation practices. The provider reportedly told one nurse practitioner that it was acceptable to document a repeat blood pressure as 139/89; that to do so would make the hypertension quality measures look better." The OIG was also told, by a different nurse practitioner, that the provider discussed being "lazy" and documented the repeat blood pressure readings as 139/89 because it was easy and convenient.

Issue 2: Leadership Responsiveness

Facility leaders were slow to respond to the OIG's concerns about the unlikely pattern of 139/89 blood pressure readings as documented by the provider.

Timeline

On June 28, 2018, the OIG notified the facility's COS of the repetitive blood pressure readings documented by the provider and recommended the facility complete a comprehensive data pull and analysis to evaluate the extent of the 139/89 entries.

On August 9, the OIG notified the Facility Director of the OIG's plan to conduct a site visit to further explore the provider's blood pressure-related documentation practices. The Director acknowledged awareness of the issues with the provider's documentation, that a focused professional review had been initiated, and that the facility's Medical Executive Board committee was tracking the outcome.²⁰ The Director deferred additional questions about actions and status to the COS.

On August 13, an OIG member spoke with the Chief of QM (who had been assigned as the OIG's liaison) to discuss the logistics of the OIG site visit. The Chief of QM had minimal information about the reason for the OIG's visit and had not been involved in discussions about

¹⁸ A blood pressure reading less than 140/90 would not require additional documentation or intervention.

¹⁹ The hypertension quality metrics relate to patients with hypertension who are assigned to a primary care provider's panel. The metric data, which include the number of patients on a provider's panel with blood pressure readings considered normal or elevated, could be used by providers to evaluate patients' responses to treatment.

²⁰ According to VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010, that was in effect at the time of the events discussed in this report, a focused professional practice evaluation (FPPE) referred to "an evaluation of privilege-specific competence of a practitioner or provider..." An FPPE occurred "at the time of initial appointment and prior to granting new or additional privileges." A FPPE was also initiated when a question arose about "a provider's ability to provide safe, high-quality care." This directive was rescinded and replaced by VHA Directive 1190, *Peer Review for Quality Management*, November 21, 2018, which defines a FPPE as an "oversight process to be employed by the facility when a practitioner does not have the documented evidence of competent performance of the privileges requested" or "documented evidence of competently performing the requested privileges of the facility."

actions needed to evaluate the extent and impact of the provider's blood pressure-related documentation practices.

On August 15, an OIG attorney requested the COR provide point-of-contact information for Valor Healthcare, the contract company who employed the provider. This contact was Valor Healthcare's first notification concerning the documentation practices.

On August 16, the OIG contacted the COS a second time to assess the facility's progress with reviewing the provider's blood pressure-related documentation practices. The COS told the OIG that the Chief of Primary Care had spoken to the provider, but a retrospective review of documentation had not been completed. According to the COS, neither the COS nor the Chief of Primary Care knew how to obtain blood pressure data that would validate the OIG's concerns or that would provide the facility with the basis for a more comprehensive review.

During the August 16 call with the COS, the OIG physician shared concerns that this provider's management of patients with hypertension was questionable and did not demonstrate evidence of appropriate follow-up. The COS indicated that a more in-depth retrospective review of the provider's patients would be conducted by the Chief of Primary Care. The COS was encouraged to contact the OIG physician if assistance was needed to identify a methodology for obtaining the needed data. On August 17, the Chief of Primary Care contacted the OIG to request guidance on obtaining the data needed to analyze the deficient documentation practices.

On August 24, the OIG learned that Valor Healthcare had terminated the provider.

The OIG subsequently learned that the provider was re-privileged²¹ on August 8, one day prior to the OIG's call to the Facility Director. The re-privileging of a provider, which occurs every two years, allows that person to continue to perform his/her duties without restriction. Although the OIG had notified the COS about this provider's documentation practices on June 28th, the facility re-privileging documents did not mention the OIG's concerns. The OIG also learned that the facility did not notify the VISN of the initial OIG contact and concerns until August 16 or 17.

The OIG found the COS's initial response to the issue of the provider's falsified documentation to be inadequate. In the context of an allegation that a provider falsified blood pressure readings using "normal numbers," the unknown duration of this practice, and the potential for patient harm, the OIG anticipated a prompt initiation of a fact-finding review and mitigation actions, as needed. It was not until the OIG contacted the COS a second time that the facility began a more in-depth review of the provider's documentation practices and management of patients with hypertension. At this point, 49 days had elapsed since the OIG's first contact with the COS. At the time of the onsite visit, the OIG team was told that the provider's patient panel had been

²¹ This re-privileging was without restriction and without mention of or investigation into the OIG's concerns about the provider's documentation practices and management of patients with hypertension.

reassigned to other clinical staff at the Danville CBOC and the facility had initiated a review of the patients' care.

Leaders' Explanations of Slow Responsiveness

The COS told the OIG that although the Chief of Primary Care had been informed of the OIG's concerns and asked to conduct a "fact-finding," the COS did not immediately act on the OIG's concerns because "I had a verbal report from [OIG]" but "I had nothing. I had no paperwork. I had the report from [OIG]. And, again, that was great, but it would have been very helpful to me to see… [the data]."

Further, the COS discussed not seeking assistance with data extraction from staff within the facility or at the VISN as the COS was unaware of anyone available who could perform this function. Also, despite knowing that the OIG had a dataset reflecting an unlikely pattern of 139/89 blood pressure readings and being advised on June 28 of the clinical concerns associated with this practice, neither the COS nor the Chief of Primary Care contacted the OIG regarding their reported inability to secure that data, nor did they seek suggestions from the OIG about methodologies to extract the data.

The COS also acknowledged not following up with the Chief of Primary Care to determine the progress of the fact-finding and review results.

The Chief of Primary Care told the OIG after hearing of the blood pressure-related documentation concerns, the Chief of Primary Care told the provider "You need to stop doing this" and discussed additional expectations. The Chief of Primary Care told the OIG that "[i]t wasn't readily evident" how to verify the OIG's concerns, and that "not a whole lot" happened between June 28 and early August as "it was still an unconfirmed report." The Chief of Primary Care did not ask anyone in the facility or the VISN for assistance. On August 17, the Chief of Primary Care contacted the OIG for guidance and reportedly also remembered about a database management system to extract the needed data. ²²

The OIG learned through interviews that several individuals within the facility and at the VISN had the skills to extract the data needed to complete a comprehensive review of the provider's documentation practices. Ultimately, a facility Pharmacy Service employee obtained the data for the COS and Chief of Primary Care.

Facility leaders failed to take prompt action to evaluate the scope of the blood pressure falsifications and initiate a timely and comprehensive review of the provider's documentation practices. The explanations given by the COS and Chief of Primary Care about the OIG not

²² The Chief of Primary Care described using the "FileMan" data base system to obtain the data. VA FileMan is a software package maintained by the Department of Veterans Affairs to retrieve clinical, administrative, and business information.

providing the supporting data and the facility not knowing how to obtain the data were unconvincing. During the approximately seven weeks between the OIG's initial notification and the follow-up contact, neither the COS nor the Chief of Primary Care contacted the OIG for clarification or assistance with the data, nor did they ask administrative staff, the Quality Manager, or the VISN for data assistance. Further, the facility did not notify the VISN of the issue, complete an Issue Brief, or notify Valor Healthcare of the concern.²³

Issue 3: Factors that Permitted Blood Pressure Falsification to Occur and Continue Unabated

Valor Healthcare—Inadequate Follow-Up of Concerns as Witnessed or Reported by Contractor's Nursing Staff

Because it may not be easy to readily identify the type of repetitive blood pressure readings discussed in this report, it is incumbent upon co-workers to report questionable practices. During interviews with Valor Healthcare staff, conducted in the presence of Valor Healthcare's senior leader and outside legal counsel, the OIG was told that

- More than a year prior to the OIG's visit, an LPN told the former Operations Nurse Manager about the provider's irregular blood pressure documentation. According to the LPN, the nurse manager later notified [the LPN] that the provider was spoken to about the problem. The LPN told the OIG, however, that the provider's practice regarding blood pressure readings did not change. The OIG confirmed that the provider continued to document 139/89 through mid-June 2018.
- In or about June 2017, the provider's LPN told a newer RN that the provider "tweaked" blood pressure readings. The RN did not speak with the provider or notify the Operations Nurse Manager of the issue. Upon interview, the RN stated, "I didn't believe...a doctor would do this." "When it was pointed out to me it jogged my memory" but "I didn't give it any more thought."
- In spring 2018, the provider told a nurse practitioner that, to improve hypertension metrics, patients' blood pressures should be documented as less than 139/89. The provider reportedly told the nurse practitioner, "people do it" and "you don't talk about it...because you don't want to talk to the wrong person." While uncomfortable with this suggestion, the nurse practitioner did not report this concern to anyone in authority.

²³ Responsibility for submitting Issue Briefs can vary depending on the subject. In this case, the COS had the broadest knowledge of the OIG's concerns.

The OIG acknowledges the discomfort subordinate staff may feel related to reporting a supervisor's discrepant practices. Nevertheless, VHA requires employees to report issues potentially affecting patient safety, and under the terms of the contract, Valor Healthcare employees must follow VHA policies. Despite efforts to find and interview the previous Danville CBOC nurse manager, the OIG was unable to independently verify that the LPN reported concerns about the provider's blood pressure-related documentation practices. Therefore, the OIG was unable to determine whether appropriate follow-up action was taken. During onsite interviews, the RN and the nurse practitioner confirmed they both were told about the provider's documentation practices; however, they did not report this safety concern.

Facility—Deficient Performance Measure Data Validation

The facility did not have processes in place to validate performance measure data. The facility used a variety of metrics to monitor the provider's performance, including hypertension management.

The VHA Support Service Center (VSSC) collects and reports data on 30 statistical metrics related to patients identified with hypertension and assigned to a provider. This data would typically be used by a primary care provider to evaluate patients' general responses to treatment for hypertension. Primary care managers would use this data to review and compare the summary level performance with the metrics across providers and divisions. In accordance with VHA guidance, Primary Care Management Module (PCMM) coordinators are supposed to validate the accuracy of the data impacting VSSC performance monitor reports.²⁵ However, the PCMM Coordinator did not routinely take steps to validate the underlying data, which may have uncovered the provider's falsified blood pressure documentation.²⁶

Table 1 is an example of the patient-specific data that are readily available by clicking on the hyperlinks in the VSSC hypertension measures.

²⁴ 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 day of March 2016, and has not been recertified.

²⁵ VHA Handbook 1101.02, *Primary Care Management Module (PCMM)*, April 21, 2009 was rescinded and replaced by VHA Directive 1406, *Patient Centered Management Module (PCMM) for Primary Care*, June 20, 2017. While VHA Handbook 1101.02 specified a monthly review, VHA Directive 1406 does not specify a timeframe for this comparative analysis. VHA Directive 1406 requires "[c]ompleting comparative analysis of VSSC reports or data sets with local PCMM data to identify data variance and ensure data integrity."

²⁶ It was not facility practice to routinely check this type of information and facility leaders did not request that the PCMM do so.

Table 1. Example of Patient-Specific Data Available in VSSC Hypertension Metric

Sex	Age	ВР	BP Date	Last PCP Visit
M	31	130/93	3/30/2010	3/30/2010
M	52	128/90	12/22/2009	12/17/2009
M	80	152/69	7/14/2010	7/13/2010
M	60	154/63	8/5/2010	8/5/2010
M	56	158/110	7/13/2010	7/13/2010
M	61	123/92	8/10/2010	7/27/2010
М	75	152/92	8/31/2010	8/31/2010

Source: VHA Primary Care Almanac

A visual scan of the provider's patient-level VSSC data likely would have revealed the pattern of blood pressure readings as the provider recorded 139/89 more than 150 times across more than 150 patients during the six-month period January 1 through June 26, 2018.

The Facility-Valor Healthcare Contract²⁷

Inconsistent Oversight of, and Compliance with, Contract Requirements

The OIG found that neither the facility nor Valor Healthcare (characterized as the Contractor in contract documents) were meeting select aspects of the contract.

The contract stated that

[t]he [facility] COR [Contracting Officer's Representative] shall be the VA official responsible for verifying contract compliance...The COR will be responsible for monitoring the Contractor staff performance to ensure all specifications and requirements are fulfilled...The COR will maintain a record-keeping system of services by reviewing the QASP [Quality Assurance Surveillance Plan] and invoices submitted by the Contractor. The COR will review this data monthly when invoices are received and certify all invoices for payment.

The OIG learned, however, that the COR had not received, nor asked for, quality-related performance reports from the Contractor since starting the position in approximately June 2017. Further, the COR reported

.

²⁷ VA 246-16-C-0142.

- Not receiving orientation or training to COR responsibilities. The facility's Contracting Office confirmed that there was no formal COR orientation and explained that the delegation letter described the COR's duties and responsibilities,
- Not understanding all requirements of being a COR, and
- Not reading the contract in its entirety.

The contract also stated, among other things, that:

- The Contractor shall conduct audits of TJC [The Joint Commission] standards that require performance measures. Those audit results shall be sent to the Contracting Officer Representative on a quarterly basis...,
- The Contractor shall conduct audits pertaining to access, quality improvement, documentation, and safety and performance measures. These reports shall be submitted to the COR on a monthly basis, and
- The results of all Quality Improvement activities performed by the [C]ontractor involving VA patients will be shared with [the] VA Quality Management Office.

During an onsite interview, the OIG team learned that the CBOC nurse manager was designated by Valor Healthcare to manage operations and communications between the CBOC and the facility. However, the CBOC nurse manager confirmed not having read the contract or being aware of the requirement for reporting quality data to the COR or QM.

While both the facility COR and the CBOC nurse manager reported regular, if not daily, communication about various issues, the OIG concluded that neither party was fully compliant with contract requirements.

Conclusion

The provider frequently documented repeat blood pressure readings of 139/89 after initially elevated blood pressure readings. These falsifications occurred across more than one hundred patients over several years. The patients included in the OIG's EHR review population were at high-risk for adverse clinical outcomes due to, in many cases, uncontrolled hypertension and multiple co-morbid conditions. While the OIG did not identify patients who experienced adverse outcomes as a result of this practice, the OIG physician found evidence of limited interventions, treatment plan adjustments, medication changes, or close follow-up. The OIG found the provider's explanation for falsifying blood pressure documentation, which was largely due to a lapse in remembering ("forgot") the actual readings, to be implausible. The provider reportedly told other CBOC employees about being "lazy" and that the 139/89 reading improved the hypertension metrics scores.

The OIG found the COS's initial response to the issue of the provider's falsified documentation to be inadequate. Despite being told of the concerns on June 28, it was not until the OIG contacted the COS a second time on August 16 that the facility began an in-depth review of the provider's documentation practices and management of patients with hypertension. Further, the facility did not notify the VISN of the issue, complete an Issue Brief, or notify Valor Healthcare of the concern.

The OIG had additional concerns, including that, at least one previous and several current Valor Healthcare staff with apparent knowledge of the blood pressure falsifications, did not adequately report those concerns. The facility did not have processes in place to validate performance measure data, which could have uncovered the provider's falsified blood pressure documentation practices. Neither the facility nor Valor Healthcare were meeting select aspects of the contract. For example, the COR, as the VA official responsible for verifying contract compliance, was not receiving quality-related performance reports from Valor Healthcare. Further, Valor Healthcare did not submit to the facility the results of quality improvement activities involving VA patients as required.

The OIG made five recommendations.

Recommendations 1-5

- 1. The Salem VA Medical Center Director ensures that patients impacted by blood pressure falsifications are evaluated and receive follow-up as clinically indicated.
- 2. The Salem VA Medical Center Director develops processes to ensure the integrity of Veterans Health Administration Support Service Center data that supports performance metrics.
- 3. The Salem VA Medical Center Director directs the development of policies and procedures that ensure compliance with clinical quality reporting requirements as outlined in the Danville community based outpatient clinic contract.
- 4. The Salem VA Medical Center Director evaluates the adequacy of the Chief of Staff's and Chief of Primary Care's responsiveness to the VA Office of Inspector General's concerns and takes action as appropriate.
- 5. The Salem VA Medical Center Director ensures the Contracting Officer's Representative receives the necessary training to fulfill all required functions and oversight responsibilities.

Appendix A: Glossary

Atherosclerotic Cardiovascular Disease (ASCVD) is caused by plaque build-up in the walls of the artery and includes, coronary heart disease, cerebrovascular disease, peripheral artery disease and aortic atherosclerotic disease.

Kaiser Permanente Definition of ASCVD:

https://wa.kaiserpermanente.org/static/pdf/public/guidelines/ascvd-primary.pdf

Blood Pressure measures the pressure in the arteries as the heart pumps.

Mayo Definition of Blood Pressure: (https://www.mayoclinic.org/tests-procedures/blood-pressure-test/about/pac-20393098)

Cholesterol is a waxy substance found in the fats in the blood.

Mayo Definition of Cholesterol: https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/symptoms-causes/syc-20350800

Congestive Heart Failure is a condition that occurs when [the] heart muscle does not pump blood effectively.

Mayo Definition of Heart Failure: https://www.mayoclinic.org/diseases-conditions/heart-failure/symptoms-causes/syc-20373142

Diabetes refers to a group of diseases that affect how [the] body uses blood sugar.

Mayo Definition of Diabetes: https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444

Heart Attack is a term used for damage to the heart muscle that occurs when the flow of blood to the heart is blocked. The blockage is most often a buildup of fat, cholesterol, and other substances, which form a plaque in the blood vessels that supply the heart.

Mayo Definition of Heart Attack: https://www.mayoclinic.org/diseases-conditions/heart-attack/symptoms-causes/syc-20373106

Home logs (home blood pressure logs) are maintained by patients or their care-givers in the home to record blood pressure measurements that may be helpful in diagnosing or monitoring high blood pressure. The measurements may be documented on paper or electronically, such as in an online personal health record or blood pressure tracker.

Mayo Definition of Home Blood Pressure Logs: https://www.mayoclinic.org/tests-procedures/blood-pressure-test/about/pac-20393098

Hypertensive crisis is a term used to describe a severe increase in blood pressure. Hypertensive crisis "is divided into two categories: urgent and emergency. In an urgent hypertensive crisis, [the] blood pressure is extremely high" but there is no damage to the organs of the body. "In an

emergency hypertensive crisis, [the] blood pressure is extremely high and has caused damage to [the] organs" of the body. "An emergency hypertensive crisis can be associated with life-threatening complications."

Mayo Definition of Hypertensive Crisis: https://www.mayoclinic.org/diseases-conditions/high-blood-pressure/expert-answers/hypertensive-crisis/faq-20058491

Chronic Kidney Disease, also known as chronic kidney failure, is the gradual loss of kidney function with decreased ability of the kidneys to filter waste and remove excess fluids from the blood through the urine.

Mayo Definition of Kidney Disease: https://www.mayoclinic.org/diseases-conditions/chronic-kidney-disease/symptoms-causes/syc-20354521

Licensed Practical Nurses are healthcare personnel have undergone training and obtained a license (as from a state) conferring authorization to provide routine care for the sick.

Webster Definition of Licensed Practical Nurse: https://www.merriam-webster.com/dictionary/licensed%20practical%20nurse

Nurse Practitioners are registered nurses who qualify through advanced training to assume some of the duties and responsibilities formerly only by a physician.

Webster Definition of Nurse Practitioner: https://www.merriam-webster.com/dictionary/nurse%20practitioner

Peripheral Artery Disease "is a common circulatory problem in which narrowed arteries reduce blood flow to [the] limbs."

Mayo Definition of Peripheral Artery Disease: https://www.mayoclinic.org/diseases-conditions/peripheral-artery-disease/symptoms-causes/syc-20350557

Registered Nurses are healthcare personnel who are licensed by a state authority after passing qualifying examinations for registration. Registered nurses have more training than licensed practical nurses.

Webster Definition of Registered Nurses: https://www.merriam-webster.com/dictionary/registered%20nurse

Stroke is a term used to describe an emergency condition that occurs "when the blood supply to part of [the] brain is interrupted or reduced, depriving brain tissue of oxygen and nutrients."

Mayo Definition of Stroke: https://www.mayoclinic.org/diseases-conditions/stroke/symptoms-causes/syc-20350113

Appendix B: VISN Director Comments

Department of Veterans Affairs Memorandum

Date: December 21, 2018

From: Director, VA Mid-Atlantic Health Care Network (VISN 6)

Subj: Healthcare Inspection—Falsification of Blood Pressure Readings at the Danville

CBOC, Salem, Virginia

To: Director, Rapid Response Team (54RR)

Director, Management Review Service (VHA 10E1D MRS Action)

- 1. The attached subject report is forwarded for your review and further action. I reviewed the response of the Salem VA Medical Center (VAMC), Salem, VA, and concur with the facility's recommendations.
- 2. If you have further questions, please contact Lisa Shear, Quality Manager, at (919) 956-5541.

LINDA C. EXNER 331939, Acting Deputy Network Director Digitally signed by Linda C. Exner 331939

Date: 2018.12.28 13:14:27

Signed for:

DEANNE M. SEEKINS, MBA, VHA-CM VA Mid-Atlantic Health Care Network Director, VISN 6

Appendix C: Facility Director Comments

Department of Veterans Affairs Memorandum

Date: December 21, 2018

From: Director, Salem VA Medical Center (658)

Subj: Healthcare Inspection—Falsification of Blood Pressure Readings at the Danville

CBOC, Salem, Virginia

To: Director, VA Mid-Atlantic Health Care Network (VISN 6)

1. I have reviewed the report, entitled "Falsification of Blood Pressure Readings at the Danville Community Based Outpatient Clinic."

2. We appreciated the opportunity to review this report. We have initiated action plans to resolve Each of the recommendations shared. We do not anticipate any barriers in completing each Action plan and anticipate completion by March 31, 2019.

Original signed by:

Rebecca J. Stackhouse, CTRS, FACHE (signature on file) Medical Center Director

Comments to OIG's Report

Recommendation 1

The Salem VA Medical Center Director ensures that patients impacted by blood pressure falsifications are evaluated and receive follow-up as clinically indicated.

Concur.

Target date for completion: March 31, 2019

Director Comments

The Salem VA Medical Center formed an interdisciplinary team to perform chart reviews and identified 805 patients on the physician's panel of patients with a diagnosis of hypertension. 100% of the active patients (N=793) were contacted via phone call, letter or by way of existing appointment to have blood pressure reassessed. As of December 19, 2018, 424 patients had been seen in the clinic, evaluated and treated if indicated. 79 patients are scheduled to be seen, 8 patients have transferred care, 220 are in the process of being scheduled, and 62 patients refused an appointment. All agreeable patients will be seen, evaluated and treated if indicated by March 31, 2019.

Recommendation 2

The Salem VA Medical Center Director develops processes to ensure the integrity of Veterans Health Administration Support Service Center data that supports performance metrics.

Concur.

Target date for completion: March 31, 2019

Director Comments

The Quality Management (QM) Department of the Salem VA Medical Center is currently hiring a Quality Consultant-Registered Nurse and two data analysts whose focus will be on Primary Care. The RN consultant along with two data analysts will provide oversight in the routine monitoring of data and data integrity. The anticipated start date for the RN Consultant and data analysts is March 4, 2019.

To ensure the integrity of VSSC data supports performance metrics, the Quality Management Department at Salem VA Medical Center will perform routine monitoring of Primary Care performance measures at all sites. Data will be reported at least quarterly to the Quality, Safety and Values (QSV) Committee. The validated VSSC data for selected measures will be provided to the Chief of Primary Care for utilization during OPPE review beginning with the next OPPE

evaluation cycle. All data is reviewed during provider's proficiency cycles. Salem VA Medical Center has completed a review of all primary care providers' panels to ensure no other similar documentation patterns existed.

Recommendation 3

The Salem VA Medical Center Director directs the development of policies and procedures that ensure compliance with clinical quality reporting requirements as outlined in the Danville CBOC contract.

Concur.

Target date for completion: March 31, 2019

Director Comments

The current contract with VALOR Healthcare will be modified to include changes to the Quality Assurance Surveillance Plan (QASP) which will reflect scheduled exchanges of all quality improvement data, quality management data and performance improvement projects. The contract shall be evaluated at least quarterly using the QASP as the basis for evaluation of services provided by VALOR Healthcare. The modification will be signed by VALOR Healthcare representatives and VHA representatives by March 31, 2019.

Quality data sharing between the Contracting Officer's Representative (COR) and VALOR Healthcare shall commence immediately and be inclusive of items outlined in the contract. The quality data received from VALOR Healthcare will be provided to the Salem VA Medical Center Quality Management department and reported by the COR through the Quality Safety Value Committee.

In addition, all staff at the Danville CBOC will receive education on the various options for reporting clinical, quality or safety concerns. Updated OIG and Joint Commission notification posters have been supplied to the Danville CBOC (12/19/18), and staff will be required to complete read and sign acknowledging methods of reporting by 12/28/2018. The staff will receive education on reporting patient safety concerns utilizing the Joint Patient Safety Reporting (JPSR) system as well as My Voice Matters training regarding establishing a Just Culture in healthcare by February 28, 2019.

Recommendation 4

The Salem VA Medical Center Director evaluates the adequacy of the Chief of Staff and Chief of Primary Care's responsiveness to the OIG's concerns and takes action as appropriate.

Concur.

Target date for completion: January 31, 2019

Director Comments

Effective December 19, 2018, the Chief Primary Care has been detailed to a staff physician role while a Fact-Finding investigation is completed by staff members external to Salem VA Medical Center. Appropriate action will be taken based on the results of the Fact Finding.

The Medical Center Director has informed the appropriate offices of the report/recommendations and a formal investigation by an external agency is underway. Upon completion of the formal investigation, appropriate action will be taken to address the Chief of Staff actions.

Recommendation 5

The Salem VA Medical Center Director ensures the Contracting Officer's Representative receives the necessary training to fulfill all required functions and oversight responsibilities.

Concur.

Target date for completion: March 31, 2019

Director Comments

Department of Veterans Affairs (VA) Acquisition Regulation (VAAR) policies and Federal Acquisition Regulation (FAR) provide guidance to the COR for contract management (801.603-70 and 801.630-71). Contracting Officer's Representatives (COR) are directed in their responsibilities for each contract as designated by the Contracting Officer (CO) when assigned via COR Nomination Memorandum. The specific responsibilities for the COR are stated in the contract.

The Contracting Officer's Representative (COR) had completed required forty (40) hour refresher training on June 16, 2018. CORs at Salem VA Medical Center will be reeducated to refer to and follow responsibilities delineated in the COR Nomination Memorandum and contracts. CORs will be provided links to Veterans Health Administration Customer Reference Guide (for Procurement) and Veterans Health Administration Procurement Manual. Salem VA Medical Center will also set up on-site, face-to-face training for all CORs and request a focus on healthcare contracts and day-to-day contract administration by March 31, 2019.

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