Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-04547-398

Healthcare Inspection

Alleged Quality of Care Concerns Gene Taylor Community Based Outpatient Clinic Mount Vernon, Missouri

July 6, 2015

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made regarding the quality of care provided to a patient at the Gene Taylor Community Based Outpatient Clinic (CBOC), Mount Vernon, MO.

We substantiated that CBOC clinical staff did not appropriately evaluate the patient's gastroesophageal reflux disease symptoms. When the patient called the CBOC to complain of increased heartburn and belching, he spoke with a registered nurse, and the electronic health record does not document that these complaints were directly discussed with the patient's primary care provider. The patient subsequently received prescriptions for an increased dose of omeprazole and ranitidine to treat his heartburn, without additional clinical evaluation.

The CBOC provider documented that the patient was under the care of a specialist in the community for this condition. That specialist diagnosed the patient with esophageal cancer within 3 months of his first complaints of increased heartburn. It is therefore unlikely that the provider's failure to evaluate the patient would have altered his clinical outcome.

However, Veterans Health Administration (VHA) policy requires VA providers to manage conditions for which they prescribe medications, even if the patient is also seeing a provider in the community for that condition (dual care). To manage a condition, a provider must understand what is being done to care for the patient in the community for that condition. The patient's electronic health record did not contain documentation regarding which medical records the patient's primary care provider had at his/her disposal when deciding to order the increased dose of medication. We also cannot determine whether the CBOC provider's summarized notes accurately reflected care the patient was receiving in the community or whether the CBOC provider should have taken additional action based on evaluations completed in the community.

We did not substantiate that the CBOC inappropriately denied the patient's request for Nexium®. Since 2009, VHA has operated under a single formulary, and this formulary lists preferred medications based on competitive pricing, safety, and efficacy. VHA also requires all of its medical centers to have a process for reviewing requests for non-formulary medications. These medications may be approved if certain criteria are satisfied. In this case, the CBOC offered to prescribe Nexium® for this patient if the patient tried other medications first, as required under VHA policy. The patient was in the process of trying other medications when he was diagnosed with esophageal cancer and requested that further medication management be done by his community (non-VA) physicians.

We recommended that the Interim Under Secretary for Health ensure that the documentation requirements in VHA Handbook 1907.01, *Health Information Management and Health Records,* for summarizing scanned records from community providers are sufficient to support VA primary care providers' compliance with VHA Directive 2009-038, *VHA National Dual Care Policy*, August 25, 2009. We also

recommended that the Veterans Health Care System of the Ozarks Director ensure that providers comply with VHA policy regarding the coordination and management of dual care.

Comments

The Interim Under Secretary for Health and Veterans Integrated Service Network and Facility Directors agreed with the review findings and recommendations and provided acceptable improvement plans. (See Appendixes A, B, and C, pages 9–13, for the full text of the Interim Under Secretary's and Directors' comments.) We consider recommendation 1 closed. We will follow up on the planned actions for the open recommendation until they are completed.

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

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made regarding quality of care concerns for a patient at the Gene Taylor Community Based Outpatient Clinic (CBOC), Mount Vernon, MO.

Background

The CBOC is assigned to the Veterans Health Care System of the Ozarks (facility), Fayetteville, AR, which is part of Veterans Integrated Service Network (VISN) 16. The CBOC has 13 Patient Aligned Care Teams and also offers audiology, gynecology, mental health, optometry, pharmacy, podiatry, and surgical services.

Veterans Health Administration (VHA) Directive 2009-038 established a national dual care policy for patients who are seen by both VA providers and community (non-VA) providers.[1] Each patient who uses VA care should be assigned a primary care provider (PCP) who oversees all aspects of care. When the patient also sees community providers, the VHA provider has the responsibility (among others) of coordinating care made known to the VHA provider by the patient or community providers and developing a treatment care plan that is consistent with VA National Formulary,[2] VISN, and local processes for obtaining non-formulary agents.

In June 2014, the OIG received a letter alleging quality of care concerns for a patient being provided medical care by the CBOC.

The following is a summary of the allegations:

- The CBOC did not appropriately evaluate the patient's gastroesophageal reflux disease (GERD) symptoms and difficulty swallowing, which resulted in a delay in diagnosing the patient with esophageal cancer. This delay resulted in the patient's death.

- The CBOC denied the patient's request for Nexium®.

Scope and Methodology

We conducted a site visit at the CBOC on October 2, 2014. We interviewed the Facility Director, Quality Management Service Chief, Health Information Management System Chief, and Patient Advocate by videoconference. We also interviewed the patient's CBOC PCP, the CBOC PCP's Registered Nurse (RN), a CBOC Pharmacist, and the CBOC Nurse Manager.

[1] VHA Directive 2009-038, *VHA National Dual Care Policy*, August 25, 2009. This Directive expired August 31, 2014 and has not yet been updated.
[2] A listing of products (drugs and supplies) that is available for prescription at VA facilities.

We spoke with the complainant and also a family member. We reviewed the patient's electronic health record (EHR); patient advocate reports; VHA, VISN, and local policies; and other relevant documents. Community providers' records were not available for review, as the patient's community care was not purchased by VA.

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

Case Summary

In winter 2014, the patient was in his 60s with a history of diabetes, GERD symptoms, hyperlipidemia, hypertension, and obstructive sleep apnea. He was first seen at the CBOC and assigned a PCP more than 10 years previously but continued to receive care from community providers.

In fall 2010, CBOC staff documented that the patient was evaluated and treated for gastrointestinal (GI) complaints by a community provider. The EHR outlined that the patient had a couple of instances where he ate spicy foods and subsequently developed abdominal pain and distress, which subsided when he was able to vomit and have a bowel movement. The community provider had ordered an ultrasound of the upper abdomen and a computed tomography (CT) of the abdomen and liver that was reportedly without acute abnormalities.

In early 2011, CBOC staff documented that the patient had been evaluated and treated by a community GI provider in late 2010 and stated that the patient had biopsies from his ileocecal valve and colon. At the time of the 2010 visit, the patient was asymptomatic, not having diarrhea, abdominal pain, or other gastrointestinal symptoms, and felt well. The patient planned to live in Texas for the winter.

In fall 2012, the patient came to the CBOC for follow-up on medical problems and to obtain lab work. CBOC staff documented the patient was alert, well oriented, in no distress, and the abdomen was soft and without bruits, tenderness, masses, or organomegaly. The plan was for the patient to return to the clinic in 12 months or sooner if needed.

In spring 2013, the patient had a teleretinal imaging scan and additional labs drawn. He called and spoke with the CBOC RN about the labs. During the call, the patient complained of a sore throat and increased belching over the past few weeks. The patient was instructed to increase current GI medication (omeprazole) from once daily to twice daily and to call back in 2–3 weeks to report whether his symptoms had resolved. The patient verbalized understanding. The PCP acknowledged receipt in reviewing the RN's telephone note and wrote an order to increase the omeprazole accordingly.

Shortly after increasing the omeprazole, the patient called and spoke with the CBOC RN. He stated that he had been taking omeprazole twice daily with no relief of his sore throat and belching. He had started taking Tums® and reported that it worked better. The RN informed the patient that the next step would be to take a combination of omeprazole and ranitidine; however, the patient did not want to take omeprazole and inquired about a prescription for Nexium®.[3] The RN informed the patient that the PCP could order the Nexium® but that the patient would have to pay out of pocket or see if private insurance would pay for this medication. The patient stated that he would check

[3] Proton-pump inhibitors (PPIs), such as omeprazole and Nexium®, are a group of drugs that reduce the production of acid in the stomach.

with his private insurance and let CBOC staff know if he wanted the PCP to order Nexium®.

During a phone call with CBOC staff approximately 2 weeks later, the patient was informed that Nexium® was not on formulary. The patient stated he could not afford Nexium® and agreed to try the combination of omeprazole and ranitidine. The PCP ordered these medications, and the RN instructed the patient to call back within 1 month.

In fall 2013, the CBOC PCP entered an EHR note summarizing non-VA records that documented two visits to community providers during the previous spring and summer. During the spring visit, the community provider noted that the patient had complaints of belching and heartburn, a history of a hiatal hernia, and a recent evaluation by a GI specialist. The community provider ordered Nexium® and made dietary suggestions. During the summer visit, the patient reported a diagnosis of esophageal cancer and asked that the community provider manage his medications rather than the CBOC.

In winter 2013, the CBOC PCP documented another summary of records received from community providers in the EHR. The patient had a diagnosis of adenocarcinoma and was receiving radiation treatments. The status of cancer was unknown, and the patient was going to be seen in the community because surgery was still being considered.

The patient passed away in early 2014.

Inspection Results

Issue 1. The CBOC Did Not Appropriately Evaluate the Patient's GERD Symptoms

We substantiated that CBOC clinical staff did not evaluate the patient's GERD symptoms but concluded that it is unlikely that the lack of a CBOC provider evaluation influenced this patient's clinical outcome.

When the patient called the CBOC to complain of increased heartburn and belching in spring 2013, he spoke with an RN. No appointment was made at that time for him to see his PCP. The RN did not document discussion of the complaints with the patient's PCP, although the PCP wrote orders to adjust the patient's medications. The patient subsequently received prescriptions for an increased dose of omeprazole and ranitidine to treat his heartburn without additional clinical evaluation.

Although the patient was not evaluated at the CBOC for his complaints of persistent belching and sore throat in spring 2013, the EHR note summarizing community provider care for the same period suggests the patient was receiving GI care from a community specialist. The patient first complained of increased GERD symptoms to the CBOC RN in spring, was seen by a community provider approximately a month later who documented a recent encounter with a GI specialist, and was diagnosed with esophageal cancer before the summer visit to a non-VA provider. It is therefore unlikely

that the CBOC PCP's failure to see and examine the patient in spring impacted his clinical outcome, as the patient was diagnosed with esophageal cancer within 3 months of his first complaint of increased heartburn. Further, even if the CBOC provider had evaluated the patient, unless there were associated findings such as weight loss or dysphagia, it is not clear that increased heartburn alone would have warranted an urgent esophagogastroduodenoscopy (EGD).

Issue 2. The CBOC Inappropriately Denied the Patient's Request for Nexium®

We did not substantiate that the CBOC inappropriately denied the patient's request for Nexium®.

Since 2009, VHA has operated under a single formulary that lists preferred medications based on competitive pricing, safety, and efficacy. VHA also requires all facilities to have a process for reviewing requests for non-formulary medications, such as Nexium®. These medications may be approved if certain criteria are satisfied.[4]

VHA's policy does not preclude VISNs from imposing additional requirements for the prescribing of non-formulary medications. In this instance, VISN 16 had imposed additional requirements on providers seeking to obtain non-formulary items for their patients. The applicable requirement is: "A documented therapeutic failure to formulary therapeutic alternatives exists."[5]

For a patient to obtain a non-formulary proton pump inhibitor, facility policy requires that the patient try formulary proton pump inhibitors in a defined order. In this case, the CBOC PCP offered to prescribe Nexium® after the patient tried other medications first, as required under VHA policy. The patient was in the process of trying other medications (omeprazole and ranitidine) when he was diagnosed with esophageal cancer; he then requested that further medication management be done by his community physicians.

Therefore, while the CBOC did not immediately authorize the use of Nexium®, we found that this decision complied with VHA policy regarding access to non-formulary medications. Further, use of Nexium® instead of omeprazole for a 3-month time period would not have altered the clinical outcome for this patient.

Issue 3. Documentation Requirements for Non-VA Care

In the course of our inspection, we reviewed VHA's Dual Care Directive 2009-038[6] and VHA's current[7] and two previous versions[8] of Health Information Management and

[4] VHA Handbook 1108.08, *VHA Formulary Management Process*, February 26, 2009. This Handbook was scheduled for recertification by the end of February 2014 but has not yet been updated.
[5] South Central VA Health Care Network Policy Memorandum No. 16-PB-47, *Formulary Management Process,* June 18, 2010.
[6] VHA Directive 2009-038.
[7] VHA Handbook 1907.01, *Health Information Management and Health Records,* March, 2015
[8] VHA Handbook 1907.01, *Health Information Management and Health Records,* September 19, 2012 and July 22, 2014.

Health Records Handbooks. VHA Directive 2009-038[9] states that VA providers are responsible for:

> *. . . ensuring that medications or diagnostic tests are not ordered for any condition that the VA provider is not managing, or any condition the Veteran does not allow the VA provider to adequately manage . . . [and for] ensuring that a treatment or medication plan recommended by community providers is not followed if the VA provider believes the plan is not medically appropriate . . .*

However, providers are not required to retain copies in the medical record of medications or diagnostic tests ordered by non-VA providers when VA does not purchase the care from those providers. VHA Handbook 1907.01 states:[10]

> …*Practitioners must indicate which documents, including images, need to be retained and limit this to pertinent, present, or continued care. A summary progress note written by an appropriate clinician after a review of the external source documents may be used in lieu of filing or scanning any external source documents.*

We found that these two policies place requirements on VA providers that they may not be able to meet in all cases. A primary care provider in the private sector who refers a patient to a community provider can track that consultation and obtain records back from that provider. A VA provider consulting with another VA specialist on a patient's care has access to records of these visits through the EHR. However, a VA provider seeing a patient who is paying separately for care in the community may not be aware of the non-VA care (the patient has the responsibility to inform the VA provider of non-contracted, non-VA care and may choose to not inform the VA provider) or may have limited access to medical records associated with that care (the VA provider may request records, but the non-contracted non-VA care provider does not have a legal obligation to provide them). Nevertheless, VHA Directive 2009-038 indicates the VA provider is responsible for coordinating care and for ensuring that treatments recommended by community providers are not followed if the VA provider believes the treatments are inappropriate.

For the patient's care we reviewed in this report, we found that the provider prescribed medications for the patient based on a condition being treated by a community provider. However, copies of records from the community provider were not available. Instead, the patient's CBOC PCP had summarized the community records. Because of this practice, it is not known what medical records the CBOC PCP had at his/her disposal when deciding to order the increased dose of omeprazole and ranitidine. We could not determine (1) whether the CBOC PCP's summarized notes accurately reflected care the patient was receiving in the community or (2) whether the CBOC provider should have

[9] VHA Directive 2009-038.

[10] VHA Handbook 1907.01, September 19, 2012. This version of the Handbook was current at the time of the events described herein; the next version published in July 2014 and the most current version of this Handbook published on March 19, 2015 have similar language regarding a summary progress note.

taken additional action based on evaluations completed in the community. Similarly, a new PCP would be unable to fully evaluate a patient receiving non-contracted, non-VA care if relying entirely on summaries contained in the EHR.

Conclusions

We substantiated that CBOC clinical staff did not appropriately evaluate the patient's GERD symptoms in 2013 but concluded that this is unlikely to have influenced this patient's clinical outcome. When the patient called the CBOC to complain of increased heartburn and belching, he spoke with an RN and the EHR does not document that these complaints were directly discussed with the patient's primary care provider. The patient subsequently received prescriptions for an increased dose of omeprazole and ranitidine to treat his heartburn, without additional clinical evaluation.

The EHR suggests the patient was under the care of a community (non-VA) GI specialist who diagnosed him with esophageal cancer within 3 months of his initial complaint of increased heartburn. It is therefore unlikely that the PCP's failure to see and examine this patient for his increased GERD symptoms impacted the clinical outcome for this patient. Further, even if the CBOC provider had evaluated the patient, unless there were associated findings such as weight loss or dysphagia, it is not clear that increased heartburn alone would have warranted an urgent esophagogastroduodenoscopy (EGD).

We did not substantiate that the CBOC inappropriately denied the patient's request for Nexium®. In this case, the CBOC had offered to prescribe Nexium® for this patient if the patient tried other medications first, as required under VHA policy. The patient was in the process of trying other medications when he was diagnosed with esophageal cancer and requested that further medication management be done by his community (non-VA) physicians.

We have concerns that VHA Directive 2009-038 places requirements on VA providers that they cannot meet in all cases because of documentation requirements found elsewhere in VA policy. These requirements allow VA providers to summarize outside medical records rather than incorporating the original records into a patient's EHR.

While staff followed VHA policy in summarizing community records in this case, the CBOC has no documentation of what community medical records the patient's PCP had at his or her disposal when deciding to order the increased dose of omeprazole and ranitidine. We therefore cannot determine (1) whether the provider's summarized notes accurately reflected care the patient was receiving in the community or (2) whether the CBOC provider should have taken additional action based on evaluations completed in the community. We are concerned this practice would also impact care should the patient change PCPs. A new PCP would also have to rely entirely on the summaries contained in the medical record.

Recommendations

1. We recommended that the Interim Under Secretary for Health review documentation requirements of Veterans Health Administration Handbook 1907.01 and determine whether the documentation requirements support the obligations placed on VA primary care providers by Veterans Health Administration Directive 2009-038.

2. We recommended that the Veterans Health Care System of the Ozarks Director ensure that providers evaluate patients and coordinate care provided in the community in accordance with Veterans Health Administration's dual care policy.

Appendix A

Interim Under Secretary for Health Comments

Department of Veterans Affairs

Memorandum

Date: April 16, 2015

From: Interim Under Secretary for Health (10)

Subj: Healthcare Inspection—Alleged Quality of Care Concerns, Gene Taylor CBOC, Mount Vernon, Missouri

To: Assistant Inspector General for Healthcare Inspections (54)

1. Thank you for the opportunity to review the OIG draft report on the Healthcare Inspection of Alleged Quality of Care Concerns at the Gene Taylor Community Outpatient Clinic in Mount Vernon, Missouri.

2. I concur with the findings and recommendations in the draft report and provide comments in response to recommendation 1. Comments in response to recommendation 2 will be provided to OIG by the facility Director.

3. Please direct questions or concerns regarding the content of this memorandum to Karen Rasmussen, MD, Director, Management Review Service (1OAR) at VHA10ARMRS2@va.gov.

(Original signed by:)

Carolyn M. Clancy, MD
Interim Under Secretary for Health

Comments to OIG's Report

The following Interim Under Secretary for Health comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 1. We recommended that the Interim Under Secretary for Health review documentation requirements of Veterans Health Administration Handbook 1907.01 and determine whether the documentation requirements support the obligations placed on VA primary care providers by Veterans Health Administration Directive 2009-038.

Concur

Target date for completion: April 9, 2015

Facility response: The VHA Health Information Management (HIM) Program Office has reviewed VHA Directive 2009-038, VHA Dual Care Policy and VHA Handbook 1907.01, Health Information Management and Health Records to compare and ensure alignment of the requirements of the two policies.

In VHA Directive 2009-038, it states that "the VA Provider is responsible for education of patients identified as dual care users regarding risks and the patient's own responsibilities, including obtaining all necessary records and documentation from the community provider for use by the VA provider. The patient is responsible for providing the VA provider with written evidence of any treatment plan changes, medication changes, or other changes in care made by the community provider, which must include the reasons for these changes."

In VHA Handbook 1907.01 it states that "only those external source documents that are authenticated may be maintained as part of the patient's VHA permanent health record at the practitioner's written request. Practitioners must indicate which documents, including images, need to be retained and limit this to pertinent, present, or continued care. A summary progress note written by an appropriate clinician after a review of the external source documents may be used in lieu of filing or scanning any external source documents. Any documents or information filed, maintained, or scanned into a patient's health record, including external source documents, are deemed to be part of the patient's VA health records."

Based on the responsibilities identified in the Dual Care Policy, VHA Directive 2009-038, for both the VHA provider and the patient, the documentation requirements in VHA Handbook 1907.01 do support the obligations placed on the VA primary care providers identified in VHA Directive 2009-038.

Appendix B

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: April 20, 2015

From: Interim Director, South Central VA Health Care Network (10N16)

Subj: Healthcare Inspection—Alleged Quality of Care Concerns, Gene Taylor CBOC, Mount Vernon, Missouri

To: Director, Kansas City Office of Healthcare Inspections (54KC)
Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. The South Central VA Health Care Network (VISN 16) has reviewed and concurs with the findings, recommendations and corrective actions included in the draft report submitted by the Veterans Health Care System of the Ozarks, Fayetteville, AR.

2. If you have questions regarding the information submitted, please contact Reba T. Moore, VISN 16 Accreditation Specialist at 601-206-7022.

(Original signed by:)

Fernando Rivera, FACHE
Interim Network Director, South Central VA Health Care Network

Appendix C

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: April 17, 2015

From: Interim Director, Veterans Health Care System of the Ozarks (564/00)

Subj: Healthcare Inspection—Allege Quality of Care Concerns, Gene Taylor CBOC, Mount Vernon, MO

To: Director, South Central VA Health Care Network (10N16)

1. Attached is the Veterans Health Care System of the Ozarks response to the October 2014 Healthcare Inspection Alleged Quality of Care Concerns Gene Taylor Community Based Outpatient Clinic, Mount Vernon, Missouri Draft Report.

2. For further concerns or questions please contact Loretta J. Allen, Chief, Quality, Safety and Value. Phone: 479-587-5858.

(Original signed by:)

Mark A. Worley, MD, PhD
Interim Director, Veterans Health Care System of the Ozarks

Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

OIG Recommendations

Recommendation 2. We recommended that the Veterans Health Care System of the Ozarks Director ensure that providers evaluate patients and coordinate care provided in the community in accordance with Veterans Health Administration's dual care policy.

Concur

Target date for completion: October 31, 2015

Facility response: All Patient Aligned Care Team (PACT) team staff will receive education on VHA National Dual Care Policy Directive 2009-038. New staff will have the Directive added to their orientation checklist. Training for all new Primary Care staff for dual care will be audited for three consecutive months with 90% compliance and reported to Leadership through the Quality, Safety, and Value Committee.

Appendix D

OIG Contact and Staff Acknowledgements

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Larry Selzler, MSPT, Team Leader Andrea Buck, MD James Seitz, RN, MBA

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