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Office of Healthcare Inspections

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Healthcare Inspection

Alleged Patient Deaths and Management Deficiencies in Home Based Primary Care Beckley VA Medical Center Beckley, West Virginia

May 8, 2017

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General conducted a healthcare inspection at the request of former Congressman Nick J. Rahall to assess the merit of allegations made by a complainant regarding patient deaths and management deficiencies in the Home Based Primary Care (HBPC) program at the Beckley VA Medical Center, Beckley, WV. The complainant alleged that:

- While on a "secret wait list," 37 veterans "potentially expired" awaiting admission to the HBPC program.
- Patient scheduling, wait times, and backlogs were mismanaged.
- A provider changed a patient's diagnosis in order to obtain inappropriate services.
- Antibiotics were inappropriately prescribed.
- Opioids were overprescribed, and patients' diagnoses were changed in order to prescribe opioids.

We substantiated that from 2007 through 2012, 25 of 40 patients died while awaiting admission to HBPC. However, we did not find that these patient deaths were associated with a delay in admission to HBPC as the patients continued to receive care from their health care providers prior to their deaths. We found that from 2008 through July 2012, HBPC staff kept an unapproved wait list in violation of Veterans Health Administration policy.

We did not substantiate HBPC patient scheduling, wait times, and backlogs were mismanaged. We found that, other than the wait list issue cited above, HBPC program managers substantially complied with VHA and facility policies. We substantiated that an HBPC provider changed a patient's diagnosis by adding a diabetes diagnosis to the patient's problem list. However, we could not determine that the change was made to obtain prosthetic shoes to the patient. We did not substantiate HBPC providers inappropriately prescribed antibiotics. We did not substantiate that providers overprescribed opioids or changed patients' diagnoses in order to prescribe opioids.

We made no recommendations.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with the report (see Appendix A and B, pages 15–16 for the Directors' comments.) No further action is required.

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

Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection at the request of former Congressman Nick J. Rahall to assess the merit of allegations made by a complainant regarding Home Based Primary Care (HBPC) management and patient deaths at the Beckley VA Medical Center (facility), Beckley, WV.

Background

Facility

The facility is a 30-bed general medical and surgical care facility with a 50-bed community living center that provides skilled nursing care, post-acute rehabilitation, restorative care, and respite care. The facility has an HBPC program and two community based outpatient clinics, one located in Lewisburg and the other in Princeton, WV. The facility treats a veteran population of more than 38,000 throughout an 11-county area of southern West Virginia.

HBPC

Veterans Health Administration (VHA) Handbook 1141.01 outlines policy and procedures for facility HBPC programs which are designed to provide long-term care services in the home and to treat the chronically ill through the months and years before death.[1] HBPC staff provide long-term, interdisciplinary, in-home primary care to patients with complex chronic disabling disease, with the goal of maximizing independence and reducing hospitalizations.[2]

Referrals to HBPC can be made from any healthcare setting, including hospital inpatient, outpatient, or nursing home, if the patient's provider concurs.[3] HBPC staff evaluate the referral to determine whether the patient and the home situation meet HBPC admission criteria.[4] According to VHA Handbook 1141.01, the patient must be enrolled in the VHA system, live within the facility's designated service area, have a

[1] VHA Handbook 1141.01, *Home-Based Primary Care Program*, January 31, 2007, p. 1. VHA Handbook 11401.01 was scheduled for recertification on or before the last working day of February 2012 and has not yet been recertified.
[2] VHA Handbook 1141.01, p. 1.
[3] VHA Handbook 1141.01, p. 14. The Handbook requires the promulgation of a local policy to address scope of program services and referral, admission and discharge procedures. Since 2007, the facility has implemented and updated the following policies to address HBPC operations. See VAMC Memorandum G&EC/HBPC-2, Admission to HBPC, September 2007; VAMC Memorandum, G&EC/HBPC-1, *Scope of Services Provided by HBPC*, September 2007; VAMC Memorandum GEC/HBPC-2, *Admission to HBPC*, August 2009; VAMC Memorandum GEC/HBPC-3, *Discharges from Home Based Primary Care*, August, 2009; VAMC Memorandum G&EC-HBPC-2, *Admission/Discharge Criteria*, December 12, 2012; VAMC Memorandum G&EC/HBPC-4, *Interdisciplinary Care Planning*, July 31, 2013; and VAMC Memorandum 517-2013 G&EC-HBPC, *Procedures for Admission, Assessment, Reassessment and Care Planning*, January 23, 2014.
[4] VHA Handbook 1141.01, p. 15.

complex disabling disease that necessitates care by an interdisciplinary team, and have a safe home environment.[5]

The facility HBPC policy admission criteria include the requirements that the patient be enrolled or on the waiting list in the facility's primary care clinic and HBPC staff can provide services to the patient.[6] If the patient does not meet criteria for the program or the program is at maximum census, HBPC staff will notify the referring provider and recommend alternative services.[7] If the patient meets criteria for admission, HBPC staff make a home visit within 30 days of acceptance of the referral as part of the initial assessment prior to admission to HBPC.[8]

During the initial visit, HBPC staff present the details of the program to the patient, assess home safety, and determine the patient's interest in participating in HBPC. If the patient meets criteria and agrees to enter the program, he or she signs the HBPC Consent for Services form for admission into the HBPC program.[9]

An interdisciplinary team develops each patient's plan of care upon admission to the program. The team reviews and modifies the plan quarterly or more frequently if a patient's condition changes. In addition, the team collaborates with ancillary services to obtain services and procedures needed by the patients.[10]

Electronic Wait List

The Electronic Wait List (EWL) is the official VHA wait list, which is used to list patients waiting to be scheduled for an appointment or to be assigned to a panel[11] and to keep track of patients who have not been seen previously in the clinics.[12] If HBPC staff cannot make the initial home visit within 30 days, they place the patient on the EWL.[13]

[5] VHA Handbook 1141.01, p. 16.
[6] VAMC Memorandum G&EC/HBPC-2, *Admission to HBPC,* September 2007, p. 2. Other admission criteria include homebound veterans with complex chronic disabling medical and psychosocial needs, the presence of a caregiver who will accept responsibility for the veteran's care, and a veteran who is medically stable and can be managed with regular HBPC visits.
[7] VAMC Memorandum G&EC/HBPC-2, *Admission to HBPC,* September 2007, p. 4.
[8] VAMC Memorandum G&EC-HBPC-2, *Admission/Discharge Criteria,* December 12, 2012, pp. 3, 4.
[9] VHA Handbook 1141.01 and VAMC Memorandum, G&EC/HBPC-2, *Admissions to HBPC,* September 2007.
[10] VHA Handbook 1141.01, p. 15.
[11] In VHA, a primary care panel is defined as the group of veterans assigned to a specific primary care provider or primary care team. VHA Handbook 1101.02, *Primary Care Management Module,* April 21, 2009, p. 2. This VHA Handbook was scheduled for recertification on or before the last working date of March 2014 and has not yet been updated.
[12] VHA Directive 2010-027, *Outpatient Scheduling Processes and Procedures,* June 9, 2010. This VHA Directive was in effect during the time frame of the events discussed in this report; it was rescinded and replaced by VHA Directive 1230, *Outpatient Scheduling Processes and Procedures,* July 15, 2016.
[13] VHA Handbook 1141.01, p. 18–19.

Antibiotics

Antibiotics, including antibacterial, antifungal, and antiviral medications, are types of antimicrobials used in the treatment and prevention of bacterial infection.[14] In HBPC, antibiotics are often given for the treatment of upper respiratory infections, urinary tract infections, and wound infections.

Opioid Medication

Opioid medications (opioids) are natural or synthetic derivatives of opium that have pain-relieving properties. Opioids are central nervous system depressants and can reduce heart rate, respiratory function, and level of consciousness. Examples of opioids include hydrocodone, oxycodone, and morphine. These opioids are prescribed for a variety of acute and chronic pain conditions.[15]

Opioids can be a useful part of chronic pain management; however, data on the safety and efficacy of long-term opioid therapy for chronic pain indicate significant risks involved for misuse, diversion,[16] and overdose. VHA policy on pain management requires that when providers prescribe opioid analgesics, they periodically document treatment effectiveness.[17]

Clinical Practice Guideline

The VA/Department of Defense (DoD) Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain (Guideline) outlines recommendations for treating chronic pain patients with opioids. The Guideline is intended to promote evidence-based management, to help identify candidates for opioid therapy, to enhance quality of life, and to decrease the incidence of complications. While not intended to define a specific standard of care, the Guideline is designed to be adapted by individual facilities in considering needs and resources and to allow providers to use their own clinical expertise in the care of individual patients.[18]

Allegations

In October 2014, OIG received a complaint from former Congressman Rahall regarding HBPC patient deaths and management deficiencies, alleging that:

[14] Merck Manual. See http://www.merckmanuals.com/professional/infectious-diseases/bacteria-and-antibacterial-drugs/overview-of-antibacterial-drugs. Accessed September 2, 2015.
[15] Rosenblum et al., *Opioids and the Treatment of Chronic Pain.* Ex Clin Psychopharmacol. 2008 October; 16(5) 405–416.
[16] Drug diversion is defined by the Centers for Medicare and Medicaid Services as the diversion of licit drugs for illicit purposes. https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaidintegrityprogram/downloads/drugdiversion.pdf. Accessed May 10, 2016.
[17] VHA Directive 2009-053, *Pain Management*, October 28, 2009. This VHA Directive was scheduled for recertification on or before the last working day of October 2014 and has not yet been recertified.
[18] VA/DoD Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010.

- While on a "secret wait list," 37 veterans "potentially expired" awaiting admission to the HBPC program.
- Patient scheduling, wait times, and backlogs were mismanaged.
- A provider changed a patient's diagnosis in order to obtain inappropriate services.
- Antibiotics were inappropriately prescribed.
- Opioids were overprescribed, and patients' diagnoses were changed in order to prescribe opioids.

Upon receipt of additional documentation of patients reportedly on a secret wait list, we determined the number of patients at issue was 40, not 37 as initially alleged.

Scope and Methodology

We initiated our review in October 2014 and completed our work in October 2016. We interviewed the complainant prior to a January 2015 site visit. We interviewed facility leadership, current and former HBPC medical directors, the acting HBPC program director, HBPC staff, pharmacy staff, outpatient laboratory staff and other staff knowledgeable about the issues outlined in the allegations.

We reviewed:

- Relevant VHA and facility policies and procedures, and facility EWLs
- Electronic health records (EHRs) of the 40 patients[19] who allegedly died while on a secret wait list awaiting admission to the HBPC program
- EHRs of an additional 40 HBPC patients who were on the HBPC EWL from 2013 through 2014
- EHRs of selected HBPC patients who were prescribed antibiotics from 2011 through 2015
- EHRs of patients who were prescribed opioids from 2011 through 2014 that were greater than or equal to (≥) 200 mg morphine equivalent daily dose (MEDD)
- EHRs of three patients who were alleged to have had diagnoses changed in order to either obtain an inappropriate service (see discussion of one patient in Issue 3) or to be prescribed opioids (see discussion of two patients in Issue 5)

[19] The total number of "potentially expired patients" was later revised to 40 patients when the complainant provided a list of unique patients.

- HBPC policies, management practices, and staffing plans

We did not address allegations in this report related to labor relations and human resource issues.

Four VHA policies cited in this report were beyond their certification dates:

1. VHA Handbook 1141.01, *Home-Based Primary Care Program*, January 31, 2007 (recertification due date, February 2012)
2. VHA Directive 2009-053, *Pain Management,* October 28, 2009 (recertification due date, October 2014)
3. VHA Handbook 1101.02, *Primary Care Management Module*, April 21, 2009, (recertification due date, March 2014)
4. VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010 (recertification due date, November 30, 2015)

We considered the policies to be in effect as they had not been superseded by more recent policy or guidance. In a June 29, 2016, memorandum to supplement policy provided by VHA Directive 6330(1),[20] the VA Under Secretary for Health (USH) mandated the "…continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."[21] The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "…the timely rescission or recertification of policy documents over which their program offices have primary responsibility."[22]

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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.

[20] VHA Directive 6330(1), *Controlled National Policy/Directives Management System,* June 24, 2016, amended January 11, 2017.
[21] VA Under Secretary for Health Memorandum. *Validity of VHA Policy Document,* June 29, 2016.
[22] Ibid.

Inspection Results

Issue 1: Alleged Patient Deaths While on "Secret" Wait List

Alleged Patient Deaths

While we substantiated that 25 of 40 patients died awaiting admission to HBPC, these patients continued to receive care from their previously assigned VA and non-VA providers or through VA and non-VA hospital admissions prior to their deaths. We did not find evidence that provision of services available through HBPC would have altered patient outcomes.

When patients are referred to HBPC, the provider-patient relationship with their previous provider does not end.[23] The previous provider is still responsible to provide and manage the care of the patient just as the provider would if referrals were made to other specialty services. Upon acceptance of the referral from the provider, HBPC has 30 days to conduct an initial assessment of the patient to determine whether the patient meets HBPC admission criteria.[24]

EHR Review 2007–2012

We reviewed the EHRs of 40 patients who allegedly died while waiting for admission to HBPC from 2007 through 2012. Of these 40 patients, 25 died before admission to HBPC and 15 died after admission to and treatment in the HBPC. Of the 25 patients who died before admission, 15 patients died within 30 days of HBPC staff receiving a referral, and 10 died 31 days or more after the HBPC referral was received.[25] These 25 patients were either admitted to the facility, a community hospital, or a nursing home, or they were followed and treated by their provider, hospice, or home health care providers.

We found no instances of adverse outcomes associated with delay in admission to HBPC for the 40 patients. The following 3 patients are examples of the 40 patients referred to HBPC from 2007 through 2012.

Patient 1. The patient was in his late 70s with a history of advanced, non-operable esophageal cancer. The patient required wound care involving daily dressing changes. The patient's primary care provider requested a referral for both HBPC and home health services. Five days later, a consult for hospice care was submitted and hospice care was initiated the same day. The HBPC team did not visit the patient; however, the patient was receiving care from an outside agency. The patient's condition worsened;

[23] VHA Handbook, 1101.10, *Patient Aligned Care Team,* February 5, 2014; pp. 8, 9, 20, 21.
[24] VAMC Memorandum, G&EC/HBPC-1, *Scope of Services Provided by HBPC*, September 2007.
[25] VHA Handbook 1114.01 and VAMC Memorandum G&EC/HBPC-2, *Admission to HBPC,* September 2007, establishes a 30-day standard for performing initial assessments of HBPC patient referrals.

inpatient care was offered but declined. The patient died at home 41 days after the HBPC referral was received.

Patient 2. The patient was in his 80s with a history of advanced dementia and other chronic medical conditions. The patient's primary care provider entered an HBPC referral, which was acknowledged the same day. A week later, the patient was admitted to the facility for management of his dementia and then discharged to a long-term care facility. The patient died 32 days after the HBPC referral was received.

Patient 3. The patient was in his 60s with a history of a chronic neurological disease. His primary care provider referred him to HBPC and home health services, and the referrals were accepted the same day. He was seen by the HBPC team 4 weeks later and was followed in his home for the next year when he was discharged from HBPC back to his primary care provider. Over the next 2 years, the patient was admitted to the facility multiple times for complications related to his neurological disease. He was again referred to HBPC; however, the referral was discontinued because the patient's condition required his admission into an extended care facility, where the patient died.

EHR Review 2013–2014

To further evaluate HBPC processes, we reviewed EHRs of 40 patients who were referred to HBPC and placed on the EWL from 2013 through 2014. Nine of these patients were admitted to HBPC after being placed on the HBPC EWL. Of the remaining 31 patients, 18 patients' HBPC referrals were discontinued due to hospitalizations, care provided by community health agencies, or treatment provided by specialty care providers. The remaining 13 patients died while on the EWL awaiting admission to HBPC.

We found no adverse outcomes associated with a delay in admission to HBPC in 11 of 13 patients. We could not determine whether HBPC admission would have affected the patients' outcomes in the remaining two patients. The following 3 patients are examples of the 40 patients referred to HBPC from 2013 through 2014.

Patient 4. The patient was in his 70s with a history of lung cancer who was admitted to the facility for severe anemia (lack of healthy red blood cells). An HBPC referral was requested in anticipation of the patient requiring home care after discharge, and the patient was placed on the HBPC EWL. At the same time, palliative/hospice care was discussed with the patient's family. Four days later, the patient was discharged to home but readmitted shortly thereafter and remained an inpatient at the facility until his death 19 days after the HBPC referral was received.

Patient 5. The patient was in his 90s with a history of coronary artery and thyroid disease who was offered and declined HBPC services in 2011. The patient was also receiving care from a non-VA provider for a lung condition. A VA primary care provider evaluated the patient and reviewed his medications, current condition, and non-VA radiology images. A follow-up CT scan was recommended after 3 months, and an HBPC referral was submitted. Forty days after the referral, the family spoke with an

HBPC team member and indicated interest in HBPC services. The patient was placed on the EWL. During the wait for admission to HBPC, the patient's VA primary care provider prescribed medications for gastrointestinal and thyroid issues. The patient died 92 days after the HBPC referral was received.

Patient 6. The patient was in his late 80s with multiple chronic medical conditions who was referred to HBPC and placed on the EWL. Two months later, an HBPC team member completed a safety screen by telephone, and an initial in-home visit was completed 73 days after the referral was received by HBPC. The patient was visited by the HBPC team for the next 3 weeks before he died.

Unapproved Wait List

We substantiated HBPC staff maintained an unapproved wait list that was accessible to Geriatrics and Extended Care Staff, which included HBPC staff.

In 2007, the VHA HBPC Handbook mandated that facilities use the EWL for patients awaiting HBPC services.[26] However, the facility's HBPC staff did not follow VHA policy and used an unapproved wait list to track referred HBPC patients from 2008 through July 2012, at which time they transitioned to the EWL.

According to VHA Directive 2010-027, *VHA Outpatient Scheduling Processes and Procedures*,[27] the EWL is the official VHA wait list for outpatient clinical care appointments. The EWL is used to list patients waiting to be scheduled. The EWL usually consists of newly registered or newly enrolled patients, or new consult requests for patients waiting for their first scheduled appointment in a particular clinic such as HBPC. Facilities can establish EWLs for multiple clinics within their facility. No other wait list formats (such as spreadsheets or paper log books) are to be used for tracking requests for outpatient appointments. VHA measures new patient wait times from the date a scheduler creates an appointment in the Veterans Health Information Systems and Technology Architecture. If patients are not added to the official EWL, but instead added to a departmental wait list spreadsheet, the length of time patients wait for appointments will not be captured in VHA's system.[28]

If an appointment cannot be scheduled for HBPC within 30 days due to program capacity, the patient is added to the EWL.[29]

[26] VHA Handbook 1141.01.
[27] VHA Directive 2010-027, *VHA Outpatient Scheduling Processes and Procedures,* June 9, 2010. This VHA Directive was in effect at the time of the events of this report; it was rescinded and replaced by VHA Directive 1230, *VHA Outpatient Scheduling Processes and Procedures*, July 2016. See also VHA Directive 2009-070, rescinded by VHA Directive 2010-027, and VHA Directive 2006-005, rescinded by Directive 2009-070.
[28] *Interim Report: Review of VHA's Patient Wait Times, Scheduling Practices, and Alleged Patient Deaths at the Phoenix Health Care System* (Report No, 14-02603-178, May 28, 2014).
[29] VHA Handbook 1141.01.

VHA Handbook 1141.01 requires that any patient who is referred to HBPC who cannot be scheduled for a visit within 30 days due to program capacity, or whose referral is not reviewed and acted upon within 7 business days, is placed on the official EWL.[30]

HBPC staff told us that starting in September 2008, an electronic spreadsheet was used to track patient flow and that the official EWL was not used until July 2012. The spreadsheet was available for HBPC staff and leadership to review and was maintained on an HBPC computer. Patients on the spreadsheet were not reassigned from primary care to HBPC until staff could screen and admit them. During this time, HBPC staff reported census and pending consults to upper management weekly.

The HBPC staff's use of an unapproved wait list from 2008 through July 2012 did not comply with VHA Handbook 1141.01's requirement, or from 2010 through July 2012 with VHA Directive 2010-027's requirement, to maintain an official EWL. Based on interviews, patient EHR reviews, and review of VHA data, we determined HBPC staff started using the official EWL in August 2012.

Issue 2: HBPC Management

We did not substantiate that patient scheduling, wait times, and backlogs were mismanaged. Although we found that HBPC staff used an unapproved wait list spreadsheet up until 2012 as explained in Issue 1, we did not find other evidence of program mismanagement related to patient scheduling, wait times, or backlogs.

We broadened the scope of our review to include staffing and management practices from 2012 through 2014. We reviewed HBPC policies, management practices, and staffing plans. We interviewed staff and evaluated patient EHRs.

The facility HBPC staffing plan assigned up to 75 patients per mid-level provider,[31] with 3 registered nurses on each panel as case managers.[32] We found facility HBPC staffing levels met the staffing plan requirements. We found medical and program directors provided adequate oversight for HBPC staff, including making patient visits along with team members in order to evaluate both patients and staff.

In accordance with facility policy, the HBPC interdisciplinary team, including the medical director, met regularly to discuss patient issues, medication usage, and whether patients should be admitted to or removed from the program.[33]

Quality Management[34] and the External Peer Review Program (EPRP) monitored the HBPC program for medication errors, infection rates,[35] falls,[36] and patient satisfaction.

[30] VHA Handbook 1141.01.
[31] According to the McGraw-Hill Concise Dictionary of Modern Medicine, 2007, a mid-level provider is a nurse practitioner or physician assistant whose activities are directed and/or dictated by a supervising physician.
[32] HBPC Memorandum G&EC/HBPC6, *HBPC Staffing Plan*, February 2011. HBPC Memorandum 517-2013 G&EC/HBPC-6, *Home Based Primary Care Staffing Plan*, August 31, 2013. HBPC Memorandum G&EC 517-2013 *Scope of Services Provided by HBPC*, August 2013.
[33] VAMC Memorandum G&EC/HBPC-4, *Interdisciplinary Care Planning*, July 31, 2013.

VHA data from 2013 through 2014 that we reviewed confirmed that HBPC was meeting standards for medication errors, infection rates, and falls. Patient satisfaction data from 2014 showed that patients were "very satisfied" with the care that they received.

In April 2014, The Joint Commission conducted a survey of the facility, which included home care organizations and hospice services. HBPC was in compliance with all standards at the time of The Joint Commission on-site survey.[37] Our review of HBPC management practices related to patient scheduling, wait times, and backlogs from 2012 through 2014 indicated the HBPC program staff substantially complied with relevant VHA and facility HBPC policies.

Issue 3. Patient Diagnosis Improperly Changed to Obtain Inappropriate Services

We substantiated that an HBPC provider added a diabetes diagnosis to a patient's problem list; however, we could not determine that the change was made to provide inappropriate services.

We reviewed the EHR of the patient who allegedly had a diagnosis changed. The patient told the HBPC provider that a non-VA provider diagnosed him with diabetes. The HBPC provider then ordered prosthetic shoes for the patient without confirming the diagnosis of diabetes with the non-VA provider. Prior to our review, the facility became aware of the added diagnosis and took action to correct the EHR.

Issue 4: Inappropriate Antibiotic Prescriptions

We did not substantiate HBPC providers inappropriately prescribed antibiotics.[38] We evaluated HBPC antibiotic prescribing practices from 2011 through 2015. A goal of antibacterial usage is to eradicate the infecting organism to achieve resolution of the clinical disease. The appropriate drug selection is dependent on the causative pathogens and their antibiotic susceptibility. Selection of antibacterial regimens is based either on predicted causative bacteria or through direct laboratory analysis.

For empiric therapy,[39] the most likely pathogens dictate what is prescribed. A direct laboratory analysis can determine the specific bacteria involved but can be impractical

[34] HBPC Memorandum 517 2013-27, *Quality Management Plan,* November 2013.
[35] HBPC Memorandum G&EC/HBPC-10, *Infection Control Plan*, March 4, 2014.
[36] VAMC Memorandum 517-2012-11-41, *Fall Prevention and Management*, February 9, 2012.
[37] The Joint Commission is an independent, not-for-profit organization. The Joint Commission accredits and certifies nearly 21,000 health care organizations and programs in the United States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. See The Joint Commission website http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx .
[38] Throughout this report we use the terms antibiotic and antibacterial interchangeably. We excluded other classifications of antibiotics such as antifungal (mostly topical agents) and antiviral medications (very limited numbers).
[39] Empiric therapy refers to initiation of treatment prior to determination of a firm diagnosis. It is most often used when antibiotics are given to a person before the specific bacterium causing an infection is known. See http://connection.ebscohost.com/c/reference-entries/21226789/empirical-therapy.

due to the length of time for analysis and a more urgent need to treat a patient's clinical condition. Providers must use their clinical judgment when weighing concerns of overtreatment and drug resistance with an HBPC patient's need for antibacterial therapy.[40] [41] [42] [43]

HBPC patients generally have chronic and complex medical problems and many are homebound. HBPC providers generally prescribe antibacterial medications based on the patient's previously diagnosed conditions, physical evaluations, and/or laboratory work or x-ray results. When a provider is not able to examine the patient directly or does not have laboratory work or x-rays available, an HBPC provider may empirically prescribe antibacterial medications. Empiric use of antibacterial medications under these circumstances may reduce the incidence of further clinical decline, potential hospitalization, and poor treatment outcomes.

Facility policy requires that HBPC staff conduct quarterly patient assessments. The scope and intensity of additional assessments are based on the patient's diagnosis, the patient's desire for care, and the patient's response to previous care, treatment, and services.[44]

We obtained a list from the facility of all HBPC antibiotic prescriptions ordered from January 2011 through March 2015. We excluded patients under hospice and palliative care, patients seen in the Emergency Department or hospitalized and sent home on antibiotics, and patients who had a home or telephone visit before, during, and after antibiotic therapy. We excluded prescriptions for antifungal and antiviral medications. We conducted a preliminary review of 63 patients who met the review criteria. We reviewed the EHRs of the 63 patients to assess the relevance of diagnostic imaging and laboratory testing for the treatment of the patient's condition for which the antibacterial was prescribed. We also conducted a secondary review of 27 of the 63 patients and found that HBPC providers had appropriate documentation and justification for prescribing antibacterial medications.

In those cases where providers gave antibacterial medications empirically, we determined that the ordering of the antibiotic was within the provider's treatment discretion. We also determined that in those cases where patients received antibiotics, the provider documented the rationale for ordering the prescription.

[40] Mandel, et al, *IDSA/ATS Guidelines for CAP in Adults,* ID 2007; 44:27–72.
[41] Stevens, et al, *Practice Guidelines for Diagnosis and Management of Skin and Soft Tissue Infections*. CID 2014:1–43.
[42] Herath, et al., *Prophylactic Antibiotic Therapy in Chronic Obstructive Pulmonary Disease*. JAMA, 2014; 331(21):2225–2226.
[43] Rowe and Juthani-Mehta, *Diagnosis and Management of Urinary Tract Infection in Older Adults,* Infect Dis Clin North Am. March 2014; 28(1):75–89.
[44] VAMC Memorandum 517-2012-G&EC/HBPC-2, *Admission/Discharge Criteria HBPC,* December 12, 2012; VAMC Memorandum GEC/HBPC-2, *Admission to HBPC*, August 2009; VAMC Memorandum GEC/HBPC-3, *Discharges from Home Based Primary Care (HBPC), August, 2009*. VAMC Memorandum 517-2013 G&EC-HBPC, *Procedures for Admission, Assessment, Reassessment and Care Planning,* January 23, 2014.

Issue 5: Patients' Diagnoses Improperly Changed and Overprescribing Opioids

We did not substantiate providers overprescribed[45] opioids or that providers changed the diagnoses of two patients in order to prescribe opioids. Based on our review of patients' EHRs, we found that the opioid prescriptions were medically appropriate.

VHA policy requires that when opioid analgesics are prescribed for regular use, the provider document treatment effectiveness, including pain control, function, and quality of life.[46] Opioids are prescribed for acute and chronic pain. Generally, opioid prescriptions are restricted to fewer than 30 days. However, pain conditions may become chronic, necessitating further pain management options. In select patients, continuing opioids may be necessary to manage their pain. A 90-day supply is available if certain conditions are met.[47]

To evaluate prescribing practices in HBPC for opioids, we obtained a list of 1,314 prescriptions from the facility for opioid medications ordered from October 2011 through December 2014. We excluded prescriptions for oral solutions, injectable medications, and for patients who were receiving palliative care. We reviewed the remaining 564 recurring prescriptions for 50 unique patients who received Schedule II opioids, which are drugs with an accepted medical use that have a high potential for abuse.[48]

The Guideline classifies high dose opioids as ≥ 200 MEDD.[49,50,51] Of the 564 prescriptions reviewed, we found 125 prescriptions ≥ the 200 MEDD threshold for 5 unique patients. We reviewed the EHRs of the 5 patients with prescriptions for ≥ 200 MEDD and found that documentation in the EHR supported providers' decisions to prescribe opioids at this dose, and that no deaths were associated with opioid overdose.

[45] We defined overprescribing based on a dosage ≥200 MEDD.
[46] VHA Directive 2009-053, *Pain Management,* October 28, 2009.
[47] VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock).* November 16, 2010. This Handbook was scheduled for recertification on/or before the last working day of November 2015 and has not yet been updated.
[48] The Controlled Substances Act, 21 USC §802(6), established five drug schedules and the criteria for each. Schedule I is the most restrictive and Schedule V is the least. The term "controlled substance" means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V.
[49] VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010; Page 45, paragraph 11.
[50] Bohnert A, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*. 2011; 305(13):1315–21. As various opioid medications have different potencies, clinicians standardize prescriptions into the "Morphine Equivalents" to convert patients from one opioid to another. The MEDD is used to translate the dose and route of each opioid medication the patient has received over the last 24 hours to a parenteral (administered other than through the digestive tract such as by intravenous or intramuscular injection) morphine equivalent using a standard conversion table.
[51] VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010.

When prescribing opioids, providers should regularly assess the patient's pain. HBPC facility policy requires HBPC team members to address pain management during home visits, and requires a quarterly clinical pharmacy review by the HBPC pharmacist.[52]

We found all 50 HBPC patients we reviewed who were receiving opioids had a quarterly encounter with clinical staff. We also found that the clinical pharmacist conducted quarterly clinical reviews of HBPC patients on opioids by reviewing patient pain medications, documenting the medications' effectiveness, and making recommendations for medication adjustments or changes to the patient's HBPC provider.

We did not find providers overprescribed opioids. We found that the opioid prescriptions ≥ 200 MEDD were medically appropriate for the patients we reviewed.

Conclusions

While we substantiated that 25 of 40 patients died awaiting admission to the facility's HBPC, these patients continued to receive care from their previously assigned VA and non-VA providers before they died. We found no instances of adverse outcomes associated with delay in admission to HBPC for the 40 patients.

We substantiated facility HBPC staff maintained an unapproved wait list from 2008 through July 2012, but we found appropriate use of the official wait list since August 2012. We did not find that the use of an unapproved wait list, rather than the official EWL, created delays that could be associated with adverse patient clinical outcomes or patient deaths. The patients we reviewed continued to receive care from their assigned providers and other appropriate services.

We did not substantiate patient scheduling, wait times, and backlogs were mismanaged. We found that, other than the wait list issue cited above, HBPC program managers substantially complied with VHA and facility HBPC policies.

We substantiated that an HBPC provider changed a patient's diagnoses by adding a diabetes diagnosis to the patient's problem list; however, we could not determine that the change was made to provide inappropriate services (prosthetic shoes).

We did not substantiate facility HBPC providers inappropriately prescribed antibiotics, overprescribed opioids, or changed patients' diagnoses in order to prescribe opioids. We found providers documented their rationale for prescribing antibiotics and opioids in the EHRs we reviewed.

We made no recommendations.

[52] HBPC G&EC 517-2013, *Home Based Primary Care Procedures for Admission, Assessment, Reassessment, and Care Planning*, January 23, 2014. VHA Handbook 1141.01, p. 10.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: March 16, 2017

From: Director, VA Capitol Health Care Network, VISN 5 (10N5)

Subj: **Healthcare Inspection**—Alleged Patient Deaths and Management Deficiencies in Home Based Primary Care, Beckley VA Medical Center, Beckley, West Virginia

To: Director, Washington DC Office of Healthcare Inspections (54DC)
Director, Management Review Service (VHA 10E1D MRS Action)

1. I would like to express my appreciation to the Office of Inspector General (OIG) Healthcare Inspection Team for their professional and comprehensive review of the Beckley VA Medical Center's Home Based Primary Care Program conducted in regards to the above referenced allegations for the period of October 2014 through October 2016.

2. I have reviewed the draft report for the VA Medical Center, Beckley, WV, and concur with the report and conclusions rendered.

3. Please express my thanks to the Team for their professionalism and assistance to us in our continuing efforts to improve the care we provide to our veterans.

4. For any further questions regarding this matter, please contact Mr. Jeffrey D. Lee, Quality Management Officer, VISN 5, at (954) 541-7514.

(original signed by:)
Joseph A. Williams, Jr.
Director, VISN 5

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: March 14, 2017

From: Director, Beckley VA Medical Center (517/00)

Subj: **Healthcare Inspection**—Alleged Patient Deaths and Management Deficiencies in Home Based Primary Care, Beckley VA Medical Center, Beckley, West Virginia

To: Director, VA Capitol Health Care Network, VISN 5 (10N5)

1. I would like to express my appreciation to the Office of Inspector General (OIG) Healthcare Inspection Team for their professional and comprehensive review of the Beckley VA Medical Center's Home Based Primary Care Program conducted in regards to the above referenced allegations for the period of October 2014 through October 2016.

2. I have reviewed the draft report for the VA Medical Center, Beckley, WV, and concur with the report and conclusions rendered.

3. Please express my thanks to the Team for their professionalism and assistance to us in our continuing efforts to improve the care we provide to our veterans.

(original signed by:)
Stacy J. Vasquez
Director, Beckley VAMC

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Myra Conway, RN, Team Leader Bruce Barnes Gail Bozzelli, RN Donna Giroux, RN Thomas Wong, DO Randall Snow, JD Natalie Sadow, MBA, Lead Program Assistant

Appendix D

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