Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Pain Management Concerns
Primary Care Clinic
Richard L. Roudebush VA Medical Center
Indianapolis, Indiana

Report No. 07-02296-44 **December 19, 2007**

VA Office of Inspector General
Washington, DC 20420

To Report Suspected Wrongdoing in VA Programs and Operations
Call the OIG Hotline – (800) 488-8244

Executive Summary

The purpose of this inspection was to determine the validity of an allegation made by the sister of a veteran regarding controlled substances prescribed to the patient in the Primary Care Clinic (PCC) at the Richard L. Roudebush VA Medical Center (the medical center). The complainant alleged the PCC physician over-prescribed controlled substances to the patient for pain management.

We did not substantiate that a PCC physician over-prescribed controlled substances. During our interviews, the patient admitted to concurrently receiving prescriptions for controlled substances from a PCC physician and a private physician. Additionally, the patient admitted to taking more than the prescribed dosage of morphine. Other than a March 2002 referral to Pain Clinic, we found no documentation that the patient was offered alternative interventions for pain control.

Medical center staff prescribed and dispensed morphine to the patient contrary to medical record documentation identifying the patient as having an allergy and/or adverse reaction to this medication. Medical center staff were not aware of this until our inspection.

We found problems with the patient-to-staff communication processes involving pharmacy staff and PCC physicians. Documentation shows that the patient contacted the pharmacy several times regarding concerns with her medication. The patient stated that the medication was causing breathing difficulties, and the PCC provider did not address this concern. The medication was reordered and dispensed monthly. We recommended that management:

- Ensure that medical center staff acknowledge and address documented historical allergy and/or adverse reactions prior medication prescription, dispensing, and administration.

- Ensure providers receive and acknowledge patient concerns communicated through primary care and pharmacy telephone calls.

- Ensure that PCC staff provide patients with alternative interventions for pain management.

DEPARTMENT OF VETERANS AFFAIRS
Office of Inspector General
Washington, DC 20420

TO: Director, Veterans Integrated Service Network 11 (10N11)

SUBJECT: Healthcare Inspection – Pain Management Concerns, Primary Care Clinic, Richard L. Roudebush VA Medical Center, Indianapolis, Indiana

Purpose

The purpose of this inspection was to determine the validity of allegations made by the sister of a veteran about over-prescribing controlled substances in the Primary Care Clinic (PCC) at the Richard L. Roudebush VA Medical Center (the medical center).

Background

The medical center, located in downtown Indianapolis, Indiana, provides acute inpatient medical, surgical, psychiatric, neurological, rehabilitation care, and primary and specialized outpatient services. The medical center operates two Community Based Outpatient Clinics located in Bloomington and Terre Haute, Indiana. The medical center has an active affiliation with Indiana University School of Medicine.

A patient's sister alleged that a PCC physician over-prescribed controlled substances for pain management. The complainant also alleged the patient had slurred speech, trembled, and was unsteady on her feet because of all the medication she was prescribed.

Scope and Methodology

Prior to our June 11–14, 2007, onsite visit, we conducted a telephone interview with the complainant and reviewed the patient's computerized medical records. During our visit, we interviewed the complainant, the patient, and medical center employees and managers. We reviewed Veterans Health Administration and medical center policies as well as other medical center documents. We performed the inspection in accordance with the *Quality Standards for Inspections* published by the President's Council on Integrity and Efficiency.

Issue: Medication and Treatment Plan Management

We did not substantiate that a PCC physician over-prescribed controlled substances.

The patient is a 66-year old female veteran who was medically discharged from the military over 40 years ago with a back injury. The patient first presented to the medical center's PCC for treatment of urinary incontinence on December 1, 1995, and continues to receive primary care service here. Morphine was documented during this initial visit as one of the patient's two allergies, causing nausea. The patient's medical record indicates a history of recurrent neck and lower back pain. The patient has received multiple combinations of medication therapy in an effort to address the subjective symptoms of pain as presented to medical center clinicians. The patient was seen in the Pain Clinic on March 22, 2002. The Pain Clinic physician evaluated the patient and recommended lower back joint injections, and an appointment was scheduled for this treatment. The patient informed us that this physician wanted to stop all medications, and that she did not like his attitude. Therefore, she did not return to the Pain Clinic. We found no documentation in our medical record review that the Pain Clinic physician intended to stop all medication.

The PCC physician historically prescribed multiple controlled substances in an effort to address the patient's pain complaints. These medications have included Vicodin®, Darvocet®, Percocet®, oxycodone sustained release, and methadone. On January 8, 2004, the patient received an initial prescription for morphine. The patient continued to receive monthly refills of morphine through January 2007.

While we found that the PCC physician continued to try different combinations of medications to address the patient's pain complaints, we did not find any evidence that the physician prescribed excessive amounts of controlled substances. However, other than the March 2002 Pain Clinic referral, there is no evidence that the patient's PCC physician offered alternative interventions for pain control.

Documented Adverse Reaction. A review of the patient's computerized and hard copy medical records reveals the patient experienced an adverse reaction of nausea when she takes morphine. The PCC physician stated during our interview that the patient never complained about any reactions to morphine. Additionally, the PCC physician did not notice that morphine was listed in her medical records as an allergy and/or adverse reaction. The patient informed us that she had previously been prescribed morphine and experienced nausea; however, she did not discuss this with the PCC physician when the medication was initially prescribed.

On February 19, medical record documentation shows the patient stated the medication was working well. The patient continued to request morphine refills through the pharmacy automated telephone service each month.

We did not find documentation that the PCC physician or the initial dispensing pharmacist addressed the issue of an adverse reaction to morphine. Medical center staff were not aware of this prescribing error until our inspection.

Failure to Address the Patient's Complaint. On June 1, 2004, the patient telephoned the pharmacist for a refill and stated the morphine was too strong. She explained that she was experiencing difficulty breathing and requested that the morphine be changed to "something else like Viocodin®." Additionally, medical records show that the patient contacted pharmacy staff on June 16, August 23, September 15, September 21, and September 28 and inquired about her initial complaint. The patient was scheduled to be evaluated in the PCC on June 16, but she cancelled the appointment. The patient continued to call the pharmacy's automated telephone service and received morphine again on July 9 and August 23. The next scheduled PCC appointment was October 14; however, the entire clinic was cancelled by the medical center for that date. The patient was next seen in PCC on December 13, at which time the patient reported that her back pain was stable on morphine. The patient stated her pain was controlled on morphine during subsequent PCC visits: May 4, 2005, February 24, and September 15, 2006. Monthly morphine refills continued through January 2007.

During an interview with the pharmacist, we were informed that the patient's complaint regarding the medication causing breathing difficulties was documented in the computerized medical record and routinely would have been documented on paper and hand-carried to the PCC as a clinical alert. However, the pharmacist could not provide a copy of the alert and the PCC physician did not recall receiving a paper alert. Currently, some clinical alerts are placed in the computerized medical record allowing an audit trail; nevertheless, physicians' preferences permits changes in this process. The alternative process used at the medical center allows for handwritten notifications of patient complaints or inquiries. Unfortunately, such communications could be lost, and therefore they allow for negative patient outcomes.

Private Hospitalization. On January 27, 2007, the patient, after being stopped by police while driving her car erratically, presented in a private hospital emergency room with lethargy, nausea, vomiting, and altered mental status. The patient was hospitalized at this facility with an admitting diagnosis of systemic sepsis syndrome secondary to urinary tract infection. Medical record documentation shows that the patient was experiencing multiple medical problems thought to be related to polysubstance withdrawal, including significant delirium. After medical stabilization, the patient was transferred to a behavioral unit for detoxification.

At the time of hospitalization, the patient was receiving the following controlled substance medications from the VA:

- Morphine sustained action 30 mg by mouth.
- Morphine immediate release 15 mg by mouth.

The patient informed us that she knowingly misused the medications prescribed to her by the PCC physician by taking more than the prescribed dosage at night. She also admitted receiving prescriptions for controlled substances from a private physician. The action of seeking medications concurrently from two physicians increased the amount of controlled substances available for misuse. Furthermore, the patient informed us that when she had scheduled PCC appointments, she would not take controlled substance medications in an attempt to mask the objective symptoms of her misuse when she arrived to see the PCC physician. The patient informed us that counseling had been previously offered by the PCC physician because of her chronic pain and the potential for chemical dependency; however, the patient declined this option.

On March 19, 2007, the patient presented to the PCC accompanied by her sister and both met with the PCC physician. The patient and her sister discussed the patient's recent hospitalization at a private hospital where she received detoxification treatment. At the time, the patient's pain score[1] was documented as 0.

The patient's sister informed the PCC physician that she had destroyed all of the patient's VA medications and she was controlling the patient's pain at this time with over-the-counter medication. The PCC physician recommended Tylenol® Arthritis for pain when necessary. The PCC physician also restarted the patient's anti-hypertensive medication since the patient's blood pressure was elevated during this visit. The patient was given two follow-up appointments, one with the PCC nurse in 4 weeks to reassess her blood pressure, and another with the PCC physician in 6 months.

Conclusions

We did not substantiate that a VA PCC physician over-prescribed controlled substances. The patient admitted receiving prescriptions for additional controlled substances from a private physician. The patient also admitted altering the medication administration schedule that was ordered by the PCC physician. However, other than a March 2002 referral to Pain Clinic, we did not find any evidence that the patient was offered alternative interventions for pain management. We concluded that staff were not aware of the morphine allergy documented in the patient's medical record, and we identified problems in the communication processes for patient complaints; both had the potential to cause negative patient outcomes.

[1] Pain is scored on a scale of 0 to 10, with 0 being no pain and 10 being the most severe pain.

Recommendations

- **Recommendation 1.** We recommended that the VISN Director ensure that the Healthcare System Director takes action to ensure that medical center staff acknowledge and address documented historical allergy and/or adverse reactions prior medication prescription, dispensing, and administration.

- **Recommendation 2.** We recommended that the VISN Director ensure that the Healthcare System Director takes action to ensure that PCC staff provide patients with alternative interventions for pain management.

- **Recommendation 3.** We recommended that the VISN Director ensure that the Healthcare System Director takes action to ensure providers receive and acknowledge patient concerns communicated through primary care and pharmacy telephone calls.

Comments

The VISN and Medical Center Directors agreed with all findings and recommendations and provided acceptable improvement plans. (See Appendixes A and B, pages 8–11 for the full text of their comments.) We will follow up on all planned actions until they are completed.

(original signed by:)
JOHN D. DAIGH JR., M.D.
Assistant Inspector General for
Healthcare Inspections

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: November 7, 2007

From: VISN Director (10N11)

Subject: **Healthcare Inspection – Pain Management Concerns in Primary Care Clinic, Richard L. Roudebush VA Medical Center, Indianapolis, Indiana**

To: Director, Chicago Office of Healthcare Inspections (54CH)

Thru: Director, Management Review Service (10B5)

Per your request, attached is the response to the draft report (2007-02296-HI-0341). If you have any questions please contact Jim Rice, Quality Management Officer, at 734-222-4314.

Linda W. Belton

Linda W. Belton, FACHE

Attachment

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: November 7, 2007

From: Medical Center Director (583/00)

Subject: **Healthcare Inspection – Pain Management Concerns in Primary Care Clinic, Richard L. Roudebush VA Medical Center, Indianapolis, Indiana**

To: Director, Chicago Office of Healthcare Inspections (54CH)

Thru: Director, Management Review Service (10B5)

The Indianapolis VA Medical Center offers the following response to the draft report:

Thank you for providing this evaluation. The medical center will use this as an opportunity to improve its pain management system.

(original signed by:)
Susan P. Bowers

Medical Center Director Comments

Medical Center Director's Comments to Office of Inspector General's Report

The following Director's comments are submitted in response to the recommendation(s) in the Office of Inspector General's Report:

OIG Recommendation(s)

Recommended Improvement Action:

1. **We recommend that the VISN Director ensure that the Medical Center Director takes action to ensure that medical center staff acknowledge and address documented historical allergy and/or adverse reactions prior medication prescription, dispensing, and administration.**

Concur **Target Completion Date: 01/08/2008**

Currently CPRS requires entry of a provider comment for routine medications and schedule III-V narcotics to which the patient has a documented allergy listed. Because schedule II narcotics are written on paper the computer based alerting system is not valid. A policy and procedure will be implemented which will require the pharmacist to directly contact the provider when a schedule II prescription is written to a patient who has an allergy to the medication. This will be documented in CPRS. To be completed within 60 days.

2. **We recommend that the VISN Director ensure that the Medical Center Director takes action to ensure that PCC staff provide patients with alternative interventions for pain management.**

Concur **Target Completion Date: 02/08/2008**

PCC staff will receive an in-service from Education on alternative interventions for pain control at the Indianapolis VA Medical Center. The Pain Management Committee will develop a patient education pamphlet for alternative interventions to be available for patients with a pain score greater then five. PCC staff will be

Medical Center Director Comments

instructed to offer this educational material to these patients. To be completed within 90 days.

3. **We recommend that the VISN Director ensure that the Medical Center Director takes action to ensure that providers receive and acknowledge patient concerns communicated through primary care and pharmacy telephone calls.**

Concur **Target Completion Date: 01/08/2008**

Patient concerns will be documented in CPRS and sent to the provider as VA alerts. Providers will be instructed on prioritizing alerts regarding patient concerns and acknowledging them in a timely manner (3 working days.) The time for alerts to fall off CPRS will be increased from 14 day to 30 days. To be completed within 60 days.

Appendix B

OIG Contact and Staff Acknowledgments

OIG Contact	Verena Briley-Hudson, MN, RN Director, Chicago Office of Healthcare Inspections (708) 202-2672
Acknowledgments	Wachita Haywood, RN, Associate Director Andrea Buck, MD, Medical Consultant Judy Brown, Program Support Assistant

Appendix C

Report Distribution

VA Distribution

Office of the Secretary
Veterans Health Administration
Assistant Secretaries
General Counsel
Director, Veterans Integrated Service Network 11 (10N11)
Director, Richard L. Roudebush VA Medical Center (583/00)

Non-VA Distribution

House Committee on Veterans' Affairs
House Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
House Committee on Oversight and Government Reform
Senate Committee on Veterans' Affairs
Senate Appropriations Subcommittee on Military Construction, Veterans Affairs, and Related Agencies
Senate Committee on Homeland Security and Governmental Affairs
National Veterans Service Organizations
Government Accountability Office
Office of Management and Budget
U.S. Senate: Evan Bayh and Richard Lugar
U.S. House of Representatives: Steve Buyer, Dan Burton, Julia Carson, Brad Ellsworth, Baron Hill, and Mike Pence

This report is available at http://www.va.gov/oig/publications/reports-list.asp.