Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Prescribing Practices in the Pain Management Clinic at John D. Dingell VA Medical Center Detroit, Michigan

Report No. 11-00057-195

June 15, 2011

VA Office of Inspector General
Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections evaluated allegations of poor prescribing practices for controlled substances in the Pain Management Clinic (PMC) at the John D. Dingell VA Medical Center (the facility), Detroit, MI. A complainant alleged that:

- PMC physicians prescribed controlled substances without adequate evaluation of patients.
- Supervisors coerced PMC providers to write controlled substance prescriptions for patients not under their care.
- Patient injuries and deaths occurred as a result of PMC providers prescribing practices.

We substantiated that providers were prescribing controlled substances without adequate evaluation of patients and found that the facility did not have a policy outlining requirements for the ongoing assessment of patients treated with opioid (narcotic) medications.

We did not substantiate the allegation that supervisors coerced providers to write controlled substance prescriptions for patients they had not evaluated. We also did not substantiate that injuries or deaths resulted from the prescribing practices of PMC providers.

We recommended that the Medical Center Director ensure that managers define the expected frequency of provider evaluations for patients treated with opioid medications and ensure peer review of the PMC physician responsible for opioid prescriptions without adequate patient evaluation. The VISN and Medical Center Directors concurred with the inspection results. We will follow up on the planned actions until they are complete.

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

TO: Director, Veterans In Partnership (10N11)

SUBJECT: Healthcare Inspection – Prescribing Practices in the Pain Management Clinic, John D. Dingell VA Medical Center, Detroit, Michigan

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections (OHI) received allegations regarding prescribing practices for controlled substances (CS)[1] in the Pain Management Clinic (PMC) at the John D. Dingell VA Medical Center (the facility), Detroit, MI. The purpose of this inspection was to determine whether the allegations had merit.

Background

The facility is part of Veterans Integrated Service Network (VISN) 11. Located in Detroit, MI, the facility has 267 beds and provides primary, secondary, and tertiary care. The facility has 108 acute care beds, an onsite 109-bed Community Living Center, and an offsite 50-bed Domiciliary Residential Rehabilitation Treatment Program. The facility provides acute medical, surgical, and psychiatric care. The facility also has two community based outpatient clinics (CBOCs) located in Yale and Pontiac, MI, which provide primary care and psychiatric evaluations. The facility is affiliated with the Wayne State University School of Medicine.

According to Veterans Health Administration (VHA) policy,[2] facilities are expected to accommodate the needs of veterans with acute and chronic pain using a stepped care delivery model, beginning with the Primary Care Provider (PCP). If pain control is inadequate, the PCP is to obtain PMC consultation. The PMC provider's role is to establish pain control through various modalities, then return the patient for ongoing primary care. In February 2010, a Behavioral Pain Clinic (BPC) was established at the facility to provide multidisciplinary care for chronic pain patients considered to be

[1] These are drug categories considered to have a potential for abuse or addiction but that also have a legitimate medical use.
[2] VHA Directive 2009-053, *Pain Management*, October 28, 2009.

unsuitable for PCP management for one or more of the following reasons:

- the need for opioid[3] titration
- problems with tolerance/addiction
- suspected diversion or medication interaction
- other complex issues that require additional time and expertise to manage

The OIG Hotline Division received a complaint regarding the management of patients on prescribed CS in the PMC.

A complainant made the following allegations:

- PMC providers prescribed CS without adequate evaluation of patients.
- Supervisors coerced PMC providers to write controlled substance prescriptions for patients not under their care and without evaluation.
- Patient injuries and deaths occurred because of PMC providers' prescribing practices of CS.

Scope and Methodology

OHI conducted an onsite inspection January 12–14, 2011. We reviewed the electronic medical records of patients provided by the complainant; facility policies and procedures governing pain management; and federal, state, and VHA policies. We interviewed senior managers, employees from the PMC, the Chief of Pharmacy Service, and other employees who provide care to patients prescribed medications for pain control. For an independent assessment of facility prescribing and monitoring practices, we identified all patients for whom oral opioid medications were prescribed during December 2010. After adjusting for the relative analgesic potency of medications,[4] we reviewed patient medical records with the largest aggregate prescribed opioid doses. This review was limited to the following oral opioid medications: morphine, hydrocodone, oxycodone, methadone, and hydromorphone.

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.

[3] Opioids are medications with effects similar to those of opium and opium derivatives. The term is often used as a synonym of "narcotics."
[4] Brunton LL, Ed. Goodman and Gilman's *The Pharmacological Basis of Therapeutics*, 11th Ed. New York: McGraw-Hill, 2006.

Inspection Results

Issue 1: Management of Patients on Controlled Substances

We substantiated that PMC providers prescribed CS without adequate evaluation of patients.

The VA/Department of Defense Clinical Practice Guideline for the Management of Opioid Therapy for Chronic Pain[5] recommends that patients be evaluated every 1–6 months. We reviewed 20 patients electronic medical records, including those named by the complainant and those with the largest aggregate opioid doses identified from among the 4,445 patients who received these medications during December 2010.

We found that during 2010 five patients on chronic opiod therapy had no evaluation and six patients had evaluations more than 7 months apart. For 10 of these patients, prescriptions were written by one PMC physician.

Issue 2: Alleged Coercion of Providers by a Supervisor

We did not substantiate the allegation that PMC supervisors coerced providers to prescribe CS to patients not under their care. We interviewed PMC staff and providers and none of the interviewees recalled witnessing this behavior. Several staff members recalled being present at a staff meeting at which a provider was asked to cover during a colleague's absence. The colleague had numerous patients who would require medication renewals. The provider agreed to provide coverage if each patient were scheduled for an evaluation. Neither the supervisor nor the colleague felt that it was necessary to re-evaluate each patient, and another PMC provider was assigned.

Issue 3: Prescribing Practices and a Patient Death

We did not substantiate the allegation that PMC providers' prescribing practices resulted in the death of a patient. We reviewed one patient's medical records who died 4 days following the initial evaluation by a BPC provider. The provider documented a thorough assessment and detailed the patient's instructions about the medication prescribed. The patient was to return in 4 weeks for a follow-up appointment.

There were no other cases of injury or death related to pain management reported or discovered during this investigation.

Case Summary

The patient was a service-connected, Iraqi war veteran who received primary care at the Pontiac CBOC. During 2006–2009, management of the patient's chronic pain included

[5] VA/Department of Defense Practice Guideline, *Management of Opioid Therapy for Chronic Pain*, May 2010.

oral opiates, a nerve block, transcutaneous electrical nerve stimulation (TENS),[6] and chiropractic manipulations. The patient had a history of taking more than the prescribed amount of hydrocodone/acetaminophen and intermittently presented to the CBOC or the facility's emergency department (ED) complaining of incomplete pain relief. The CBOC provider prescribed oxycodone and morphine sulfate, but the patient reported adverse reactions to both.

In mid-February, a CBOC provider noted that the patient reported inadequate pain relief and that he was "having trouble staying asleep." Additionally, the patient informed the CBOC provider that he was receiving treatments from a chiropractor twice a week and that the treatments had provided "some improvement in mobility of neck and back, but the pain is persistent." The CBOC provider ordered a magnetic resonance imaging (MRI) study of the cervical spine and changed the patient's medication from hydrocodone/acetaminophen to oxycodone.

In March, the CBOC provider contacted the patient regarding the MRI results. The report indicated herniated cervical discs in two areas. The provider then ordered a neurology consult for further assessment. During this encounter, the patient also reported an adverse reaction to oxycodone. The provider changed the patient's pain medication back to hydrocodone/acetaminophen and requested the patient return any unused oxycodone. The patient returned 26 oxycodone tablets to the provider that same day.

During a follow-up appointment at the CBOC later that month, the patient reported a pain level of 9 on a 1–10 pain scale, and that he was using 16–20 hydrocodone/acetaminophen tablets daily to relieve pain. As a result, the provider changed the medication from hydrocodone/acetaminophen to morphine sulfate tablets. The provider advised the patient to go to the ED if he experienced any problems prior to his next appointment.

Within two weeks, the patient reported that he developed a rash from the morphine sulfate. In response, the provider discontinued the morphine sulfate, restarted the hydrocodone/acetaminophen, and requested a pain management consultation, advised the patient to use a TENS unit along with analgesic cream, and continue chiropractic care. The patient returned the unused morphine sulfate to the pharmacy for disposal.

Four days later, a Neurology Service provider evaluated the patient and recommended referral to the Neurosurgery Service. At that time, the patient again reported continuing pain unrelieved by medications.

[6] Transcutaneous electrical nerve stimulation is a technique used to control chronic pain in which electrodes applied to the skin deliver intermittent stimulation to surface nerves and block the transmission of pain signals.

In early May, a BPC provider evaluated the patient. During this encounter, he reported that he had run out of pain medication. The provider prescribed methadone, and documented patient education on the medication and its possible side effects. In addition, the provider also documented that the patient was instructed not to combine pain medications. The BPC scheduled a follow-up appointment for 4 weeks. On the day after this last BPC visit, a Neurosurgery Clinic provider evaluated the patient and advised him to continue with the current pain medication and treatment modalities.

The patient did not return to the BPC as scheduled and facility staff later learned that the patient had died 4 days after his last clinic visit. The facility obtained a copy of the patient's death certificate, which listed the cause of death as multi-drug toxicity.

Conclusions

We substantiated the allegation that PMC physicians prescribed CSs without adequate evaluation of patients.

We did not substantiate the allegation that PMC supervisors coerced providers to prescribe CSs to patients not under their care.

We did not substantiate the allegation that PMC providers' prescribing practices resulted in the death of a patient.

Recommendations

Recommendation 1. We recommended that the Medical Center Director ensure that managers define the expected frequency of provider evaluations for patients treated with opioid medications.

Recommendation 2. We recommended that the Medical Center Director ensure peer review of the PMC physician responsible for opioid prescriptions without adequate patient evaluation.

Comments

The VISN and Medical Center Directors concurred with the inspection results (See Appendixes A and B, pages 6–9, for the full text of the Directors' comments). We will follow up on the planned actions until they are complete.

(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: May 25, 2011

From: Director, Veterans In Partnership (10N11)

Subject: **Healthcare Inspection — Prescribing Practices in the Pain Management Clinic at John D. Dingell VA Medical Center, Detroit, Michigan**

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

Thru: Director, VHA Management Review Service (10A4A4)

Attached is the response from the Detroit VAMC. If you have any questions, please contact Kelley Sermak, Acting Quality Management Officer at (734) 222-4302.

Michael S. Finegan
Director, Veterans In Partnership (10N11)

Appendix B

Medical Center Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 25, 2011

From: Medical Center Director, John D. Dingell VA Medical Center (553/00)

Subject: **Healthcare Inspection — Prescribing Practices in the Pain Management Clinic at John D. Dingell VA Medical Center, Detroit, Michigan**

To: Director, Veterans In Partnership (10N11)

The information attached includes response to the recommendation in the Office of Inspector General's report.

Pamela Reeves MD

Dr. Pamela D. Reeves
Director, John D. Dingell VA Medical Center (553/00)

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

The following Director's comments are submitted in response to the recommendations in the Office of Inspector General's report:

OIG Recommendation

Recommendation 1. We recommended that the Medical Center Director ensure that managers define the expected frequency of provider evaluations for patients treated with opioid medications.

Concur **Target Completion Date: September 30, 2011**

Facility's Response:

In February 2010, the Pain Management Service initiated a process to bring itself into compliance with the stepped care delivery model for treatment of chronic pain. For Veterans chronically receiving stable doses of Schedule II Opioids, responsibility for prescriptions was transferred to Primary Care. This process continues to the present with the goal of relieving the Pain Management Service from providing prescriptions; except for those Veterans who require close supervision and those requiring relative high doses of opioids for which the Primary Care Providers lack adequate experience. These represent a relatively small number of Veterans.

The process will be completed by September 30, 2011, with the result that treatment of chronic pain will be based again in Primary Care.

This process will increase capacity and will allow the pain management team to conduct frequent, face to face encounters with our patients on Schedule II Opioids. To increase the capacity, the nurse practitioner in the pain clinic will have an added 8 hours of clinic time by June 1, 2011.

The Medical Center has established a policy for Schedule II Opioid use that requires patient visits for evaluation of pain management at a frequency of not less than every 6 months. In addition, telephone contact must be made between visits at a frequency of not less than every 3 months. All Veteran contacts regarding issues of pain management require documentation as stated in Medical Center Numbered Memorandum 11I-71, Chronic Opioid Use, dated May 16, 2011:

If the dose or frequency changes, long-term prescriptions of opioids for chronic pain will be re-entered and/or rewritten and adjusted accordingly,

patients who are undergoing dose modifications will be evaluated via a face-to-face encounter with the prescribing provider on a 30-day basis or more frequently.

If the therapy continues without a change in dose or dosing frequency for at least 3 months, a new prescription should be submitted to the Pharmacy to be refilled every 28 days and the patient must have a face-to-face encounter with prescribing provider every 6 months or sooner.

There should be at least one telephone encounter during the 6 month gap between face-to-face visits ideally at the 90 day mark.

The patient database on Schedule II Opioids will be reviewed periodically by the ACOS for Integrated Clinical Services and the Chief of Pharmacy to identify Veterans who have not been seen within 6 months. This process has been implemented. The national data reporting software was modified to allow those alerts to be generated for patients on Schedule II Opioids not seen in the VA within 6 months, as opposed to the previous version that allowed such a monitor only after 12 months of not having a VA visit. By August 31, 2011, all patients will receive appointments.

Recommendation 2. We recommended that the Medical Center Director ensure peer review of the PMC physician responsible for opioid prescriptions without adequate patient evaluation.

Concur **Target Completion Date: August 15, 2011**

Facility's Response:

With respect to the Pain Management Clinic physician responsible for 10 of the 11 patients referred to in the draft report receiving opioid prescriptions without adequate evaluation, all 10 cases will be sent out to a VISN 11 VA Medical Center for a Focus Professional Practice Evaluation. This was the decision made with discussion between the Chief of Staff at the John D. Dingell VAMC and the Senior Medical Officer at the Office of Quality and Performance. A Focus Professional Practice Evaluation (FPPE) will be completed by August 15, 2011.

Appendix C

OIG Contact and Staff Acknowledgments

OIG Contact	For more information about this report, please contact the Office of Inspector General at (202) 461-4720.
Acknowledgments	Verena Briley-Hudson, NP, Chicago Regional Director JoDean Marquez, RN, Team Leader Wachita Haywood, RN Jerome Herbers, Jr., MD Judy Brown, Program Support Assistant

Appendix D

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