Department of Veterans Affairs
Office of Inspector General

Healthcare Inspection

Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic

Report No. 12-01872-258

August 21, 2012

VA Office of Inspector General
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 by a complainant concerning management of chronic opioid therapy at the VA Maine Healthcare System Community Based Outpatient Clinic (CBOC) in Calais, Maine.

We reviewed the following allegations:

- Providers did not adequately assess patients who were prescribed opioids for chronic pain.
- Providers did not adequately monitor patients who were prescribed opioid medications for misuse or diversion of the medications.
- Facility managers asked providers to write opioid prescriptions for patients they had not assessed.

We substantiated the allegation that providers did not adequately assess patients who were prescribed opioids for chronic pain. Although providers performed initial pain assessments of patients, reassessments were not consistently documented at the minimum required frequency.

We substantiated the allegation that providers did not adequately monitor patients who were prescribed opioids for misuse or diversion of the medications. One provider did not properly follow-up on a patient's positive urine drug test, and due to staffing constraints at the CBOC, patients often obtained prescriptions from multiple providers.

We substantiated the allegation that facility managers asked providers to write opioid prescriptions for patients whom the providers had not assessed; however, VHA regulations do not require a provider to see a patient before writing an opioid prescription.

We recommended that the facility Director implement procedures to ensure that providers comply with all elements of management of chronic pain patients on opioid therapy at the Calais CBOC, including those highlighted in this report, as required by VHA and local policies.

The Veterans Integrated Service Network and Facility Directors concurred with the recommendation and provided an acceptable action plan. We will follow up on the planned actions until they are completed.

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

TO: Director, VA New England Healthcare System (10N1)

SUBJECT: Healthcare Inspection—Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections conducted an inspection to assess the merit of allegations made by a complainant concerning management of chronic opioid therapy and opioid prescribing practices at a VA Maine Healthcare System Community Based Outpatient Clinic (CBOC) located in Calais, Maine.

Background

Calais CBOC

The CBOC is part of the VA Maine Healthcare System (facility) and Veterans Integrated Service Network 1. The facility has 67 general medical, surgical, intermediate, and mental health beds; a 100-bed Community Living Center; and 6 CBOCs, including Calais. The CBOC is located in the northeast corner of Maine and offers primary care, preventative health, social work, and mental health services to approximately 1,100 veterans. The CBOC staffing is expected to include one medical administrative assistant, one licensed practical nurse, one registered nurse, and one provider.

Allegations

The OIG Hotline Division received an email from a complainant with concerns regarding management of patients on chronic opioid therapy and opioid prescribing practices at the CBOC. Specifically, the complainant alleged that:

- Providers did not adequately assess patients who were prescribed opioids for chronic pain.
- Providers did not adequately monitor patients who were prescribed opioid medications for misuse or diversion of the medications.

- Facility managers asked providers to write opioid prescriptions for patients they had not assessed.
- Patients or their family members are misusing or diverting opioid prescriptions.
- Facility employees are profiting from diversions of opioid prescriptions.

Management of Chronic Pain Patients on Opioid Medications

Opioid medications are natural or synthetic derivatives of opium that have pain-relieving properties. Examples of opioid medications include hydrocodone, oxycodone, methadone, and morphine. Although opioid medications can be a useful part of the management of chronic pain, patients on long-term opioid medications are at high risk for complications from the use of these medications, including the risk of death from accidental overdose. The number of poisoning deaths from prescribed opioid medications now exceeds that of heroin and cocaine combined.[1] Further, national surveys indicate that opioid medications are second only to marijuana as the most common drug of abuse and that most people who become addicted to this class of drugs begin by using prescribed medications.[2] Appropriate medical management for patients taking opioid medications, including initial assessments and regularly scheduled reassessments, is essential in reducing the risk of addiction or misuse of medication, drug diversion, and accidental overdose.

Scope and Methodology

We interviewed the complainant, facility managers, pharmacy staff, and CBOC staff. We reviewed Veterans Health Administration (VHA) and local policies governing chronic pain management and opioid prescriptions, relevant clinical practice guidelines, and medical literature. We also reviewed the electronic health records (EHRs) of 15 patients who received one or more opioid prescriptions from November 1, 2011, through January 31, 2012, from any CBOC provider. We selected the 15 patients who were prescribed the highest total number of morphine equivalents[3] during the 3-month review period and reviewed their EHRs from January 2011 through January 2012.

For the two allegations pertaining to drug diversion, the complainant was unable to provide specific information; therefore, we did not review these allegations.

[1] Centers for Disease Control and Prevention, *Vital Signs: Overdoses of Prescription Pain Relievers—United States 1999–2008*, Morbidity and Mortality Weekly Report, November 4, 2011 / 60(43); 1487–1492.
[2] Substance Abuse and Mental Health Administration, *Results from the 2009 National Survey on Drug Use and Health: Volume 1 Summary of National Findings*, http://www.samhsa.gov/data/2k9/2k9Resultsweb/web/2k9results.pdf, accessed on June 12, 2012.
[3] Morphine equivalents allow the direct comparison of opioids of different strengths and numbers of pills.

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.

Inspection Results

Issue 1: Patient Assessments

We substantiated the allegation that providers at the CBOC did not adequately assess patients who were prescribed opioids for chronic pain. Although providers performed initial pain assessments of patients, reassessments were not consistently documented at the minimum required frequency.

According to VHA policy, providers treating a patient with chronic pain must perform a comprehensive pain assessment and develop and implement a pain treatment plan. Furthermore, providers must periodically reassess the patient's "adherence, response to interventions, and achievement of time limited therapeutic goals."[4] This reassessment may include such elements as the response to treatment, changes in physical or psychosocial function or salient co-morbidities, and adherence to an opioid treatment agreement or prescribed therapy.

Facility policy also requires providers to perform a thorough diagnostic assessment[5] and recommends that periodic reassessments of patients be "no less frequently than every 6 months."[6] Facility policy also requires patients on chronic opioid therapy to have an opioid medication management agreement.[7]

Timeliness of Reassessments. For the 15 patients' reviewed, providers documented initial pain assessments and treatment plans, but 6 of the patients were not reassessed at least every 6 months. Reassessment time frames for these six patients ranged from 7 to 13 months.

Documentation of Reassessments. During the review period, the 15 patients had a total of 26 scheduled visits. One of the 26 reassessments did not include documentation of the patients' responses to treatment, and 12 reassessments did not include documentation related to patients' adherence to opioid medication management agreements and/or prescribed therapies. One reassessment did not include documentation of changes or stabilization of that patient's physical or psychosocial function or co-morbidities.

[4] VHA Directive 2009-053, *Pain Management*, October 28, 2009.
[5] Togus VA Medical Center Circular 00-09-25 (11), *Outpatient Prescription of Opioids*, April 1, 2009.
[6] Togus VA Medical Center Memorandum170-02-00, *Primary Care Service Line Pain Policy*, January 8, 2008.
[7] Togus VA Medical Center Circular 00-09-25 (11), *Outpatient Prescription of Opioids*, April 1, 2009.

Issue 2: Monitoring for Misuse

We substantiated the allegation that providers at the CBOC did not adequately monitor patients who were prescribed opioids for misuse or diversion of the medications. One provider did not properly follow-up on a patient's positive urine drug test (UDT), and patients often obtained prescriptions from multiple providers.

Facility policy requires that systems be in place to monitor for the potential of misuse or diversion of the medications including obtaining an Opioid Medication Management Agreement to establish expectations for patient behavior while on opioid medications.[8] As part of this agreement, patients agree to abstain from the use of illegal substances, to obtain medications from a single provider, and to cooperate with UDTs. UDTs, which may be done in conjunction with a scheduled clinic visit or on a different date, not only allow providers to determine whether a patient is currently taking his/her opioid medication, but also allow for the detection of other substances, such as illicit drugs.[9] According to the *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, the use of an illicit substance is considered a strong predictor of opioid misuse and "may warrant referral to a substance abuse/addiction consultant."[10] The VA/DoD Guideline also recommends that patients receive their medications from a single provider to reduce the risk of drug diversion.

Follow-Up on UDTs. Of 10 patients who had UDTs during the review period, 2 had UDTs that were positive for illicit substances. Although one of these results was addressed by the provider in the EHR, the positive test result for the other patient, who had a history of substance abuse, was not acknowledged. When CBOC staff alerted a provider of the results of the positive UDT, the provider documented that the labs were "generally satisfactory" without commenting on the UDT.

Multiple Prescribers. Thirteen of the 15 patients received opioid prescriptions from 2 or more providers at the facility. Two patients had their stable multiple opioid medication regimens abruptly changed by a float provider, including discontinuation of a long-standing medication for each patient. One patient's medication was discontinued and restarted on the same day by a different provider. The second patient experienced increased pain following the changes and requested reinstatement of his previous regimen within 1 month.

Issue 3: Prescriptions for Patients Not Assessed

We substantiated the allegation that facility managers asked providers to write opioid prescriptions for patients whom the providers had not assessed. Due to provider staffing

[8] Togus VA Medical Center Circular 00-09-25 (11), *Outpatient Prescription of Opioids*, April 1, 2009.
[9] *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, Version 2.0, 2010.
[10] Ibid.

constraints at the CBOC, providers frequently wrote renewal prescriptions for patients whom they had not personally assessed.

Because certain opioid prescriptions are restricted to a 30-day supply with no refills, patients on chronic opioid therapy must obtain a new prescription every month.[11] In situations where a patient's primary care provider is absent, facility policy allows a covering provider or the Service Line Manager for Primary Care (or designee) to approve a new prescription.[12] Although it is not against VHA or facility policy for a provider to renew an opioid prescription for a patient he or she has never seen, it is advisable for a provider to have a face-to-face visit or, at a minimum, a thorough review of the patient's chart before renewing an opioid medication.

CBOC staff told us that they forwarded telephone opioid renewal requests to the provider on duty. If no provider was on duty, staff sent the requests to a designated provider at the main facility. Because of the frequent changes in providers at the CBOC during the past year, requests for opioid medication renewals sometimes went to providers who had not evaluated the patient.

Staff also told us that the CBOC was heavily booked because of provider shortages. Consequently, if a new provider wanted to evaluate a patient before renewing a medication, it was not always possible to see the patient before their monthly medication was due for renewal. The provider would need to continue prescribing the medication until a clinic appointment could be scheduled.

Provider Shortage at the CBOC

Based on our reviews of facility policies and interviews with facility managers and CBOC staff, we determined that the poor opioid management practices and lack of coordinated care occurred, in part, because of a chronic shortage in provider staffing at the Calais CBOC. Since January 2011, the CBOC has been without a full-time provider. During that time, coverage has been provided by a combination of "float" providers from the main facility and another CBOC, locum tenens[13] providers, and telemedicine. For example, a physician assistant provides coverage 1 day a week, a physician provides telemedicine services 1.5 days per week, and a locum tenens physician provided regular coverage for a period of just less than 1 month. Facility leaders told us that they have been actively recruiting for a permanent provider without success.

Conclusion

We substantiated the allegations that CBOC providers did not appropriately assess chronic pain patients on opioid therapy and did not adequately monitor for the misuse of

[11] VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010.
[12] Togus VA Medical Center Circular 00-09-25 (11), *Outpatient Prescription of Opioids*, April 1, 2009.
[13] A provider contracted to work on a temporary basis to fill in for a vacancy, vacation, or extended leave.

opioid medications. Providers did not consistently assess pain at an appropriate frequency or follow up when monitoring patients for possible substance abuse. In addition, multiple providers prescribed opioids for the same patients. We also substantiated that facility managers asked providers to write opioid prescriptions for patients they had not assessed. While we recognize that a shortage of providers at the Calais CBOC contributed to these deficiencies, facility leaders need to strengthen procedures to ensure that patients on chronic opioid therapy are properly managed and monitored as directed by VHA and local policies.

Recommendation

Recommendation 1. We recommended that the facility Director implement procedures to ensure that providers comply with all elements of management of chronic pain patients on opioid therapy at the Calais CBOC, including those outlined in this report, as required by VHA and local policies.

Comments

The VISN and Facility Directors concurred with our recommendation and provided an acceptable action plan. (See Appendixes A and B, pages 7–12 for the Directors' comments.) We will follow up on the planned actions until they are completed.

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

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: July 26, 2012

From: Director, VA New England Healthcare System (10N1)

Subject: **Healthcare Inspection—Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic**

To: Director, Bedford Office of Healthcare Inspections (54BN)

Thru: Director, Management Review Service (10A4A4)

I have reviewed and concur with the action plans included in the attached memorandum regarding the Healthcare Inspection—Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic.

Sincerely,

(original signed by:)

Michael Mayo-Smith, MD, MPH
Network Director

Appendix B

Acting Facility Director Comments

Department of Veterans Affairs **Memorandum**

Date: July 23, 2012

From: Acting Director, VA Maine Healthcare System (402/00)

Subject: **Healthcare Inspection—Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic**

To: Director, VA New England Healthcare System (10N1)

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

OIG Recommendation:

Recommendation1. We recommended that the facility Director implement procedures to ensure that providers comply with all elements of management of chronic pain patients on opioid therapy at the Calais CBOC, including those highlighted in this report, as required by VHA and local policies.

The VA Maine Healthcare System concurs with the findings contained in the draft Healthcare Inspection Report as written. Please find our implementation plan showing corrective actions and target completion dates.

(original signed by:)

SUSAN A. MACKENZIE, Ph.D

Acting 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 Recommendations

Recommendation 1. We recommended that the facility Director implement procedures to ensure that providers comply with all elements of management of chronic pain patients on opioid therapy at the Calais CBOC, including those highlighted in this report, as required by VHA and local policies.

Concur **Target Completion Date:** December 2012

Facility Response:

Issue 1 – Patient Assessments. Providers did not adequately assess patients who were prescribed opioids for chronic pain.

Resolution/Actions to Be Taken. Providers will adequately assess patients prescribed opioids for chronic pain as evidenced by:

1. Scheduling an onsite visit with the medical provider for periodic reassessment at no less frequency than every six months either at the clinic or via a Telemedicine visit.

2. Letter sent to all Veterans receiving treatment for chronic non-malignant pain informing them of process in place to improve their care provided by their PCPs.

Status/Completion Date. Initial and reassessment scheduling implemented June 4, 2012. Letters sent June 7–8, 2012. Monitoring via chart reviews implemented August 2012 through December 2012.

Issue 2 – Monitoring for Misuse. Providers did not adequately monitor patients who were prescribed opioid medications for misuse or diversion of the medications.

Resolution/Actions to Be Taken. Providers will adequately monitor patients prescribed opioid medications for misuse or diversion of the medication by evidence by:

1. Patients will be required to provide periodic urine screens with no less frequency than annually as part of the Opioid Care Management Agreement on file for each veteran receiving treatment for chronic pain management per facility policy 00-12-02.

2. Patient with aberrant urine drug test (UDT) result will be referred by their provider to the Opioid Review Committee for review and treatment recommendations.

3. Patients will be asked to provide consent to participate in the Maine Prescription Monitoring Program. **Note:** Patient written consent is necessary for participation per VHA Directive. If a Veteran refuses to sign consent, this refusal will not eliminate the Veteran from participating in the opioid treatment program and none of their existing VA care and/or benefits will be affected by such refusal.

4. VA Maine will be developing Guidelines for maximal acceptable morphine equivalency for treatment of chronic non-malignant pain. Patients who are currently receiving chronic pain medication in excess of those identified levels of morphine equivalency will be identified and contacted individually to work with their providers to taper current medications to levels within the acceptable morphine equivalency ranges.

Status/Completion Date. August 6, 2012 for referrals to the Opioid Review Committee for patients with aberrant UDT results and participation in the Maine Prescription Monitoring Program. November 5, 2012 for the developing of Guidelines for maximal acceptable morphine equivalency for treatment of chronic non-malignant pain.

Issue 3 – Prescriptions for Patients Not Assessed. Facility managers asked providers to write opioid prescriptions for patients they had not assessed.

Resolution/Actions to Be Taken. All providers prescribing opioids for patients will assess patients per VA protocol as evidenced by:

1. Whenever possible, it will be the provider on record prescribing opioids for patients undergoing non-malignant chronic pain therapy. On site locum tenens providers who are unfamiliar with the patient(s) requesting opioid prescription(s), must review the most recent reassessment documented in the patient's record prior to prescribing additional therapy. Documentation of the review will be entered into the patient's record.

2. Action steps listed within this plan will minimize the frequency when an opioid prescription is requested outside regularly scheduled reassessment

appointments by the clinic RN, on-site Provider or by a Telemedicine visit. In special circumstances the assistance of the covering Primary Care Provider will be necessary.

Status/Completion Date. Ongoing until VA Maine's Leadership determines consistent compliance is evident and sustained for six consecutive months.

Additional Action Items:

Provider Coverage. VA Maine is continually challenged to maintain Provider coverage to this remote location in Maine. Leadership fully understands that extended gaps of inconsistent provider coverage undermine optimal care.

Resolution/Actions to Be Taken. VA Maine's Leadership will continue to aggressively find ways to attract and recruit a Licensed Provider for the Calais CBOC as evidenced by:

1. Continued discussions regarding recruitment incentives to include the following options to consider:

    a. Increasing salary proposal

    b. Initiate more extensive recruitment efforts

Status/Completion Date. Ongoing

Medical Marijuana. Guidelines for Managing Chronic Opioid Therapy in Patients that may have a State of Maine Medical Marijuana Authorization.

Resolution/Actions to Be Taken. Managing chronic opioid therapy and concomitant marijuana use will be evidence by use of recently implemented guidelines that include:

1. Guidelines developed to communicate to VA Maine's Providers the facility position on opioid therapy and concomitant marijuana use.

2. Providers are encouraged to discontinue use chronic opioid prescriptions when concomitant marijuana use is objectively evidenced.

3. Multidisciplinary committee review will be the avenue of appeal for limited special exceptions as listed in guidelines.

Status/Completion Date. Guidelines published 6/15/2012.

Documentation of Assessments. Inconsistencies found in documentation of required elements for the initial and subsequent periodic reassessments.

Resolution/Actions to Be Taken. Standardized and consistent documentation of patients initial and follow up assessments for receiving chronic opioid therapy for pain will be evidenced by the:

1. Development of a standardize note template, "OPIOID CARE PLAN REASSESSMENT NOTE," that will include required elements per VHA Directive to document individualized plan for patient receiving chronic pain opioid therapy. Elements will include:

    a. Current pain medications prescribed

    b. Date of last visit

    c. Date of last UDS

    d. Current pain level with medication

    e. Current level of physical/psychosocial function

    f. Opioid Care Plan Agreement (OCPA) is in place and current level of adherence to OCPA and prescribed therapy

    g. Any noted changes in comorbidities or medication changes

Status/Completion Date. In development with proposed implementation Sept. 4, 2012.

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	Claire McDonald, MPA, Project Leader Lynn Sweeney, MD, Team Leader Annette Acosta, MN, RN Jerome Herbers, MD Jeanne Martin, PharmD Matt Frazier, MPH

Appendix D

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