Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 14-00351-53

Healthcare Inspection

Alleged Inappropriate Opioid Prescribing Practices Chillicothe VA Medical Center Chillicothe, Ohio

December 9, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to allegations that physicians at the Chillicothe VA Medical Center, Chillicothe, OH prescribed opioid medications for patients they had never evaluated. In addition, patients were alleged to be at risk because no prescriber was monitoring them for adverse reactions, pain relief, or opioid abuse. The purpose of the inspection was to determine the merit of the allegations.

We did not substantiate that physicians improperly prescribed opioid medications for patients whom they had not seen or examined. We did substantiate that physicians prescribed opioids for patients with whom they had no direct interaction, but this is not a violation of law or VA policy.

We substantiated that physicians did not consistently document medication effectiveness prior to renewing prescriptions for patients at increased risk for adverse medication effects or diversion. We also found that physicians were not consistently documenting use of the Ohio Automated Rx Reporting System, a state prescription drug monitoring program. We did find that urine drug screens were routinely performed.

According to Veterans Health Administration policy, patients on chronic opioid therapy are to be evaluated every 1 to 6 months. Although renewing opioid prescriptions without examining patients is not a violation of law or VA policy, a minimum review of patient information is required. Our review of 88 patients for whom opioids were prescribed in 2013 and 2014, and who were at increased risk for complications or abuse of opioids, revealed that physicians did not appropriately assess patients before renewing opioid prescriptions.

We recommended that the Facility Director ensure that patients receiving recurrent prescriptions for high potency and/or large quantities of opioid medications are routinely identified and provided appropriate follow-up care, and prescribing physicians review the prescription history reports contained in the Ohio Automated Rx Reporting System for patients who are prescribed opioids.

Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 7–10 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

Purpose

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection in response to allegations that physicians at the Chillicothe VA Medical Center (facility), Chillicothe, OH, prescribed opioid medications for patients they had never evaluated. In addition, patients were alleged to be at risk because no prescriber was monitoring them for adverse reactions, pain relief, or opioid abuse. The purpose of the inspection was to determine the merit of the allegations.

Background

The facility provides tertiary and long-term care including acute and chronic mental health care, primary care, acute inpatient medical care, and long-term care. It is part of Veterans Integrated Service Network (VISN) 10, the VA Healthcare System of Ohio, and serves a veteran population of about 22,000 throughout 17 counties in southeastern Ohio. The facility has 35 acute medical beds, 28 acute psychiatric beds, 28 Psychosocial Residential Rehabilitation Treatment Program beds, and 50 Domiciliary Residential Rehabilitation Treatment Program beds. Long term care is provided in a 162-bed Community Living Center. Outpatient care is provided at five community based outpatient clinics in Athens, Cambridge, Lancaster, Marietta, and Portsmouth, OH.

A 2009 Veterans Health Administration (VHA) directive on pain management requires that when opioid analgesics are prescribed for regular use physicians periodically document treatment effectiveness.[1] In 2010, VHA and the Department of Defense (DoD) jointly published guidelines for the management of opioid therapy in patients with chronic pain.[2]

An anonymous complaint was made to the Ohio State Medical and Pharmacy Boards, which referred the allegations to the Drug Enforcement Administration. The case was then forwarded to the VA Office of Inspector General. The complainant alleged that physicians were prescribing opioid medications for patients they had never seen and that patients were at risk since no prescriber was directly examining and monitoring them for adverse reactions, pain relief, or opioid abuse.

Scope and Methodology

We conducted a site visit on March 25, 2014, and interviewed facility leaders, physicians, and pharmacists. We reviewed VHA and relevant facility policies governing pain management and prescribing practices, the *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain (*VA/DoD Guideline*)*, and medical literature. We also reviewed relevant statutes and regulations.

[1] VHA Directive 2009-053, Pain Management, October 28, 2009
[2] *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain,* Version 2.0, 2010.

Patients prescribed higher potency and/or larger quantity medications are known to be at increased risk for problems associated with opioid use[3,4] and warrant more frequent clinical evaluations.[5]

To evaluate prescribing practices for pain medications, we obtained from the facility a list of the 5,202 prescriptions for opioid medications ordered from January 1, 2013, through March 31, 2014, by the two physicians named by the complainant. After excluding oral solutions and injectable medications, we assessed prescribing practices for the periods January–March 2013 and January–March 2014 by reviewing 88 patient electronic health records (EHRs). These time frames were selected to represent periods of concern described in the allegations and to assess more recent practices. To focus on patients with an increased risk of adverse medication effects and medication diversion, we reviewed recurring prescriptions for:

- Fentanyl 100 microgram (mcg)/hour patches
- Hydrocodone 10/ APAP 325 tablets
- Hydromorphone tablets
- Methadone 10 milligram (mg) tablets in quantities of 100 or greater
- Morphine 60 mg tablets in quantities of 100 or greater
- Oxycodone 20 mg and 80 mg tablets, oxycodone 10 mg in quantities of 160 and greater, and oxycodone 20 mg in quantities of 100 or greater

We excluded prescriptions for:

- Lower potency preparations (hydrocodone 5 mg; oxycodone 5 mg; morphine sulfate 15 and 30 mg; methadone 5 mg; codeine; and fentanyl transdermal 25, 50, and 75 mcg/hour)
- Oxycodone 10 mg in quantities less than 160
- Morphine, methadone, and oxycodone 20 mg in quantities less than 100

In March 2013, the facility Chief of Staff directed providers to begin use of the Ohio Automated Rx Reporting System, a state drug monitoring program. We therefore reviewed use of the state system by facility providers in 2014.

[3] Bohnert ASB, Valenstein M, Bair MJ, et al. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*. 2011; 305:1315–1321.
[4] Centers for Disease Control and Prevention. Policy impact: prescription painkiller overdoses. Available at: http://www.cdc.gov/homeandrecreationalsafety/rxbrief. Accessed September 15, 2014.
[5] VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010, p. 51. http://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf.

The VA/DoD Clinical Guideline recommends that patients on chronic opioid therapy undergo periodic or random urine drug screen (UDS) testing, and local policy[6] requires at least annual testing. We included an assessment of UDS testing in EHR reviews.

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.

[6] ChillicotheVAMC Policy Memorandum No. 11-138, February 2011, p. 3.

Inspection Results

Issue 1: Opioid Medications

We did not substantiate that physicians improperly prescribed opioid medications for patients whom they had not seen or examined. Although we found that physicians renewed opioid prescriptions for patients with whom they had no direct interaction, this practice is not a violation of law or policy.

VHA policy requires that when opioid analgesics are prescribed for regular use, physicians document treatment effectiveness, including pain control, function, and quality of life.[7] Certain opioid prescriptions are restricted to a 30-day supply with no refills, requiring patients to obtain renewal prescriptions every month.[8] We found that physicians did renew opioid prescriptions for patients whom they had not seen in order to prevent patients from being without their prescribed medications. These physicians prescribed opioids for patients of physicians who had evaluated and examined the patient but were on leave, new to the facility, had left the facility, or had computer access problems.

The Ohio state code specifies that in exceptional circumstances, physicians may renew opioid prescriptions for patients they have not evaluated[9]—for example, renewing prescriptions for care provided in an institutional setting, cross-coverage for another provider, on-call situations, and in hospice settings. VHA policy does not prohibit a provider from renewing an opioid prescription for a patient he or she has not evaluated.

Issue 2: Patient Review

We substantiated that physicians did not consistently document medication effectiveness prior to renewing prescriptions for patients at increased risk for adverse medication effects or diversion. We also found that physicians were not consistently documenting use of the Ohio Automated Rx Reporting System for these patients. We did find that urine drug screens were routinely performed.

VHA policy requires that physicians treating a patient with chronic pain must periodically evaluate the patient's condition.[10] VHA policy also calls for the use of published clinical guidelines for pain management protocols, including the VA/DoD Guideline. The VA/DoD Guideline recommends that "at every visit and telephone contact for opioid renewal, assess and document adherence with appropriate use of opioid analgesics, and any evidence of misuse, abuse, or addiction."[11] The VA/DoD Guideline also recommends random periodic urine drug tests.

[7] VHA Directive 2009-053, *Pain Management*, October 28, 2009.
[8] VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 6, 2010.
[9] Ohio Administrative Code §4731-11-09.
[10] VHA Directive 2009-053.
[11] VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010. http://www.va.gov/painmanagement/docs/cpg_opioidtherapy_fulltext.pdf.

During January–March 2013, the two named physicians entered 72 prescriptions for high potency preparations and/or large quantities of opioid medications for 53 patients. During January–March 2014, the same physicians entered 61 such prescriptions for 35 patients.

We reviewed documentation in the EHR of each in-person and telephone encounter for these patients during the 90-day period preceding the renewal of an opioid prescription.[12] For 18 (14 percent) of the 133 recurring prescriptions for opioids, patients had no encounters in the 90 days prior to renewal. For 18 (14 percent) of the 133, encounters were documented, but there was no assessment of the effectiveness of the opioid medication.

Of the 88 increased-risk patients whose EHRs were reviewed, we identified 14 who were at even greater risk because of a history of substance abuse. Two of these 14 patients had no encounter in the 90 days prior to prescription renewal, and 2 of the remaining 12 who did have an encounter had no documented assessment of the effectiveness of the opioid medication.

Of the 14 patients with a history of substance abuse, 5 were also prescribed benzodiazepine medications, which are known to further increase the risk associated with opioid use. One of the five patients with a substance abuse history who was also prescribed a benzodiazepine had no documented pain assessment within 90 days of prescription renewal.

In 2014, physicians at the facility began using the Ohio Automated Rx Reporting System. Our review showed documented checks of the system in 26 of 61 (43 percent) prescriptions reviewed.

Of the 88 patients reviewed, 75 (85 percent) had urine drug screens within the past year.

Conclusions

We did not substantiate that physicians improperly prescribed opioid medications for patients whom they had not seen or examined. Although we found that physicians renewed opioid prescriptions for patients with whom they had no direct interaction, this practice is not a violation of law or policy.

We substantiated that physicians did not consistently document medication effectiveness prior to renewing prescriptions for patients at increased risk for adverse medication effects or diversion. We also found that physicians were not consistently

[12] Ibid. The VA/DoD Guideline recommends that "Patients who are on a stable dose of medication without evidence of adverse effects or adherence problems may be followed every 1–6 months." We selected the 90-day timeframe because patients at increased risk for adverse medication effects and/or medication diversion would generally require more frequent follow-up than every 6 months.

documenting use of the Ohio Automated Rx Reporting System for these patients. We did find that urine drug screens were routinely performed.

Recommendations

1. We recommended that the Facility Director identify patients receiving recurrent prescriptions for high potency and/or large quantity opioid medications and ensure appropriate periodic assessments.

2. We recommended that the Facility Director ensure that prescribing physicians check the Ohio Automated Rx Reporting System for patients who are prescribed high potency and/or large quantity opioid medications.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: November 12, 2014

From: Director, VA Healthcare System of Ohio (10N10)

Subj: Healthcare Inspection—Alleged Inappropriate Opioid Prescribing Practices, Chillicothe VAMC, Chillicothe, Ohio

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

1. Attached, please find the comments and corrective action plan for the report of Healthcare Inspection of Alleged Inappropriate Opioid Prescribing Practices at the Chillicothe VA Medical Center, Chillicothe, Ohio.

2. I have reviewed and concur with the Medical Center Director's response.

3. For additional questions, please feel free to contact Ms. Jane Johnson, VISN 10 Acting Deputy Network Director at 513-247-4631.

(*original signed by Jane Johnson, Acting Deputy Network Director, VISN 10 for:)*
Jack G. Hetrick, FACHE Network Director,
VA Healthcare System of Ohio (10N10)

Appendix B

Facility Director Comments

Department of Veterans Affairs

Memorandum

Date: November 12, 2014

From: Director, Chillicothe VA Medical Center, Chillicothe, Ohio (538/00)

Subj: Healthcare Inspection— Alleged Inappropriate Opioid Prescribing Practices, Chillicothe VAMC, Chillicothe, Ohio

To: Director, VA Healthcare System of Ohio (10N10)

1. Thank you for the opportunity to review the draft report of Healthcare Inspection of Alleged Inappropriate Opioid Prescribing Practices at the Chillicothe VA Medical Center, Chillicothe, Ohio. I have reviewed the document and concur with the recommendations. A corrective action plan is in place and I will ensure it is tracked to completion.

2. If you have any questions regarding our response or planned corrective action, please feel free to contact me at 740-772-7002.

(*original signed by:)*
Wendy J. Hepker, FACHE
Medical Center Director

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the Facility Director identify patients receiving recurrent prescriptions for high potency and/or large quantity opioid medications and ensure appropriate periodic assessments.

Concur

Target date for completion: April 1, 2015

Facility response: The Chillicothe VAMC strengthened processes to ensure that physicians and other prescribers evaluate Veteran's condition prior to prescribing an opioid; to include evaluation of effectiveness, adherence to care plan, and quality of life. This evaluation can be by office visit or telephone assessment at least once every 90 days.

A monthly audit of an appropriate sample size from Veterans receiving recurrent prescriptions for high potency and/or large quantity opioid medication will be implemented. The audit will assess if the required practice adherence is demonstrated by the Veteran being properly evaluated in the past 90 days; to include medication effectiveness, adherence, and quality of life. Monthly audits will continue until three consecutive months of at least 90% compliance demonstrates practice adherence. Any deficiencies will be addressed with the appropriate clinical staff through training or other appropriate steps. Audit results will be reported and tracked through the Quality Council.

Recommendation 2. We recommended that the Facility Director ensure that prescribing physicians check the Ohio Automated Rx Reporting System for patients who are prescribed high potency and/or large quantity opioid medications.

Concur

Target date for completion: April 1, 2015

Facility response: The Chillicothe VAMC strengthened processes to ensure that prescribing physicians and physician extenders use the Ohio Automated Rx Reporting System (OARRS) before prescribing any high potency and/or large quantity opioid medications. A specific tool for documenting the utilization of the OARRS in CPRS has been deployed.

A monthly audit of Veterans receiving recurrent prescriptions for high potency and/or large quantity opioid medication will take place. The review will assess if the State Prescription Drug Monitoring Program progress note is present. Monthly reviews will

continue until three consecutive months of at least 90% compliance demonstrates practice adherence. Any deficiencies will be addressed with the appropriate clinical staff through training or other appropriate steps. Audit results will be reported and tracked through the Quality Council.

Appendix C

Office of Inspector General Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
Contributors	Bruce Barnes, Team Leader Lisa Barnes, LCSW Myra Conway, RN Jerome Herbers, MD Randall Snow, JD Natalie Sadow, MBA

Appendix D

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