Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-00133-12

Healthcare Inspection

Alleged Improper Opioid Prescription Renewal Practices San Francisco VA Medical Center San Francisco, California

November 7, 2013

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 complaints concerning improper opioid prescription renewal practices in the Medical Practice Clinic at the San Francisco VA Medical Center (facility), San Francisco, CA. We reviewed the following allegations: (1) attendings on-duty are tasked with evaluating numerous opioid renewal requests for patients with whom they are unfamiliar, (2) providers do not routinely document patients' opioid prescription renewal problems in the electronic health record, and (3) there have been patient hospitalizations and deaths related to opioid misuse.

We substantiated that attendings on-duty are tasked with evaluating numerous opioid renewal requests for patients with whom they are unfamiliar; however, Veterans Health Administration regulations and local policy do not prohibit such practice.

We partially substantiated that providers do not routinely document patients' opioid prescription renewal problems in the electronic health record. The providers did not consistently document an assessment for adherence with appropriate use of opioids and monitor patients for misuse, abuse, or addiction. The primary care providers did not consistently complete the templated Narcotic Instructions Note for patients with opioid prescription renewal problems.

We partially substantiated that there have been hospitalizations and deaths of patients related to opioid misuse. Seven patients were hospitalized for opioid overdose; however, the primary care provider, Psychiatry Service, and/or the facility's Substance Abuse Program assessed and appropriately monitored the patients for misuse. There were no deaths related to opioid overdose.

We recommended that the Facility Director (1) ensure that providers comply with all elements of the management of opioid therapy for chronic pain, as required by Veterans Health Administration and the *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain,* and (2) ensure that the Narcotic Instructions Note is reevaluated for appropriate use in the Medical Practice Clinic and that providers comply with established protocol.

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided an acceptable action plan. (See Appendixes A and B, pages 6–9 for the Director's 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

At the request of Senator Patty Murray, former Chairperson of the Senate Committee on Veterans' Affairs, 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 improper opioid prescription renewal practices in the Medical Practice Clinic (clinic) at the San Francisco VA Medical Center (facility) in San Francisco, CA.

Background

The facility, part of Veterans Integrated Service Network (VISN) 21, is a tertiary care facility that delivers comprehensive medical care for veterans throughout Northern California. It has 104 operating beds and provides services in primary care, surgery, pain management, mental health, rehabilitation, and other specialties.

The clinic serves approximately 10,000 patients and is staffed with 10 nurse practitioners and 30 primary care physicians. All of the primary care physicians are part-time in the clinic, with hours ranging from 2 to 20 per week. The clinic also has physician attendings on-duty[1] (AODs) which includes primary care physicians, internists, and geriatricians. The AODs' responsibilities include supervising resident physicians, other clinicians, and ancillary staff; reviewing cases and co-signing medical records; addressing time sensitive test results; and evaluating requests for medication renewals when the ordering provider is unavailable. The clinic schedules one to four AODs per half-day clinic.[2] The 28 AODs have varying on-duty schedules from 2 half-days per week to 1 half-day per month.

Allegations

In October 2012, the OIG's Hotline Division contacted the complainant to follow up on the allegations made. According to the complainant, the clinic's opioid prescription renewal practices were "less than ideal," and the AODs had problems adequately evaluating patients with opioid prescription renewal requests. Specifically, the complainant alleged the following:

- AODs are tasked with evaluating numerous opioid renewal requests for patients with whom they are unfamiliar.
- Providers do not routinely document patients' opioid prescription renewal problems in the electronic health record (EHR).
- There have been hospitalizations and deaths of patients related to opioid misuse.

[1] The clinic uses the term preceptor; however, in our interviews, the staff referred to this position as the attending on-duty.
[2] The clinic divides each clinic day into two half-day clinics, with each half-day consisting of a 4-hour period.

Scope and Methodology

We conducted telephone interviews with the complainant in October 2012. We visited the facility the week of December 10, 2012, and interviewed facility leadership, 12 AODs, and other clinical staff. We reviewed Veterans Health Administration (VHA) and local policies governing pain management and prescribing practices, the *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*[3] (*VA/DoD Guideline*), and medical literature. For fiscal year 2012, we reviewed the EHRs of 20 clinic patients who received chronic opioid therapy and the EHRs of all clinic patients with a discharge diagnosis related to opioid overdose. We identified the patients for our EHR review from the VHA Corporate Data Warehouse. We also reviewed the EHRs of 11 clinic patients named by the complainant.

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

Inspection Results

Issue 1: Opioid Prescription Renewal Process

We substantiated the allegation that AODs are tasked with evaluating numerous opioid renewal requests for patients with whom they are unfamiliar.

VHA policy requires that certain opioid prescriptions are restricted to a 30-day supply with no refills requiring patients to obtain a new or renewal prescription every month.[4] During the course of our inspection, we found that all clinic physicians were part-time; therefore, patients requiring opioid prescription renewals every 30 days could be subjected to extended periods without their opioid medication(s). Senior leaders reported that in an effort to avoid such situations, a prescription renewal process was implemented for those instances when a patient requires a medication renewal but is unable to schedule a timely encounter with his or her primary care provider (PCP). The renewal process, established in 2006, assigned the AODs responsibility for evaluating all medication renewal requests, including opioids. At that time, the facility hired clinical pharmacists designated to screen all renewal requests prior to the AOD's evaluation.

The AODs we interviewed validated the complainant's allegation that within their on-duty half-day clinics they evaluate multiple opioid renewal requests for patients unknown to them. VHA policy, however, does not prohibit a provider from renewing an opioid prescription for a patient he or she has not evaluated in person. In addition, facility protocol requires a clinical pharmacist to screen every opioid renewal request of

[3] *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, Version 2.0, 2010.
[4] VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 6, 2010.

patients who call or present to the clinic without an appointment. The screen includes a comprehensive review of the EHR for appropriate timing of prescription renewal and adherence with medication and PCP visits prior to referring the request to the AOD. The AOD performs a subsequent EHR review and based on clinical judgment, renews the opioid prescription for 30 days, prescribes a limited quantity to "bridge" the patient until the next PCP appointment, denies the request, or defers it to the patient's PCP.

All AODs reported having knowledge of the option to deny opioid renewal requests and defer them to the PCP, and none expressed any pressure from their colleagues to grant renewal requests. In addition, it was the general consensus of the AODs that the clinical pharmacist's preliminary review of the EHR was extremely helpful.

Issue 2: Documentation of Adherence and Misuse, Abuse, or Addiction

We partially substantiated the allegation that providers do not routinely document patients' opioid prescription renewal problems in the EHR.

VHA policy requires that providers treating a patient with chronic pain must periodically evaluate the patient's adherence.[5] VHA policy[6] also calls for the use of published clinical guidelines for pain management protocols, including the *VA/DoD Guideline*.[7] The *VA/DoD Guideline* recommends that at every visit and for every telephone contact requesting opioid prescription renewal, providers assess and document adherence with appropriate use of opioids and any evidence of misuse, abuse, or addiction. The *VA/DoD Guideline* also recommends random periodic urine drug tests to confirm adherence.

We reviewed the EHRs of 31 patients on chronic opioid therapy, including the 11 patients the complainant identified, for evidence of a provider encounter that included an appropriate assessment for all opioid prescription renewals. Of the 11 patients, one did not have any opioids prescribed during the 12 months reviewed, and one was no longer under the care of the clinic; therefore, those patients were not included in further analysis. Of the remaining 29 patients' EHRs, we found that 140 (53 percent) of the 264 opioid prescription renewals reviewed did not have any documentation of a provider assessment. In the 124 encounters[8] with a provider assessment, 10 encounters (8 percent) did not have documented evidence of an assessment for adherence with appropriate use of opioids, and 23 (19 percent) encounters did not have documented evidence of an assessment for misuse, abuse, or addiction. Additionally, 10 patients' EHRs did not have documentation of a urine drug test.

We also found that the clinic uses a paper Prescription Request Form to communicate the status of the renewal request among clinic staff; however, the form is shredded and does not become a permanent part of the patient's EHR.

[5] VHA Directive 2009-053, *Pain Management*, October 28, 2009.
[6] Ibid.
[7] *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, Version 2.0, 2010*
[8] An encounter includes both face-to-face visits and telephone contacts.

In addition, we reviewed the EHRs for the presence of a templated Narcotic Instructions Note which the clinic implemented to provide AODs and other providers with guidance regarding opioid prescription renewals. The PCP completes the note which addresses the following parameters: (1) on time opioid prescription renewal by any provider, (2) early opioid prescription renewal by any provider, (3) necessity and frequency of urine drug tests prior to opioid prescription renewal, and (4) necessity and timeliness of an appointment with PCP prior to opioid prescription renewal.

All of the AODs interviewed were familiar with the templated Narcotic Instructions Note. Several of the AODs told us that the prevailing practice among the PCPs was to complete the note only if the patient had opioid prescription renewal problems (non-adherence to prescribed medication or misuse, abuse, or addiction), and that in the absence of the note, the presumption was permissible opioid renewals.

Of the 29 patients' EHRs reviewed, we found 22 (76 percent) that had evidence of opioid prescription renewal problems. We found that 13 (59 percent) of the 22 did not have the Narcotic Instructions Note.

Issue 3: Alleged Patient Deaths and Hospitalizations

We partially substantiated the allegation that there have been patient hospitalizations and deaths related to opioid misuse.

We reviewed the EHRs of all clinic patients who were hospitalized for a drug overdose and found seven that overdosed on an opioid. We found that three of the patients attempted suicide with opioids, three patients took more than the prescribed dose of opioid medications, and one patient took opioids with illicit drugs. We also found that the Psychiatry Service and/or the facility's Substance Abuse Program closely monitored five of the seven patients, a PCP monitored one patient on a weekly basis, and one patient was registered at the facility but had not established care with the clinic prior to the overdose.

We did not find any deaths related to opioid overdose. The complainant provided the name of one patient who was receiving chronic opioid therapy and apparently died at another hospital. The facility reported that the patient's cause of death was unknown; therefore, we were not able to obtain any further information.

Conclusions

Although we substantiated the allegation that AODs are tasked with evaluating numerous opioid renewal requests for patients with whom they are unfamiliar, VHA policy does not prohibit such practice. The AODs could defer an opioid renewal request to the PCP if uncomfortable renewing the prescription.

We partially substantiated the allegation that providers do not routinely document opioid prescription renewal problems in the EHR. We determined that the providers did not consistently document an assessment for adherence with appropriate use of opioids.

While we recognize that the clinical pharmacists perform a comprehensive review of the EHR, VHA policy requires documentation of all elements of pain management including adherence. In addition, we determined that the PCPs did not consistently monitor patients for misuse. We did find that the facility had developed a templated Narcotic Instructions Note for the PCPs to provide specific guidance for opioid renewals; however, the PCPs did not consistently complete the note for patients with opioid prescription renewal problems.

We partially substantiated the allegation that there have been patient hospitalizations and deaths related to opioid misuse. Although we found seven patients that were hospitalized for opioid overdose, we determined that the PCP, Psychiatry Service, and/or the facility's Substance Abuse Program assessed and appropriately monitored the patients for misuse. We did not find any deaths related to opioid overdose.

Recommendations

1. We recommended that the Facility Director ensures that providers comply with all elements of the management of chronic pain patients on opioid therapy, as required by VHA and the *VA/DoD Guideline*.

2. We recommended that the Facility Director ensures that the Narcotic Instructions Note is reevaluated for appropriate use in the clinic and that providers comply with established protocol.

Appendix A

VISN Director Comments

Department of Veterans Affairs **Memorandum**

Date: September 24, 2013

From: VISN Director

Subject: **Healthcare Inspection – Alleged Improper Opioid Prescription Renewal Practices, San Francisco VAMC, San Francisco, CA**

To: Director, San Diego Office of Healthcare Inspections (54SD)

Director, Management Review Service (VHA 10AR MRS OIG Hotline)

1. Attached is the action plan developed by the San Francisco VAMC in response to the site review that occurred in regards to the allegations of Improper Opioid Prescription Renewal Practices.

2. I am confident that their detailed plan will correct any deficiencies noted and will improve the care provided to the Veterans.

3. If you have any questions please contact Terry Sanders, Associate Quality Manager at (707) 562-8370.

Sheila M. Cullen

Attachments

Appendix B

Facility Director Comments

Department of Veterans Affairs **Memorandum**

Date: September 24, 2013

From: Facility Director

Subject: **Healthcare Inspection – Alleged Improper Opioid Prescription Renewal Practices, San Francisco VAMC, San Francisco, CA**

To: Director, Sierra Pacific Network (10N21)

1. I appreciate the opportunity to provide comments to the draft report of the Healthcare Inspection on Alleged Improper Opioid Renewal Practices at the San Francisco VA Medical Center.

2. I concur with all of the findings and suggested improvement actions.

3. In closing, I would like to express my thanks to the OIG review team whose members were professional, helpful, and courteous.

Bonnie S. Graham, MBA
Director, San Francisco VA Medical Center

Comments to OIG's Report

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

OIG Recommendations

Recommendation 1. We recommended that the Facility Director ensure providers comply with all elements of the management of chronic pain patients on opioid therapy, as required by VHA and the *VA/DoD Clinical Guideline*.

Concur

Target date for completion:

1) 10/01/2013: PACT team primary assumption of opioid therapy renewal
2) 12/31/2013: Education and process improvement changes

Facility response: As of 10/01/2013, San Francisco VA Medical Center (SFVAMC) Medical Practice will discontinue the use of Attending on Duty coverage for routine review and completion of opioid prescription urgent renewals (defined as patient same day requests by telephone or walk in). The primary responsibility for review and renewal of all opioid prescriptions (including urgent renewals) will be with the primary care provider (PCP) and his/her Patient Aligned Care Team (PACT). The PACT teams will include proactive opioid management in their regular huddles to reduce the need for urgent renewals and utilize the opioid dashboard on a regular basis to identify patients with higher risk for safe use of opioids and the need for urine drug testing. All primary care PACT teams will be educated and actively use the opioid dashboard in their huddles. Monitoring of the number of opioid urgent renewals will be reported to the SFVAMC Leadership Board monthly starting in November 2013.

In addition, further education is planned for providers, clinic staff and patients on the expectations of the elements of the management of chronic pain patients on opioid therapy, as required by VHA and the *VA/DoD Clinical Guideline* and the facility is participating as a pilot site for a new opioid decision support tool, ATHENA-OT, which integrates the VA/DOD guidelines. In addition, Pharmacy has completed comprehensive Opioid Optimization Support Notes on all Medical Practice patients on >200 mg/day of morphine equivalents, and is currently in the process of completing comprehensive notes on all Medical Practice patients on >120 mg/day of morphine equivalents which will be completed by the 12/1/2013. PCPs are required to place an addendum to the pharmacy notes in the chart within 2 weeks to document their plan. PCP completion of an appropriate Opioid Optimization Support Note addendum will be monitored and reported to the SFVAMC Leadership Board monthly starting in November 2013.

Recommendation 2. We recommended that the Facility Director ensures that the Narcotic Instructions Note is reevaluated for appropriate use in the clinic and that providers comply with established protocol.

Concur:

Target date for completion: 12/31/2013

Facility response: As part of the education and review efforts outlined above, the Narcotic Instructions Note (NIN) will be reviewed and reevaluated for appropriate use by the clinic. A protocol for NIN use in patients on >120 mg/day of morphine equivalents will be developed and implemented. All Medical Practice patients on >120 mg/day of morphine equivalents will have a NIN. Monitoring data on note compliance with the requirement for a NIN will be reported to the SFVAMC Leadership Board monthly starting in November 2013.

Appendix C

OIG Contact and Staff Acknowledgments

Contact	For more information about this report, please contact the OIG at (202) 461-4720.
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Appendix E

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