



Department of Veterans Affairs Office of Inspector General

Healthcare Inspection

Alleged Quality of Care Issues Captain James A. Lovell Federal Health Care Center, North Chicago, Illinois

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an inspection to determine the validity of multiple allegations regarding the quality of care in the mental health clinic and two medical specialty clinics at Captain James A. Lovell Federal Health Care Center (the medical center), Chicago, IL.

We substantiated the allegation that two mental health providers issued narcotics on 2 days leading up to the patient's death. We did not substantiate the allegation that narcotics were given outside the narcotic agreement; the agreement addressed patient behaviors, not a specific narcotic regimen.

We determined that the patient received additional prescriptions for hydrocodone before his prior prescriptions had elapsed. We found that pill counts to assess the patient's medication compliance were not documented; therefore, we were unable to determine if pills counts were done for this patient. While the choice of fentanyl patches was reached after extended discussion between the patient and physician, we had concerns with the prescription; fentanyl is a potent, long-acting agent and the patient's fentanyl prescription was a substantial increase in his opioids. We believe that other possible options, including hospitalization or shorter prescriptions, would have allowed closer monitoring of the patient while adjusting his medications.

We substantiated the allegation that urine drug screens were not performed. We substantiated the complainant's allegation that medical center staff were aware of the positive drug screens done at Hines VA 2 weeks prior to the patient's death.

While we did not substantiate the allegation that the patient's death was not properly reported and investigated, we found that the peer reviewer of the case was not certified in pain management. We believe that a specialist in pain management should review this case due to the nature of the incident.

We determined that a contract physician specialist received fee basis referrals; however, we did not substantiate that the physician self-referred. We did find that the contract physician was the only available option listed in the fee basis consult package for service. The medical center added two additional fee basis physician specialists while we were on-site.

We recommended that the Medical Center Director ensure that (1) patients with narcotic agreements are appropriately monitored for compliance with prescription medications and (2) a physician certified in pain management review this case.

The VISN and Medical Center Directors agreed with our findings and recommendations. The implementation plans are acceptable, and 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 Great Lakes Health Care System (10N12)

SUBJECT: Healthcare Inspection – Quality of Care Issues, Captain James A. Lovell Federal Health Care Center, Chicago, IL

Purpose

The VA Office of Inspector General (OIG) Office of Healthcare Inspections received multiple allegations regarding the quality of care in the mental health (MH), oncology, and dermatology clinics at Captain James A. Lovell Federal Health Care Center (the medical center), Chicago, IL. The purpose of the review was to determine whether the allegations had merit.

Background

The medical center is a tertiary care hospital that is part of the Veterans Integrated Service Network (VISN) 12. The medical center provides a broad range of outpatient services including MH. The Mental Health Clinic provides outpatient services Monday through Friday from 8:00 a.m. to 5:00 p.m. In fiscal year (FY) 2011, 26,382 unique patients were seen in the clinic.

On February 1, 2011, an anonymous complainant contacted the OIG hotline and alleged that:

- Two MH providers issued narcotics outside the narcotic agreement on 2 days leading up to the patient's death.
- The patient did not have urine drug screens completed prior to being prescribed narcotics.
- MH staff was aware of the drug screen performed at Hines VA 2 weeks prior to the patient's death, which showed multiple high levels of illegal substances in his system.
- Email messages sent to the Director of Mental Health 1 day prior to the patient's death and to the Medical Center Director the day after his death warned of narcotic issuing and its relation to the patient's death.

- The patient's death was not properly reported and investigated.
- A physician in a medical specialty clinic took multiple weeks of annual leave without making provisions to ensure patient care needs were met.
- Management was aware that a physician was on vacation for 5 weeks and approximately 100 patients did not receive care.
- A contract physician self-referred patients for fee basis¹ service.

There were other allegations regarding administrative issues, which were referred elsewhere for review.

Scope and Methodology

We conducted a site visit on April 12–13, 2010. We interviewed the Chief of Staff, Chief, Ambulatory Care, quality manager, neurologist, psychiatrists, Emergency Department (ED) physicians, clinical pharmacist, nursing staff, and a clinic scheduling clerk. We reviewed the patient's medical records and pertinent medical center and Veterans Health Administration (VHA) policies and procedures.

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.

Case Summary

The patient was a male with a psychiatric history that includes bipolar, depression, anxiety, and personality disorders. He had a long history of substance abuse, primarily cocaine and alcohol dependence with numerous hospital admissions for treatment of substance abuse and psychiatric disorders. His medical history includes chronic low back pain secondary to degenerative disk disease.

In mid-November, 2009, the patient signed a patient treatment contract and a narcotic agreement. The conditions of the treatment contract were:

- 14 day prescriptions with no refills.
- No early refills.
- ED visit for acute new onset issues.

¹ Fee basis referral is an authorization to receive care in the community by a non VA provider.

- Compliance with all aspects of the narcotic agreement including random urine drug screens.

The narcotic² (opiate) agreement described specific behaviors the patient was to adhere to while receiving opiate treatment and did not stipulate a specific medication regimen. The following were the conditions of the agreement:

- Receive treatment for persistent pain from only one health care provider and discuss all aspects of pain including how well the medicine is relieving pain.
- Receive a comprehensive pain assessment and treatment plan.
- Avoid the use of any illegal substances, including marijuana, cocaine, and heroin.
- Avoid sharing, selling or trading medications with anyone.
- Protect medication from loss or theft.
- Refill pain medicine during clinic hours.
- Take medicine as prescribed by health care provider.
- Contact health care provider if pain is poorly controlled.
- Bring unused pain medicine and prescription vials for pill counts to each office visit.
- Submit to random blood and/or urine testing.
- Keep all scheduled appointments.

At that time, the patient was prescribed hydrocodone³ 5 milligram (mg)/acetaminophen 500 mg 1 tablet every 6 hours as needed for pain. The patient's urine screen was positive for opiates and benzodiazepines (class of drugs used for treating anxiety) and negative for cocaine.

One month later, a neurologist was consulted to assess the patient for non-pharmacologic pain treatment. The neurologist noted that the patient had no clinical signs or symptoms of spinal nerve root irritation. The neurologist did a trigger point

² Narcotic is an addictive drug, such as opium, that reduces pain, alters mood and behavior, and usually induces sleep or stupor.

³ Hydrocodone is a synthetic opioid analgesic similar to but more active than codeine.

injection and noted that the patient responded well. The neurologist ordered a transcutaneous electrical nerve stimulation unit⁴.

One week later, the patient presented to the ED with complaints of back pain. He rated the intensity of his pain at 7 out of 10.⁵ He reported that his medications were stolen and presented a police report. He received hydromorphone⁶ 1 mg intramuscular (IM) for pain and lorazepam (relieve anxiety) 1 mg IM. The patient received a prescription for hydrocodone 10 mg/acetaminophen 650 mg 1 tablet 3 times a day as needed for pain. He was issued a 5 day supply and referred back to his MH primary care physician (PCP) for follow up. The patient saw his MH PCP 4 days later. The MH PCP noted “patient continues to exhibit inconsistent behavior necessitating weekly visits and medication refills.”

In early January 2010, the patient presented to the ED with complaints of back pain. He rated the intensity of his pain at 8. The ED physician wrote, “patient hostile, verbally abusive, and demanded narcotics.” The physician consulted a neurologist who recommended a nonsteroidal anti-inflammatory drug, skelaxin (muscle relaxant) and referral to a pain clinic. The patient was given hydromorphone 1 mg IM for acute pain and referred back to MH PCP for follow up.

Three days later, the MH PCP wrote “patient continued to engage in negative behaviors as evidenced by visiting Hines VA. Patient stated that he lost his valium and Vicodin[®] [hydrocodone] while at his families’ home. He visited the ED at the medical center without a medical rationale for worsened pain. He was hostile and abusive to providers.” The MH PCP noted that the patient was noncompliant with the narcotic agreement and in early February, the patient met with a new MH PCP. At that time, the new provider prescribed hydrocodone 10 mg/acetaminophen 650 mg 1 tablet 3 times a day as needed for pain. Twenty-four days later, the patient accessed the ED again for complaint of back pain and received hydromorphone 2 mg IM.

In mid-March, the MH PCP wrote that the undersigned would coordinate all medical care. The patient was advised to keep scheduled appointments or medications would not be prescribed, nor would he receive any early refills. The patient was seen in the ED once in March but was referred back to his MH PCP for changes in pain management.

The patient received a fee basis referral to a non-VA pain clinic and was seen in late March. The patient received a transforaminal epidural steroid injection.⁷ He was to

⁴ Transcutaneous electrical nerve stimulation unit modify the perception of pain through the release of endorphins as well as alterations in nerve sensitivity.

⁵ Intensity of pain ranges from 0-10 with 10 as most severe.

⁶ Hydromorphone is a synthetic derivative of morphine used as a respiratory sedative and analgesic that is more potent than morphine.

⁷ Transforaminal epidural injections are commonly given to patients with nerve compression or irritation to relieve pain.

return in 7 to 10 days for re-evaluation; however, there was no documentation of a follow up visit.

One day later, the patient was admitted to the inpatient MH unit for drug seeking behavior and depression. His drug screen was positive for cocaine. The patient wanted to leave on hospital day (HD) 2 due to the restrictive nature of the inpatient environment. The patient signed out against medical advice on HD 3. The physician noted that he was not suicidal or homicidal.

Twenty-five days later, the patient had positive drug screens for cocaine and was admitted to the inpatient substance abuse treatment program for withdrawal from cocaine and heroin. He attended the physical fitness program and group therapy. He participated in Alcoholics Anonymous 12-step educational group, recreational therapy, dietician's educational group, and other psychoeducational groups. The patient was discharged on HD 23.

For a 21 day period starting from 8 days post-discharge, the patient was seen in the ED six times requesting narcotics for complaints of back pain and received narcotic injections IM. Random urine drug screens were negative for cocaine.

The clinical pharmacist noted that the patient had tried multiple different medications in the past for pain including acetaminophen, aspirin, naproxen, ibuprofen, diclofenac, celecoxib, indomethacin, carisoprodol, cyclobenzaprine, metaxalone, tramadol, hydrocodone, and lidocaine patches. The patient reported that most of these medications had offered him no relief and that only the hydrocodone was helpful. He was willing to sign another narcotic agreement if it was necessary to continue his current treatment. The pharmacist noted that the patient admitted to an addictive personality and understood the risks of using opiates.

Thirty-four days post-discharge, the patient signed a second narcotic agreement with the new MH provider, which contained the same conditions as the first agreement. The MH PCP prescribed fentanyl patch 12.5 mcg every 3 days; however, the medication was not in stock in the pharmacy. The MH PCP instructed the patient to continue hydrocodone 10 mg 3 times a day for 2 days until the fentanyl patch was available. He was to follow up with psychiatry every 2 weeks. Due to increased complaints of pain, the MH PCP increased the dosage of the fentanyl patch to 25 mcg 10 days later.

Five days later, a urine drug screen was positive for benzodiazepine and negative for opiates and cocaine. There were no other urine drug screens ordered. The patient accessed the ED once in August and again in September seeking narcotics to treat his back pain. He received hydromorphone 2 mg IM at both visits.

In early September, the patient was admitted to the Milwaukee VA for detoxification from opiates and benzodiazepine. The physician noted that the patient reported

frustration with pain control and did not feel the current fentanyl patch was effective in controlling his pain; thus, he relapsed to cocaine, using large amounts. The physician requested outpatient consults for neurosurgery and an electromyogram.⁸ The patient was discharged on HD 3. He had an appointment for the electromyogram 11 days later; however, he did not present for his appointment.

In early October, the patient's family took him to the Hines VA for concerns about suicidal ideation and escalating drug use. His urine drug screen was positive for cocaine, marijuana, barbiturates, and opiates. His blood alcohol level was also high. The patient was admitted to the Jesse Brown VA inpatient psychiatric unit for treatment of depression and polysubstance abuse. The patient left treatment abruptly 4 days later. The psychiatrist recommended further treatment, but noted the patient was not suicidal and was able to articulate the discharge plan. The patient was deemed safe for discharge at that time. The physician prescribed hydrocodone 5 mg/acetaminophen 500 mg 2 tablets every 6 hours as needed for pain. The patient was given a 2 week supply with one refill. He was advised to abstain from drinking and drugs and to follow through with his plan to start rehabilitation.

Nine days later, the patient presented to the medical center's Mental Health Clinic. A psychiatrist saw the patient and documented that he was alert, oriented, pleasant, and cooperative. His mood was stable, insight was poor, and judgment was intact. The psychiatrist noted that the urine drug screens from the Hines VA were positive. The patient wanted his pain medication changed to something other than hydrocodone; however, he was given a prescription refill for 1 week of hydrocodone 10 mg/acetaminophen 650 mg 1 tablet 3 times a day.

The next day, the patient presented to the ED requesting temporary pain management. He reported not having any medication and his pain was not being managed. The patient rated the intensity of his pain at 8 and was given hydromprphone 2 mg IM.

Later that day, the patient met with the MH treatment team (MH PCP, MH attending physician, clinical pharmacy specialist, nurse, and the MH program manager). The patient reported hydrocodone did not relieve his pain. He requested oxycontin⁹, which was declined. The MH PCP noted that the team expressed concerns about his use of cocaine, alcohol, and barbiturates and the danger of mixing these substances with narcotics. The patient stated that he had been tolerating these medications for a while. He acknowledged that he had been "buying stuff from the streets" and blamed "inadequate pain control for his use of cocaine and alcohol." The MH PCP noted that the patient rejected methadone treatment, but reluctantly agreed to the fentanyl patch. The patient was informed that he would be checked for toxicology and the need for evaluation by pain clinic providers at Jesse Brown was discussed. The meeting ended with an

⁸ Electromyogram is an electrical recording of muscle activity that aids in the diagnosis of neuromuscular disease.

⁹ Oxycontin is a potent narcotic pain reliever with high abuse potential.

agreement for the patient to receive fentanyl patch 37.5 microgram (mcg) and referral to a pain clinic. He was advised to use “2–3 Vicodin® [hydrocodone] for breakthrough pain.”

The patient received fentanyl patch 50 mcg due to the unavailability of the fentanyl patch 37.5 mcg in pharmacy. The MH PCP instructed the patient not to use “any illicit substances, any alcohol, and any additional opiates for breakthrough pain or recreational purposes.”

The next day, the patient died from an accidental overdose. The toxicology screen was positive for cocaine, fentanyl, and hydrocodone.

Inspection Results

Issue 1: Mental Health Chronic Pain Management

We substantiated the allegations that two MH providers issued narcotics 2 days leading up to the patient’s death; however, we did not substantiate the complainant’s allegation that the MH providers issued narcotics outside the narcotic agreement. We substantiated the allegation that the patient did not have random drug screens and that the staff was aware of the drug screen performed at Hines VA 2 weeks prior to the patient’s death. We could neither substantiate nor refute the allegation that email messages sent to the Medical Center Director and Director of Mental Health warned of narcotic issuing and its relation to the patient’s death. We did not substantiate the allegation that the medical center did not properly report and investigate the patient’s death.

Narcotic Prescriptions. We reviewed the medical record and found that opiate treatment was warranted for this patient due to failure of less potent pain management options. We also found that the patient was a known substance abuser and attributed his use of illicit drugs to poor pain management. We substantiated the complainant’s allegation that the patient received two prescriptions for narcotics prior to his death. We found that on 2 days in October, the patient received new narcotic prescriptions while he would have been expected to have significant quantities of his prior prescriptions. We determined that the patient’s last narcotic prescription was for a potent, long-acting medication at a larger dose. In addition, we found that pill counts were not documented; therefore, we were unable to determine if the pill counts for this patient were done. We reviewed the narcotic agreement which specified pill counts would be completed at each clinic visit to assess compliance with prescriptions. We did not validate the allegation that narcotics were given outside the narcotic agreement. The agreement addressed patient behaviors, not a specific narcotic regimen.

We also found that from December, 2009 to October, 2010, the patient accessed the ED 14 times seeking narcotics for complaints of back pain. He received a narcotic injection IM during 12 of the 14 visits. The ED providers were aware that the patient was on a

narcotic agreement. Medical center leadership acknowledged the need for a pain management specialist and reported that a request to hire an anesthesiologist to start a pain management program was recently approved.

Urine Drug Screens. We reviewed the medical record and found that random urine drug screens were not ordered after June 2010. The veteran had 24 urine drug screens in the first half of 2010, and none at the medical center in the second half of the year. Urine drug screens are an important part of monitoring adherence with prescriptions and identifying the use of illicit substances. We validated the complainant's allegation that staff at the medical center was aware of the results of the positive urine drug screens done at Hines VA.

Email Messages. Only a subset of emails from the Medical Center Director and the Director of Mental Health could be reviewed. We searched the available email of the Medical Center Director and the Director of Mental Health and found no messages warning of narcotics prescribed for this patient.

Death Investigation. We found that the medical center did a peer review¹⁰ of the incident; however, the peer reviewer was not certified in pain management. We also found that the incident was reported according to local policy.

Issue 2: Medical Clinic Physician Coverage

We did not substantiate the allegation that the physician in a medical clinic took multiple weeks of annual leave without properly handling patient care needs. We also did not substantiate the allegation that management was aware that approximately 100 patients did not receive care during the 5 weeks the physician was on vacation.

We reviewed the physician's official time and leave record for FY 2010 and found that the physician was on leave for 3 consecutive weeks in July. We found that the physician's leave was scheduled months in advance and provisions were made for patients to be seen through fee basis referrals including all new consultations. We reviewed six fee basis referrals initiated in July 2010 during the time the physician was on leave. We also reviewed the clinic's patient advocate reports for FY 2010, and there were no issues related to access to care or the quality of care of patients assigned to this provider.

Issue 3: Medical Clinic Contract Physician

We did not substantiate the allegation that a contract physician was self-referring patients. We determined that the physician received fee basis referrals for all initial consultations. However, our review of 50 consultations for this service revealed that the

¹⁰ Peer review is an organized process carried out by an individual health care professional or select committee of professionals, to evaluate the performance of other professionals.

contract physician was not the requestor on any of the consults. We found that the nurse in the clinic reviewed the consults and generated a fee basis referral for all initial consultations. The nurse also notified the patients and instructed them to call the contract physician's private office to make an appointment.

Medical center leaders reported that the number of patients that required this specialty's services exceeded the available clinic hours, and they were unsuccessful in recruiting a full time physician. In addition, we were told that efforts had been made in the past to locate physicians to provide this service in the community; however, none were willing to accept VA patients on a fee for service basis.

VHA requires that patients who are authorized short-term fee basis treatment may select a qualified physician of their choice to render the services required. In the absence of this selection, VHA requires that medical administration personnel arrange for treatment by a qualified physician located within a reasonable distance of the patient's residence. We determined that the contract physician was the only physician listed on the electronic fee basis outpatient consult as an option to provide this fee basis service. While we were on-site, medical center leaders added two additional fee basis physicians to provide this service.

Conclusions

We substantiated the allegation that two MH providers issued narcotics on 2 days leading up to the patient's death. We believe that the patient's treatment team did many things well with the management of his care including extensive consultation for non pharmacologic approaches to pain management. The treatment team regularly followed the patient and had a narcotic agreement in place with him. However, the facility did not have a pain management consultant available to advise the patient's mental health providers. The patient received additional prescriptions for hydrocodone before his prior prescriptions had elapsed without pills counts to determine his medication compliance. While the choice of fentanyl patches for control of pain was reached after extended discussion between the patient and physician, we had concerns with the prescription; fentanyl is a potent, long-acting agent and the patient's fentanyl prescription was a substantial increase in his opioids. We believe that other possible options including hospitalization or shorter prescriptions would have allowed closer monitoring of the patient while adjusting his medications.

We do not believe that the ED provider's actions were inappropriate. The patient was given an injection of short-acting narcotics and referred back to the MH PCP for chronic pain management.

We substantiated the allegation that urine drug screens were not performed. We substantiated the complainant's allegation that the medical center staff were aware of the drug screens done at Hines VA, which were positive for illegal substances. Although we

did not substantiate the allegation that the patient's death was not properly reported and investigated, we found that the peer reviewer was not certified in pain management. We believe that a specialist in pain management should review this case due to the nature of the incident.

We could neither substantiate nor refute the allegation involving email messages warning of the narcotics prescribed for this patient.

We determined that a contract physician received fee basis referrals; however, we did not substantiate that the physician self-referred. We did find that the contract physician was the only available option listed in the fee basis consult package for services. The medical center added two additional fee basis physicians while we were on-site.

We did not substantiate the other allegations related to MH providers issuing narcotics outside the narcotic agreement, or the physician in a medical clinic taking multiple weeks of annual leave and that managers were aware that multiple patients did not receive care during that time.

Recommendations

Recommendation 1. We recommended that the Medical Center Director ensure that patients with narcotic agreements are appropriately monitored for compliance with these agreements.

Recommendation 2. We recommended that the Medical Center Director ensure that a physician certified in pain management review this case.

Comments

The VISN and Medical Center Directors agreed with the findings and recommendations. The implementation plans area acceptable, and 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: August 2, 2011

From: Director, VA Great Lakes Health Care System (10N12)

Subject: **Healthcare Inspection – Alleged Quality of Care Issues at
Captain James A. Lovell Health Care Center, North Chicago,
Illinois**

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

Thru: Director, Management Review Service (10B5)

Attached please find the Lovell FHCC response to the alleged quality of care issues. I have reviewed and concur with the response.

(original signed by:)

Jeffrey Murawsky

Director, VA Great Lakes Health Care System (10N12)

Medical Center Director Comments

**Department of
Veterans Affairs**

Memorandum

Date: August 2, 2011

From: Director, Captain James A. Lovell Federal Health Care Center (556/00)

Subject: **Healthcare Inspection – Alleged Quality of Care Issues at Captain James A. Lovell Health Care Center, North Chicago, Illinois**

To: Director, VA Great Lakes Health Care System (10N12)

This is to acknowledge receipt and review of the recommendation of the Office of the Inspector General. Attached is our response and request for closure.

(original signed by:)

Patrick Sullivan

Director, Captain James A. Lovell Federal Health Care Center (556/00)

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 Medical Center Director ensure that patients with narcotic agreements are appropriately monitored for compliance with prescription medications.

Concur: **Target Completion Date: October 1, 2011**

Facility's Response:

JAL FHCC will comply with the current requirement of the Narcotic Agreement, which includes random blood and /or urine testing. The Narcotic Agreement will be modified to also include random pill counts. Education of providers regarding Narcotic Agreements will be completed by September 30, 2011. A random sample of 10 percent of records of patients with narcotic agreements will then be monitored monthly for 6 months to validate compliance.

Status: In process.

Recommendation 2. We recommended that the Medical Center Director ensure that a physician certified in pain management review this case.

Concur: **Target Completion Date: October 1, 2011**

Facility's Response:

The case was reviewed by a physician certified in pain management on August 1, 2011.

Status: Completed.

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	Deborah Howard, RN, Project Leader Judy Montano, MS Robert Yang, MD Derrick Hudson, Program Support Assistant

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