Department of Veterans Affairs
Office of Inspector General

Office of Healthcare Inspections

Report No. 13-02665-197

Healthcare Inspection

Medication Management Issues in a High Risk Patient Tuscaloosa VA Medical Center Tuscaloosa, Alabama

June 25, 2014

Washington, DC 20420

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Executive Summary

The VA Office of Inspector General Office of Healthcare Inspections conducted an evaluation in response to allegations that providers at the Tuscaloosa VA medical center (facility) mismanaged opioid therapy for a high-risk patient and that facility managers did not take appropriate actions after the patient's death. The purpose of the evaluation was to determine whether the allegations had merit.

We substantiated that facility providers collectively prescribed oxycodone, methadone, and benzodiazepines to a high-risk patient who died of an accidental multi-drug overdose. Three factors contributed to this outcome:

- Providers did not consistently comply with Veterans Health Administration (VHA) and local policies for the management of complex chronic pain in this high-risk patient. Additionally, the patient's primary care provider did not conduct key portions of the pain assessment, such as previous pain treatments and their effectiveness, high risk for suicide status, and history of overdose. The primary care provider also did not initiate an opioid pain care agreement, ensure adequate patient monitoring and follow-up after prescribing methadone, or document patient education regarding the specific dangers of methadone.

- The facility did not ensure access to an interdisciplinary pain management team or Pain Clinic to provide needed services to this patient.

- Multiple providers did not ensure communication and coordination of care. The primary care provider did not read other providers' progress notes reflecting concerns about prescribing opioids and benzodiazepines, and the primary care and mental health providers did not communicate directly about this high-risk patient. Further, the Suicide Prevention staff did not assist in coordinating this patient's care; although, the patient was on the High Risk for Suicide list.

We did not substantiate the allegation that the facility covered up the patient's subsequent visit to the facility or delayed the autopsy report. However, the facility did not comply with selected aspects of VHA Directives on clinical reviews and patient safety processes.

We recommended that the Facility Director ensure that providers comply with local policies related to opioid therapy in patients with chronic pain and that all patients who are prescribed methadone are educated about potential adverse effects. We also recommended that the Facility Director develop a system to ensure communication and coordination of care and that Suicide Prevention staff follow policies regarding communication and coordination of care for patients on the High Risk for Suicide list. Further, we recommended that clinical reviews and root cause analyses comply with VHA and local policies and that the Facility Director evaluate the care of the patient summarized in this report, confer with Regional Counsel regarding the need for possible disclosure, and ensure access to interdisciplinary pain management care for chronic pain patients who do not respond to standard medical treatment.

The Veterans Integrated Service Network and Facility Directors concurred with the report and provided an acceptable action plan. (See Appendixes A and B, pages 14–18, 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 (OIG) Office of Healthcare Inspections conducted an evaluation in response to allegations that providers at the Tuscaloosa VA medical center (facility) mismanaged opioid therapy for a high-risk patient and that facility managers did not take appropriate actions after the patient's death. The purpose of the evaluation was to determine whether the allegations had merit.

Background

The facility, part of Veterans Integrated Service Network (VISN) 7, operates a 381-bed teaching hospital offering a range of inpatient and outpatient care, including mental health (MH), a Homeless Domiciliary, a Psychosocial Residential Rehabilitation Treatment Program, and a community living center. The facility also operates a VA-staffed outpatient clinic in Selma, AL, and a mobile clinic that offers primary care and MH services to veterans living in highly rural areas.

Medications Central to this Case

Chronic pain is a condition involving medical, cognitive, psychosocial, and substance abuse issues. Opioid therapy can be a useful part of chronic pain management; however, patients on long-term opioid medications are at risk for misuse, diversion, and overdose. In the United States in 2010, three-quarters of prescription overdose deaths were related to opioid medications.[1]

Opioids are natural or synthetic derivatives of opium that have pain-relieving properties. Opioids are central nervous system (CNS) depressants and can reduce heart rate, respiratory drive, and level of consciousness. Examples of opioid medications include methadone, hydrocodone, oxycodone, and morphine. Oxycodone is a frequently used opioid medication prescribed for a variety of acute and chronic pain conditions. Oxycodone's principal actions are pain relief and sedation.

Methadone is a synthetic opioid used to relieve moderate to severe pain. Methadone's pharmacokinetics (the process by which a drug is absorbed, distributed, metabolized, and eliminated by the body) are substantially different from other opioids and need to be considered in order to safely prescribe this medication.[2] Because the overdose death rate for methadone is significantly greater than other opioids, the Centers for Disease Control and Prevention (CDC) recommends that methadone not be considered a drug of first choice by prescribers.[3]

Clonazepam is a benzodiazepine typically prescribed for anxiety and depression; zolpidem is a prescription sleep aid; and diphenhydramine is an over-the-counter antihistamine and sleep aid. All of these medications are classified as CNS

[1] .http://www.cdc.gov/homeandrecreationalsafety/overdose/facts.html, updated access June 2, 2014.
[2] http://www.fda.gov/Drugs/DrugSafety.htm, accessed April 4, 2014.
[3] Morbidity and Mortality Weekly Report, 61(26); 493–497. July 6, 2012

depressants. Divalproex is prescribed for mood stabilization in bipolar disorder. It is not a CNS depressant itself but has a potentiating effect when used in combination with CNS depressants.

Guidance, Resources, and References

The *VA/Department of Defense Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* (VA/DoD Guideline), dated May 2010, outlines recommendations for providers when assessing patients, prescribing opioids, consulting with specialists, and following up for safety and effectiveness. The Veterans Health Administration (VHA) sponsors a website devoted to pain management with links to resources and tools for practitioners.[4] Facility policies relevant to this case include *Outpatient Chronic Opioid Use for Non-Malignant Pain Management,*[5] *Pain Management,*[6] *Drug Policy,*[7] *Suicide Risk Assessment and Documentation,*[8] and *Hand-Off Communications.*[9]

Allegations

In April 2013, the OIG Hotline Division received a complaint about opioid prescribing practices to a high-risk patient and, in accordance with OIG policy and practices, referred the case to facility leadership for review. The facility's response was insufficient; therefore, OHI conducted an evaluation to determine whether:

- Facility providers over-prescribed oxycodone and methadone to a high-risk patient who subsequently died of an overdose.
- Facility staff covered up a visit the patient made to the facility after April 25 and delayed the autopsy report.

Scope and Methodology

We conducted telephone interviews with the complainant in September 2013. We visited the facility October 24–25, 2013, and interviewed the Chief of Staff, involved medical providers, the risk manager, clinical laboratory managers, pharmacists, the patient safety manager (PSM), and the suicide prevention coordinator (SPC). We reviewed provider training records for use of opioids in managing acute and chronic pain; quality management documents; the medical examiner's report; and the patient's electronic health record (EHR), including information from some private-sector medical and behavioral health centers, from May 2006 to May 2012.

[4] www.va.gov/painmanagement.
[5] Medical center memorandum (MCM) 11-45, July 27, 2010.
[6] MCM 11-66, July 21, 2011.
[7] MCM 119-02, February 6, 2013.
[8] MCM 11-13, July 13, 2010.
[9] MCM 11-75, November 30, 2012.

We reviewed the VA/DoD Guideline; VHA and local policies and procedures governing coordination of care, pain management, and prescribing practices; and medical literature on this topic.

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

Events from 2006 to 2011

The patient had a history of chronic pain syndrome, anxiety, depression, polysubstance abuse/dependence, and suicidal ideation (SI). The patient initially presented to the facility in May 2006 with complaints of chronic right foot pain.

While his VA physicians initially ordered approximately 1 month of opioid medications, they otherwise managed his chronic pain without opioids from 2006 to 2011. For a brief period from March to May 2009, the patient received opioids after he fractured his left foot. The patient completed an opioid pain care agreement (OPCA) with a primary care provider (PCP)-1, which specified that the opioids were intended as a short-term measure. The patient also received prescriptions for opioids (codeine) for treatment of cough and migraine headaches. These prescriptions were ordered intermittently and typically only for a few days.

The patient's only other treatment with chronic opioids at a VA facility (medical center B) occurred in September 2010. The patient signed an OPCA and was prescribed opioids monthly for management of chronic foot pain. After using illegal drugs several months later, he was discontinued from the program. He did not receive opiate prescriptions from medical center B after November 2010.

Between 2007–2011, the patient was treated at various VA health care facilities and was hospitalized more than 24 times, usually for anxiety, depression, or substance use-related issues. Clinical providers routinely ordered psychotropic[10] medications, including anti-depressants and benzodiazepines, to treat the patient's mood disorders. The patient was referred for substance abuse rehabilitation several times but usually did not stay more than a few days. The EHR reflects that he was also periodically hospitalized at private sector hospitals. At least one hospitalization (in October 2011) was for an apparent accidental overdose of hydrocodone. While the patient usually received opioid pain medications while hospitalized, he was not prescribed opioids upon discharge.

After being away for almost 2 years, the patient returned to the facility in late November 2011 seeking admission to the MH unit. His urine drug screen (UDS) was positive for marijuana, cocaine, and opioids. In December 2011, the patient was treated at a non-VA hospital for a possible overdose of "unknown quantity" of clonazepam and had a UDS positive for benzodiazepines, cocaine, and tricyclic anti-depressants.[11] After the overdose event, the SPC placed the patient on the High Risk for Suicide list and activated an electronic patient record flag in his EHR.

[10] Psychotropic medications are medications that affect mental activity, behavior, or perception.
[11] The benzodiazepines and tricyclic anti-depressants had not been prescribed by the facility. Tricyclic anti-depressants potentially interact with opioid medications.

Events in 2012

In January 2012, the patient saw an outpatient MH provider who prescribed bupropion for depression and clonazepam for anxiety and insomnia. The patient was to return to clinic in 4–6 weeks.

Five days later, the patient's newly assigned PCP (PCP-2), who last treated the patient in 2009, initiated chronic opioid medications in spite of documenting risk factors predictive for opioid misuse. He wrote:

> "Vet had multiple streams of getting his pain medication and this issue was raised with him today. Vet earnestly pleaded that he is cleaning up and had made a pact with his MH [provider]. I will honor his request due to MH [provider] providing him with a second chance. Vet had requested many medications by name and by doses, which is a sign of h/o [history of] addiction. Vet agrees to abide by TVAMC [the facility] PCP and MH [provider] management. He was notified that any deviation from the set treatment would be a violation of trust and [the] opioid contract."

PCP-2 prescribed a 1-month supply of oxycodone 30 mg tablets, educated the patient on the importance of taking medications appropriately, and documented, "Will monitor how and when Vet requests refills." The patient was to follow up in 3 months.

One week later, the SPC completed a suicide risk assessment and documented the patient's recent use of illegal drugs and alcohol. The patient saw his MH provider that same day and again 1 week later, at which time he was prescribed zolpidem for insomnia. During both visits, the MH provider documented that the patient was taking the previously ordered clonazepam more often than prescribed.

At the end of January 2012, PCP-2 ordered the first refill of opioid medications, a 1-month supply of oxycodone 30 mg tablets to be mailed to the patient 1 week later (exactly when the previous prescription would have run out.) Two weeks later, PCP-2 ordered an early refill for a 1-month supply of oxycodone at the patient's request after the patient reported that his medications had been stolen.

In mid-February 2012, a different psychiatrist documented an exchange with the patient the previous day about the patient refusing admission for suicidality. He wrote, "We recommend outpatient management of chronic pain with non-opioid therapies and without benzodiazepines."

The following month, the patient was hospitalized at the facility for suicidality, during which inpatient psychiatry staff documented their recommendation to stay away from non-extended-release opioid agents. The patient was placed on extended-release morphine during his admission and provided four tablets upon discharge.

Two days after discharge, the patient returned to the facility and saw PCP-1, who had previously completed the OPCA in 2009. PCP-1 documented concerns about the patient's medications, writing, "patient advised that oxycodone was not suitable given

his past history" and "I would be concerned about writing for any more than 5 days at a time." He ordered a 5-day supply of extended-release morphine (as the patient had been switched to this medication a few days earlier) and indicated that the patient would need to return to receive more medications.

In early April 2012, the patient presented to another VISN 7 health care facility with a UDS positive for cocaine and alcohol. He was referred to a private-sector behavioral health facility for detoxification where he remained until discharge 2 weeks later.

At the end of April, the patient presented back to his primary care clinic at the facility requesting refills of his opiate medications. The nurse conferred with PCP-2 and wrote, "Per PCP, given veteran's history of opioid contract violations and extensive substance abuse, he will not reorder oxycodone." The patient was instructed to return the following day for his scheduled appointment.

The following day, the patient had an initial visit with a different outpatient MH provider[12] who documented that the patient had been compliant with his psychotropic medications and reported no side effects. This outpatient MH provider prescribed an increased dose of clonazepam, as well as bupropion and extended-release divalproex. The patient was educated on the plan of care and medication changes and was instructed to return to clinic in 3 months or as needed.

The patient kept his previously scheduled primary care appointment about 2 hours later. PCP-2 noted that although a UDS that month had been "clean," a UDS the previous month had been positive for cocaine. He documented:

> "Vet's primary concern is having oxycodone. Explained to Vet that he had broken the trust between patient and physician and I am not inclined to treat him further as he is exhibiting signs of drug seeking behavior."

PCP-2 also documented:

> "At this point, it does not benefit [the] Veteran to see me again as I have expressed to him that I will initiate chronic pain management and it is up to his new assigned PCP to modify [the] Rx [prescription] plan as seen fit. Vet will need to sign an opioid contract for pain management with his newly assigned PCP."

PCP-2 decreased the oxycodone from 30 to 20 mg tablets while keeping the frequency of the medication the same. He also initiated methadone for the purpose of eventually having the patient on a single long-acting opioid. When the patient left the clinic that day, an appointment with another primary care physician had not yet been scheduled. The appointment was requested a few days later and scheduled for mid-May.

[12] The patient requested a new outpatient MH provider after the original MH provider declined to increase his clonazepam dose.

Prior to leaving the clinic, the patient picked up his prescriptions from the pharmacy. Later that day, in the early evening, facility personnel found him "stuporous and sedated" in the waiting area. From pill counts of his medications, staff determined that 12 oxycodone, 11 clonazepam, and 3 methadone tablets were missing from the patient's recent pharmacy order.

Clinical providers arranged transport to a local private facility for emergency treatment of a probable overdose. A facility nurse gave the patient's medications to ambulance personnel for transport with the patient.

Records indicate that the patient was treated and released from the private-sector emergency department (ED) the next day with instructions to avoid taking any more methadone until he saw his VA PCP. The patient's UDS from the private-sector ED was positive for opioids, methadone, tricyclic antidepressants, and benzodiazepines. The private-sector ED returned the patient's medications to him upon discharge. The patient did not return to the facility. He died 3 days later of an accidental drug overdose. Toxicology results were positive for methadone, oxycodone, diphenhydramine, a clonazepam metabolite, and antidepressants.

Inspection Results

Issue 1: Management of Opioid Therapy

We substantiated the allegation that providers prescribed oxycodone and methadone to a high-risk patient who subsequently died of an overdose. The complainant specifically expressed concern that the types and quantities of medications prescribed contributed to the patient's death.

From January through April 2012, PCP-2 and two MH providers were writing concurrent prescriptions for opioids (the PCP) and benzodiazepines (the MH providers) without apparent communication or coordination of care. In late April, PCP-2 wrote for 1-month supplies of oxycodone and methadone but did not arrange to closely monitor the patient. On the same date, the MH provider increased the clonazepam dose and wrote for 1-month supplies of both clonazepam and divalproex.

The autopsy report identified the manner of death as "accidental multi-drug overdose," with toxicology results positive for oxycodone, methadone, and a clonazepam metabolite, among other drugs. The medical literature, product informational brochures, and clinical guidelines are replete with warnings about the potentially lethal effects of benzodiazepine-opiate interactions and about the importance of assuring close monitoring when prescribing methadone.

We could not say with certainty that the number of pills prescribed to the patient in late April contributed to the outcome. However, limiting the number of pills prescribed would have reduced the total dosage available to the patient on which to overdose and would have had the added benefit of allowing providers to assess the patient at more frequent intervals when he presented for prescription refills.

Contributing Factors

During the course of our review, we identified three factors that contributed to the patient's outcome:

1. Non-Compliance with VHA and Local Policies

Providers did not consistently follow clinical guidelines or comply with VHA and local policies for the management of complex chronic pain in this high-risk patient.

Initial Pain Assessment. PCP-2 did not conduct a sufficient pain assessment to evaluate the patient's pain status when he (the patient) returned after not being seen at the facility for almost 2 years.

In January, PCP-2 documented evidence of misuse including the patient having "multiple streams of getting his pain medication" and requesting "medications by names and doses, which is a sign of h/o addiction." The note did not contain information of what the patient had been doing in the preceding 22 months, what pain treatments he received, or whether those treatments were effective. The VA/DoD guideline states that such medical history "regarding an individual's response to past pain treatment efforts is essential." Further, the note did not include relevant recent medical history such as the patient's High Risk for Suicide electronic patient record flag, his recent hospitalization for overdose, or the previous UDS evidence of substance abuse.

OPCA. PCP-2 did not obtain an OPCA as required. An OPCA describes roles and responsibilities of both the provider and the patient and typically defines expectations regarding UDSs, single-source prescribing providers, and the prohibition on use of alcohol, other sedating medications, or illegal drugs. Facility policy requires a new OPCA if the patient changes pain management providers. In this case, the patient and PCP-1 signed an OPCA in 2009; however, PCP-2 did not complete a new OPCA when he assumed management of the patient's opioid therapy. PCP-2 appeared to be unaware of local policy, as he referred to the previous OPCA in his April progress note as the basis for dismissing the patient from his clinic.

Reassessments, Monitoring, and Follow-Up. PCP-2's reassessments were problematic in that warning signs in this high-risk patient did not receive sufficient attention.

The patient's first refill of opioid medication was mailed to him on schedule after PCP-2 reviewed blood tests and a UDS. However, the second opioid refill was requested 2 weeks early after the patient reported his medications had been stolen. OPCAs often specify that patients must manage and physically control their medications because patients who misuse medications falsely report stolen medications as a tactic to obtain additional opioids. While the provider documented that he reviewed blood tests and a UDS, these were the same tests he had reviewed for the first prescription. PCP-2 did not alter his approach to this patient despite the markedly different circumstances of the refill requests.

PCP-2 did not adequately monitor this patient while converting him from oxycodone to methadone. The Food and Drug Administration (FDA) recommends providers "closely monitor patients" who receive methadone, especially during treatment initiation, during conversion from one opioid to another, and during dose adjustments. PCP-2 initiated methadone treatment with the intent of transferring the patient's pain management care to another physician. However, PCP-2 did not arrange for monitoring during this transition, as the primary care follow-up appointment with the new provider was not promptly requested and the appointment was scheduled for a date more than 2 weeks in the future.

Patient Education. The EHR did not reflect that PCP-2 instructed the patient, either verbally or in writing, of the specific dangers of methadone and the potentiating effects when combined with other drugs. Patients should receive appropriate education when a new medication is initiated.

2. Lack of Chronic Pain Management Resources

The facility lacked the resources to provide care to patients with complex chronic pain. By definition, patients with complex chronic pain do not respond to standard medical treatment, and their functioning declines over time despite aggressive and risky medical treatments. These patients are often perceived to be demanding, dissatisfied, and drug-seeking.

Local policy requires the facility and providers to meet standards consistent with VHA's National Pain Management Strategy. Local policy assigns responsibility for chronic pain management to the PCP but also states, "The complexity of chronic pain management is often beyond the expertise of a single practitioner…" and that "Veterans with complex chronic pain conditions are best served by a comprehensive, interdisciplinary approach within a continuum of care that is informed by a biopsychosocial model."

In this case, the facility did not have an interdisciplinary pain management team or Pain Clinic to provide needed services to this complex, high-risk patient. In addition, the facility's Pain Committee (which is responsible for monitoring and reviewing ongoing pain assessment measures, planning, education, and patient satisfaction and for taking actions to improve processes) had been defunct for several years and, at the time of our visit, had just started to meet.

3. Poor Communication and Coordination of Care

Providers did not ensure communication and coordination of care. The patient's EHR reflects that facility staff made numerous efforts to engage him in appropriate treatment; however, he usually refused treatment or, if he agreed, left against medical advice after a few days. The patient often did not comply with his treatment plan, displayed drug-seeking behaviors, used illicit substances, and showed evidence of medication misuse and abuse. He had been hospitalized more than 20 times in 5 years, had recently overdosed on prescription medications, and was currently on the High Risk for Suicide list. Despite these "red flags," we found no evidence of outpatient care coordination or

interdisciplinary team discussion regarding this complex patient from the time he re-presented for primary care in January 2012 to his death a few months later.

We identified the following deficiencies:

- PCP-2 did not take initial responsibility for care coordination, nor did he consult with MH and/or other specialists to assess the patient's needs or designate an appropriate care coordinator. PCP-2 told us that he did not read the MH providers' progress notes recommending outpatient management of chronic pain with "non-opioid therapies and without benzodiazepines" and later, to "stay away from non-extended release opioid agents." He also did not read another primary care physician's note expressing concern about "writing for [pain medications] any more than 5 days at a time." PCP-2 told us that had he read the other providers' notes, he would not have prescribed the opioid medications the way he did in April.

- PCP-2 stated that he did not contact the patient's MH providers to discuss the case and told us that MH providers should "call him or copy him on a note" if they wanted him to know something. PCP-2 did not indicate that he had the same responsibility towards MH.

- While the MH providers who prescribed opioids, clonazepam, and/or zolpidem typically documented their concerns about medication management in the EHR, we did not find documented evidence that they contacted PCP-2 to discuss these concerns.[13]

- Although the patient was on the High Risk for Suicide list due to multiple risk factors, including a previous suicide attempt and several apparent unintentional overdoses, Suicide Prevention staff did not "coordinate and monitor services" as required by policy. The SPC told us that the patient "looked bad" after he returned for care in January 2012 and that staff were "worried about him." While the Suicide Prevention staff did conduct some specified suicide prevention activities as required, they did not ensure care coordination.

- PCP-2 told us that during a January visit, the patient told him he had been receiving oxycodone 60 mg from a private-sector provider and that this information influenced his (PCP-2's) decision to start the patient on the 30 mg dose. PCP-2 did not document this relevant medical history in the EHR, nor did he speak with the private-sector provider or secure copies of those records to confirm the patient's account.

Issue 2: Facility Follow-Up Actions

We did not substantiate allegations that staff covered up a visit the patient made to the facility after late April or that they delayed the autopsy report. According to the EHR, the patient's last visit to the facility occurred at the end of April when he was transferred to a private-sector hospital for treatment of a probable overdose. Facility staff

[13] MCM 11-75, *Hand-Off Communications,* November 30, 2012.

repeatedly attempted to reach the patient for several days after his overdose and transfer. Staff tried to contact the patient at the homeless shelter and local hospital, to no avail. We found no evidence that the patient returned to the facility after transfer to the local hospital. Further, the State Medical Examiner conducted the autopsy, and facility managers had no control over the process or outcome. Facility leaders had not seen the results of the autopsy prior to our site visit.

During the course of our review, however, we did identify weaknesses in the facility's evaluation of the event. Specifically, the facility did not comply with VHA and local clinical review and patient safety policies, as follows:

- *Clinical Review*. One of the primary reviewers (reviewer 1) had previously provided care for the patient. According to policy, reviewers are responsible to withdraw from participation in a case review if they had direct involvement in the patient's (the subject's) care. Reviewers are also to abstain from review in cases in which there is a conflict of interest or, if for any other reason, the reviewer is unable to conduct an objective, impartial, accurate, and informed review. Reviewer 1 told us he knew the patient well and had been repeatedly involved in his treatment in the past. The EHR reflects that the reviewer had an interaction with the patient the month prior to the patient's death. Because the patient was well known to many, if not all, of the MH providers, the case would have been more appropriately evaluated by an external reviewer who could provide an unbiased opinion.

  Reviewer 2 told us that that he only evaluated the notes of the prescribing provider and the circumstances surrounding the events of the patient's late April visit. The charge, however, asked reviewer 2 to evaluate "documentation within the medical record" from August 2009 through April 2012. By not including all relevant documentation, reviewer 2 missed important information that may have changed his findings.

- *Systems Review*. The facility did not conduct a Root Cause Analysis (RCA), reportedly because the death was not ruled a suicide. RCAs focus on systems and processes rather than individual performance. VHA requires an RCA be conducted in some cases involving suicide but does not expressly require one in cases involving accidental overdose. Rather, VHA expects clinical managers and the PSM to determine whether deficient systems and/or processes could have contributed to the adverse event, and if so, whether an RCA is indicated.

  In this case, clinical managers did not communicate to the PSM the details of the adverse event; that there were initial questions about the medications, dosages, and number of pills prescribed; or that the clinical reviews both identified system and process concerns. The facility chartered an RCA team after our site visit.

At the time of the patient's death, the facility did not believe that institutional or clinical disclosure was necessary, reportedly because the cause of death was not known. We have since provided facility leaders with the autopsy report, and we briefed them on our

preliminary findings related to quality of care deficiencies. Based on this data, the need for disclosure should be re-evaluated.

Conclusions

We substantiated that facility providers collectively prescribed oxycodone, methadone, and benzodiazepines in late April 2012, to a high-risk patient who died 3 days later of an accidental multi-drug overdose. Several factors contributed to this outcome:

- Providers did not consistently comply with VHA and local policies for the management of complex chronic pain in this high-risk patient. Additionally, PCP-2 did not conduct key portions of the pain assessment, such as previous pain treatments and their effectiveness, high risk for suicide status, and history of overdose. PCP-2 also did not initiate an OPCA, ensure adequate patient monitoring and follow-up after prescribing methadone, or document patient education regarding the specific dangers of methadone.

- The facility did not ensure access to an interdisciplinary pain management team or Pain Clinic to provide needed services to this patient.

- Multiple providers did not ensure communication and coordination of care. PCP-2 did not read other providers' progress notes reflecting concerns about prescribing opioids and benzodiazepines, and the primary care and mental health providers did not communicate directly about this high-risk patient. Further, the Suicide Prevention staff did not assist in coordinating this patient's care although the patient was on the High Risk for Suicide list.

We did not substantiate the allegation that the facility covered up the patient's subsequent visit to the facility or delayed the autopsy report. However, the facility did not comply with selected aspects of VHA Directives on clinical reviews and patient safety processes.

Recommendations

Recommendation 1. We recommended that the Facility Director ensure that providers comply with local policies related to opioid therapy in patients with chronic pain.

Recommendation 2. We recommended that the Facility Director ensure that all patients who are prescribed methadone are educated about potential adverse effects and warned about interactions with other over-the-counter, prescribed, and/or illicit drugs.

Recommendation 3. We recommended that the Facility Director develop a system to ensure communication and coordination of care, particularly for patients who receive routine and ongoing care from multiple providers.

Recommendation 4. We recommended that the Facility Director ensure that Suicide Prevention staff follow policies regarding communication and coordination of care for patients on the High Risk for Suicide list.

Recommendation 5. We recommended that the Facility Director ensure that clinical reviews and root cause analyses comply with Veterans Health Administration and local policies.

Recommendation 6. We recommended that the Facility Director evaluate the care of the patient summarized in this report and confer with Regional Counsel regarding the need for possible disclosure.

Recommendation 7. We recommended that the Facility Director ensure access to interdisciplinary pain management care for chronic pain patients who do not respond to standard medical treatment.

Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: **May 27, 2014**

From: Director, VA Southeast Network (10N7)

Subj: **Draft Report—Healthcare Inspection—**Medication Management Issues in a High Risk Patient, Tuscaloosa VA Medical Center, Tuscaloosa, AL

To: Director, Atlanta Office of Healthcare Inspections (54AT)

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

1. I concur with the facility's response and action plans as presented in the Medication Management Issues in a High Risk Patient of the Tuscaloosa VA Medical Center.

2. VISN 7 Network Office will provide support and oversight to ensure the successful completion of this action plan. If there are any questions, please contact Robin Hindsman 678-924-5723.

R. Shuron Hunter for
Charles E. Sepich, FACHE

Appendix B

Facility Director Comments

Department of Veterans Affairs **Memorandum**

Date: May 20, 2014

From: Facility Director (679/00)

Subj: **Draft Report—Healthcare Inspection**—Medication Management Issues in a High Risk Patient, Tuscaloosa VA Medical Center, Tuscaloosa, AL

To: VISN Director, VA Southeast Network (10N7)

1. I concur with the recommendations presented in the Medication Management Issues in a High Risk Patient of the Tuscaloosa VA Medical Center.
2. Attached are the facility actions taken as a result of these findings.
3. Thank you for these opportunities for improvement. The OIG Team conducted the audit in a very professional, comprehensive, impartial and educational manner. The Tuscaloosa VAMC staff have already begun corrective actions on all recommendations to enhance the quality of care and safety of our Veterans.
4. If you have any additional questions or need further information, please contact me at (205) 554-2000, ext. 2201.

Maria R. Andrews

Maria R. Andrews, MS, FACHE

Director, Tuscaloosa VA Medical Center (679/00)

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 ensure that providers comply with local policies related to opioid therapy in patients with chronic pain.

Concur

Target date for completion: November 15, 2014

Facility response: The current facility opioid policy will be updated to ensure compliance with the newly released VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain dated May 6, 2014. Mandatory training on the opioid policy and other training modules will be conducted for all staff with prescribing authority of controlled substances. The facility will monitor provider's compliance with management of opioid therapy through routine clinical pertinence and/ or medical record reviews. A for cause Focused Professional Practice Evaluation related to prescribing opioids and controlled substances will be utilized to monitor compliance for six (6) months for provider(s) identified in this report.

Recommendation 2. We recommended that the Facility Director ensure that all patients who are prescribed methadone are educated about potential adverse effects and warned about interactions with other over-the-counter, prescribed, and/or illicit drugs.

Concur

Target date for completion: June 30, 2014

Facility response: Methadone will be immediately converted to a restricted drug. Prescribing requirements will include:

a) Completion of a drug specific consult which will provide detailed inclusion and exclusion criteria for use.
b) Patient education will be performed by a dedicated Clinical Pharmacy Specialist who will meet with the patient after the order is entered and before the medication is dispensed ensuring a comprehensive medication reconciliation and verification of an EKG. Education will include potential adverse effects and warnings about interactions with other over-the-counter, prescribed, and/or illicit drugs.

Recommendation 3. We recommended that the Facility Director develop a system to ensure communication and coordination of care, particularly for patients who receive routine and ongoing care from multiple providers.

Concur

Target date for completion: June 30, 2014

Facility response: Modification to the medication ordering process will be made to include a "pop-up" warning to the ordering provider when patients are prescribed both opioid and benzodiazepine class medications. A CWAD flag will be created on the medical record cover sheet to alert ordering providers that both opioid and benzodiazepine class medications are being provided. The facility has assigned a Mental Health Treatment Coordinator (MHTC) to Mental Health patients. The MHTC provider is listed in the banner of CPRS and will allow easy identification of providers in other specialties who may be prescribing medications of concern.

Recommendation 4. We recommended that the Facility Director ensure that Suicide Prevention staff follow policies regarding communication and coordination of care for patients on the High Risk for Suicide list.

Concur

Target date for completion: August 15, 2014

Facility response: The facility policy regarding Patient Record Flag to Identify Patients at High Risk for Suicide and the VHA Directive 2008-036 dated July 18, 2008 were reviewed with actual practice to mitigating risk of suicide and identify opportunities for improvement. The following initiatives have been implemented.

a) The facility recently initiated the development of an Integrated Project Team, which combines Primary Care and Mental Health services into a joint treatment objective, utilizing improved communication, improved care coordination, and measurement-based care across treatment settings.
b) In mid-February, the facility established a No-Show Follow-up Tracking Spreadsheet to specifically address Mental Health and Substance Abuse clinic missed appointments. All veterans who are flagged for high suicide risk receive up to three attempts at phone contact to follow up when they have missed an appointment, to check on them, and attempt to reschedule the appointment. These attempts/contacts are documented in the patient's medical record and on the tracking spreadsheet.
c) The SPC will assist with facilitating communication of identified issues/ concerns with Interdisciplinary Treatment Team members across services, as appropriate.

Recommendation 5. We recommended that the Facility Director ensure that clinical reviews and root cause analyses comply with Veterans Health Administration and local policies.

Concur

Target date for completion: June 15, 2014

Facility response: Education will be provided to appropriate staff to ensure clinical reviews and root cause analyses comply in accordance with VHA Handbook 1050.01 dated March 4, 2011 and local facility policy, Patient Safety Improvement Program.

Recommendation 6. We recommended that the Facility Director evaluate the care of the patient summarized in this report and confer with Regional Counsel regarding the need for possible disclosure.

Concur

Target date for completion: June 15, 2014

Facility response: The facility will consult with Regional Counsel regarding the need for possible disclosure.

Recommendation 7. We recommended that the Facility Director ensure access to interdisciplinary pain management care for chronic pain patients who do not respond to standard medical treatment.

Concur

Target date for completion: November 15, 2014

Facility response: An Interdisciplinary Pain Management Consultation Service (IPMCS) is being created at the facility. This service will consist of a physician trained in pain management, a pain psychologist, an advanced practice nurse and a Clinical Pharmacy Specialist (PharmD). The service will address the initially identified list of complex pain patients (approximately 350) in both group and individual visits with the goal of reducing the opioid doses of medications being used and offering alternatives to opioid therapy for chronic pain management. Concurrently the service will begin an educational program facility wide for primary care providers and PACT teamlets. The IPMCS will also serve in a consulting role in regards to the ongoing management of patients on chronic opioid medications and for patients for whom the primary care or mental health provider feels opioids are indicated for other than episodic short-term therapy.

Appendix C

OIG Contact and Staff Acknowledgments

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Appendix D

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