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Office of Healthcare Inspections

Report No. 16-01077-255

## Healthcare Inspection

### Opioid Management Practice Concerns

John J. Pershing VA Medical Center  
Poplar Bluff, Missouri

June 1, 2017

Washington, DC 20420

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## Executive Summary

The VA Office of Inspector General conducted a healthcare inspection to determine the merit of a complainant's allegations regarding opioid management practices at the John J. Pershing VA Medical Center (facility), Poplar Bluff, MO.

The summarized allegations include the following:

- Long-term opioid therapy for pain was poorly managed for certain patients.
- Opioid prescriptions were written for patients without documentation of an opioid risk stratification tool, such as the opioid risk tool (ORT).
- Some providers did not consistently use urine drug screening (UDS), order confirmatory tests to evaluate for diversion, or further evaluate UDS results that were suggestive of urine tampering.
- Opioid pain care agreements, including signed informed consents, were not consistently completed prior to initiating long-term opioid therapy for pain.

We substantiated the allegation of poor management of long-term opioid therapy for pain for the 10 patients we reviewed. We found documentation for the condition requiring opioid therapy but did not find evaluation of risks when clinically significant changes to a patient's health status occurred. We found that a provider lacked knowledge of safe and effective methods for tapering patients' opioids.

We substantiated the allegation that opioid prescriptions were written for patients without documentation of an opioid risk stratification tool, such as the ORT. The Veterans Health Administration's Opioid Safety Initiative provides guidelines to develop tools to identify high-risk patients. Using the ORT helps a provider risk stratify patients for initiating or continuing opioid therapy, and the ORT can help guide providers in determining the frequency of obtaining UDS for patients on long-term opioid therapy for pain.

We substantiated the allegation that some providers did not consistently use UDS, order confirmatory tests to evaluate for diversion, or further evaluate UDS results that were suggestive of urine tampering for the patients reviewed. We reviewed electronic healthcare records for 10 patients who received long-term opioid therapy for pain and found:

- Five patients did not have a UDS performed as recommended.
- Five patients had UDS results that were not consistent with the patient taking prescribed opioids as ordered, and providers did not order confirmatory testing.
- Two patients had UDS results suggestive of urine tampering, and providers did not document consideration of these results in the electronic health record.

We substantiated the allegation that some patients did not have signed informed consents prior to initiating long-term opioid therapy for pain. We found that 5 of the 10 patients' EHRs were missing signed informed consents.

We recommended that the Facility Director:

- Develop processes to ensure that the relevant providers complete timely patient evaluations for continued long-term opioid therapy for pain based on clinically significant changes or findings to a patient's health status.
- Ensure that reviews of the cases of the identified patients with clinically significant changes are completed and take action as appropriate.
- Ensure that the relevant providers receive education on the concurrent prescribing of dual short acting opioids and tapering of opioids.
- Ensure that the relevant providers review Veterans Health Administration recommendations regarding the use of opioid risk stratification tools, such as the ORT, to identify high-risk patients for long-term opioid therapy for pain.
- Ensure that the relevant providers order UDS frequency based on risk assessment and complete UDS at least annually.
- Ensure that the relevant providers consistently use UDS confirmatory testing.
- Develop processes that minimize the potential for UDS tampering.
- Ensure that the relevant providers consistently complete the informed consent process prior to initiating long-term opioid therapy for pain as specified by Veterans Health Administration policy.

## Comments

The Veterans Integrated Service Network and Facility Directors reviewed the report; the Facility Director concurred with our recommendations and provided acceptable action plans. (See Appendixes A and B, pages 12–19 for the Directors' comments.) The Facility Director considers all recommendations completed; however, we consider all recommendations open until we receive and review written documentation that proposed actions were completed.



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## Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to determine the merit of a complainant's allegations regarding opioid management practices at the John J. Pershing VA Medical Center (facility), Poplar Bluff, MO.

## Background

The facility has 58 beds (40 Community Living Center and 18 acute medicine beds), operates 7 community based outpatient clinics in Missouri and Arkansas, and is under the oversight of Veterans Integrated Service Network (VISN) 15. In the first quarter of fiscal year 2016, 24,735 veterans were enrolled for care, and the facility provided 204,863 encounters during 141,943 veteran visits.

### *Chronic Pain*

Chronic pain is a prevalent condition among veterans and may be challenging to treat.<sup>1</sup> Chronic pain has been "...described as ongoing or recurrent pain, lasting beyond the usual course of acute illness or injury or more than 3 to 6 months, and which adversely affects the individual's well-being."<sup>2</sup> Pain has biological, psychological, and social contributing factors. Pain treatment may be complex and includes medications, surgery, psychological treatment, rehabilitative and physical therapy, and/or complementary therapies. A patient's pain management may require a coordinated multidisciplinary approach. The primary care provider (PCP) is often the care plan coordinator who gauges effectiveness of treatments with follow-up reassessments.

### *Opioids*

Opioids are medications that relieve mild to severe pain and include codeine, hydrocodone, oxycodone, and morphine.<sup>3</sup> The Veterans Health Administration (VHA) recognizes that "[t]he safe and effective use of opioid analgesics for the management of pain, particularly complex chronic pain conditions, requires special attention to personal and public health risks."<sup>4</sup> Opioid pain care agreements (OPCA) document providers' discussions with patients "...regarding potential risks and benefits of opioids, provider and patient responsibilities related to opioid use, and the parameters for continued opioid use."<sup>5</sup> Benefits of OPCAs include "...their potential to improve adherence,

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<sup>1</sup> Witness Testimony of Robert. L. Jesse, M.D., Principal Deputy Under Secretary for Health, Veterans Health Administration, U.S. Department of Veterans Affairs, October 10, 2013.

<sup>2</sup> *Glossary*. American Chronic Pain Association Website, <http://theacpa.org/glossary>. Accessed April 12, 2016.

<sup>3</sup> National Institute on Drug Abuse, *Prescription Drug Abuse*, <http://www.drugabuse.gov/publications/research-reports/prescription-drugs/opioids/what-are-opioids>. Accessed March 18, 2016.

<sup>4</sup> VHA Directive 2009-053, *Pain Management*, October 28, 2009. This Directive expired October 31, 2014 and has not yet been updated.

<sup>5</sup> VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 6, 2014.

reduce misuse and diversion, and clarify treatment goals, expectations, and responsibilities.”<sup>6</sup>

The development of an individualized pain management plan that includes patient education, reassessments, and follow-up planning for any changes can require significant time and effort. The PCP, who is often the care plan coordinator, may wish to utilize the expertise of specialists. However, access to specialty care may be difficult due to a lack of specialists or a patient’s remote location. When a specialist is not readily available, a PCP’s experience, education, and knowledge of pain practices may contribute significantly to helping a patient decrease reliance on opioids, or continue to use opioids safely and effectively.

Recent changes in U.S. Drug Enforcement Administration regulations that govern controlled substances, such as opioid medications, had a significant impact on prescribing practices. Hydrocodone, one of the most commonly prescribed opioid medications, was changed from Schedule III<sup>7</sup> to Schedule II<sup>8</sup> on October 6, 2014. Additionally, on August 18, 2014, tramadol, previously not classified as a scheduled drug, became a Schedule IV drug.<sup>9</sup> These changes resulted in the need for additional patient clinic visits and, in some VA facilities, eliminated the ability of mid-level practitioners to prescribe hydrocodone.

#### *VHA’s Pain Management and Opioid Safety Efforts*

VHA policy requires adherence to VHA’s National Pain Management Strategy objectives, including implementation of a stepped care model of pain care that provides for management of most pain conditions in the primary care setting.<sup>10</sup> Providers are expected to meet standards of pain management as outlined in Directive 2009-053, including pain assessment and treatment, evaluation of outcomes and quality of pain management, and clinical competence and expertise in pain management.<sup>11</sup>

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<sup>6</sup> VHA Directive 1005.

<sup>7</sup> “Substances in this schedule have a potential for abuse less than substances in Schedules I and II and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit..., and buprenorphine...,” <http://www.deadiversion.usdoj.gov/schedules/>. Accessed April 14, 2016.

<sup>8</sup> “Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples of Schedule II narcotics include: hydromorphone..., methadone..., [and] oxycodone...,” <http://www.deadiversion.usdoj.gov/schedules/>. Accessed April 14, 2016.

<sup>9</sup> Substances in Schedule IV, compared to Schedule III, have a lower potential for abuse, <http://www.deadiversion.usdoj.gov/schedules/>. Accessed April 14, 2016

<sup>10</sup> VHA Directive 2009-053.

<sup>11</sup> Ibid.

VHA's National Pain Management Strategy had several aims, including but not limited to:

1. *Ensure that pain assessment is performed in an appropriately timely, regular, and consistent manner along the continuum of care from acute to chronic pain in all VHA settings.*<sup>12</sup>
2. *Ensure that pain treatment is prompt and strives to achieve pain management objectives along the continuum of care from acute to chronic pain in all VHA settings.*<sup>13</sup>
3. *Provide for appropriate level and frequency of monitoring for improvement in outcomes of pain management including pain control, physical and psychosocial function, quality of life, and complications.*<sup>14</sup>

In May 2010, VA and the Department of Defense (DoD) issued the *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* (Guideline).<sup>15</sup> Clinical practice guidelines are defined as "Recommendations for the performance or exclusion of specific procedures or services derived through a rigorous methodological approach...."<sup>16</sup> The scope of the Guideline was to:

1. Address assessment and evaluation of chronic pain and appropriateness of opioid therapy.
2. Present and discuss formal treatment plans and treatment agreements.
3. Provide guidance on assessing response to treatment, and determinations of adherence or abuse (aberrant drug-related behaviors).<sup>17</sup>

For providers conducting chronic pain assessment, the Guideline outlined the following steps:

1. Review of medical history.
2. Administration of a physical exam to determine baseline function and pain.
3. Review of prior attempts to treat pain with non-opioid modalities.
4. Assessment of the risk of medication abuse through use of the opioid risk tool or consideration of any psychiatric comorbidity.
5. Determination of factors that could put the patient at increased risk for adverse outcomes.<sup>18</sup>

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<sup>12</sup> VHA Directive 2009-053.

<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</sup> VA and DoD, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, May 2010.

<sup>16</sup> Ibid.

<sup>17</sup> Ibid. Aberrant drug related behaviors may include lost prescriptions, multiple requests for early refills, unauthorized dose escalation, and any history of positive UDS for illicit drugs.

<sup>18</sup> VA and DoD, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, May 2010.

## *Opioid Safety Initiative*

The *Opioid Safety Initiative* (OSI) dated April 2, 2014,<sup>19</sup> and the OSI Update dated December 10, 2014, established goals for safe, evidence-based, veteran-centric pain care as part of VHA's OSI.<sup>20</sup> Created in July 2014, the *VA Pain Management Opioid Safety, VA Educational Guide (2014)* (Educational Guide) outlines chronic pain treatment strategies, including considering non-opioid treatment options, opioid treatment with an assessment of the patient at every visit, re-evaluations of the treatment plan, and consultation with a specialist based on selected clinical factors.<sup>21</sup>

The Educational Guide also outlines screening for risk factors of addiction and misuse. The screening tools include the Opioid Risk Tool (ORT), which may be useful for predicting risk of future aberrant drug related behavior. Patients may be classed into three different categories for risk of misuse: Low, Moderate, and High.<sup>22</sup> The ORT is a guide that helps the provider determine whether pain management should include opioids. Additionally, the risk categorization gives the provider guidance on the intervals for ordering a UDS on a patient prescribed opioids.

On October 1, 2014, VHA's "National Pain Management Program office convened a national task force comprised of multidisciplinary pain experts to create an OSI Toolkit..."<sup>23</sup> The toolkit consists of "documents and presentations that can aid [VHA providers in their] clinical decisions about starting, continuing, or tapering opioid therapy, and other challenges related to safe opioid prescribing."<sup>24</sup>

In 2014, VHA also issued Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*,<sup>25</sup> regarding OPCAs, patient education, and informed consent for long-term opioid therapy for pain.<sup>26</sup> This directive outlined a standardized informed consent process that replaced facilities' locally created OPCAs, and the use of an electronic document, *Consent for Long-Term Opioid Therapy for Pain*. Prior to initiating long-term opioid therapy for pain, VHA opioid providers must complete the patient education and informed consent process. Providers are responsible for providing the patient with a copy of "*Taking Opioids Responsibly for Your Safety and the Safety of Others*,"<sup>27</sup> one of the documents provided in the OSI toolkit. This document provides patient information

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<sup>19</sup> Under Secretary for Health Memorandum, *Opioid Safety Initiative*, April 2, 2014.

<sup>20</sup> Acting Deputy Under Secretary for Health for Operations and Management Memorandum, *Opioid Safety Initiative (OSI) Update*, December 10, 2014.

<sup>21</sup> *VA Pain Management Opioid Safety, VA Educational Guide (2014)*.

<sup>22</sup> Ibid. Low (no moderate to high risk characteristics, Moderate (high-risk characteristics absent), High (may include history of or current troublesome aberrant drug related behaviors).

<sup>23</sup> VHA Opioid Safety Initiative Toolkit, October 1, 2014,

[http://www.va.gov/PAINMANAGEMENT/Opioid\\_Safety\\_Initiative\\_OSI.asp](http://www.va.gov/PAINMANAGEMENT/Opioid_Safety_Initiative_OSI.asp). Accessed May 18, 2016.

<sup>24</sup> Ibid.

<sup>25</sup> VHA Directive 1005. Long-term Opioid Therapy for Pain is the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days to treat non-cancer pain.

<sup>26</sup> Ibid

<sup>27</sup> *Taking Opioids Responsibly for Your Safety and the Safety of Others*,

<http://www.va.gov/PAINMANAGEMENT/docs/TakingOpioidsResponsibly20121017.pdf>.

Accessed on May 18, 2016.

on opioid safety, additional modalities for the care plan, do's and don'ts of taking opioids, side effects, and urine drug screening (UDS).<sup>28</sup>

## UDS

The Guideline<sup>29</sup> recommends that UDS be done prior to initiating long-term opioid therapy for pain, and the Educational Guide recommends UDS<sup>30</sup> at least yearly during therapy. Providers use UDS to monitor patients on opioids for illicit substances, medication compliance, and diversion.<sup>31</sup> Because each patient is unique and each visit or refill circumstance may be different, the provider must take into account the reason for the UDS and evaluate UDS results based on the individual patient's clinical circumstance. The provider must consider the type of opioid, the amount, and how the drug is taken (as needed or at set times). The provider must also understand the metabolism of the drug, and know how and when confirmatory testing<sup>32</sup> should be ordered. In cases of suspected diversion, the provider needs to first interpret the UDS and consider confirmatory tests. However, the provider must also understand that not all negative UDSs represent drug diversion. Further, the provider must also understand the significance of certain results in a UDS that are consistent with UDS tampering.<sup>33</sup>

A UDS can result in a urine sample not showing a drug that should be present (prescriptions) or a drug that should not (illegal substances). Providers order confirmatory urine testing when the UDS results conflict with the clinical context of what was prescribed. This confirmatory testing of the urine is conducted through further laboratory analysis.

The use of blood testing to confirm the presence or absence of a drug is not reliable. Many medications are metabolized quickly and may not show up in the blood at the time of blood testing. Additionally, a drug that is confirmed to be in the blood does not exclude diversion since a patient may take a medication just prior to the blood test. Since urine testing of a medication is directly proportional to the level stored in the body over time, the test generally represents a patient's use of medication measured in weeks and not hours.

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<sup>28</sup> We use the terms urine drug screen(ing) and urine drug test(ing) interchangeably. These terms appear in the Guideline and OSI policy and education materials.

<sup>29</sup> VA and DoD, *VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain*, May 2010.

<sup>30</sup> *VA Pain Management Opioid Safety, VA Educational Guide (2014)*.

<sup>31</sup> Centers for Medicare and Medicare Services (CMS) defines drug diversion as "the illegal distribution or abuse of prescription drugs or their use for unintended purposes," <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Drug-Diversion-ICN901010.pdf>. Accessed May 18, 2016.

<sup>32</sup> A confirmatory test is a secondary analysis performed on the same specimen using completely different technology than the initial method. It is used to confirm the presence of a drug, or further pinpoint which drug made the initial result positive.

<sup>33</sup> SCI Test Laboratories states that "tampering is a deliberate malicious attempt to subvert the drug test and is an ongoing concern for urine drug testing," <http://scitestlabs.com/Specimen-Validity-Testing/>. Accessed September 28, 2016.

A UDS may also show evidence of dilution. Diluting a urine sample lowers the laboratory test ability to detect illegal substances in the urine by adding water to a sample or by drinking large amounts of water prior to the test. The urine's creatinine and specific gravity values are indicators of dilution. A provider should request a repeat UDS if dilution is suspected.

Routine and random UDS is recommended<sup>34</sup> for all patients with chronic pain prior to and during opioid therapy. Routine UDS is recommended at least annually.<sup>35</sup> Using screening tools like the ORT, which assesses each patient's opioid risk classification, the frequency of the UDS can be determined. The higher the assessed risk, the more frequently UDS should be performed. The VA *Pain Management Opioid Safety, A Quick Reference Guide (2014)*<sup>36</sup> has tables of the ORT, opioid risk calculation, and recommended frequency of UDS.

### *Facility's Pain Management and Opioid Safety Efforts*

In January 2015, the facility implemented a Pain Management Committee with the purpose of providing oversight, coordination, and monitoring of pain management activities and processes across the system. Committee membership includes a variety of clinical staff with the overarching goal of aligning facility pain management efforts with OSI goals. At the time of our site review in January 2016, committee meetings had been held quarterly during 2015, and action items to support OSI goals were ongoing.

### **Allegations**

In the fall of 2015, the OIG received allegations that included opioid patient care and pain management. Allegations discussed in this report are summarized below:

- Providers poorly managed long-term opioid therapy for certain patients.
- Opioid prescriptions were written for patients without documentation that an opioid risk stratification tool was used, such as the ORT.
- Some providers did not consistently use UDS, order confirmatory tests to evaluate for diversion, or further evaluate UDS results that were suggestive of urine tampering.
- OPCAs, including signed informed consents, were not consistently being completed prior to initiating long-term opioid therapy for pain.

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<sup>34</sup> VA and DoD, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010.

<sup>35</sup> VA *Pain Management Opioid Safety, VA Educational Guide (2014)*.

<sup>36</sup> VA *Pain Management Opioid Safety, A Quick Reference Guide (2014)*.

## Scope and Methodology

We initiated our review in January 2016 and completed our work in May 2016. We conducted a site visit the week of January 11, 2016.

We interviewed the facility's Acting Director, Chief of Staff, Nurse Executive, Associate Chief of Staff for Specialty Care, Associate Chief of Staff Primary Care, Administrative Officer for Primary Care, pain clinic staff, pharmacy staff, primary care staff from the facility and community based outpatient clinics, and a laboratory supervisor.

We reviewed relevant VA/DoD, VHA, VISN, and facility directives, guidelines, handbooks, policies and procedures, and committee minutes. We also reviewed electronic health records (EHR) for 10 patients who received long-term opioid therapy for pain.

VHA Directive 2009-053, *Pain Management*, October 28, 2009 cited in this report expired October 31, 2014. We considered this policy to be in effect as it had not been superseded by more recent policy or guidance. In a June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),<sup>37</sup> the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."<sup>38</sup> The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility."<sup>39</sup>

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

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.

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<sup>37</sup> VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016.

<sup>38</sup> VA Under Secretary for Health Memorandum, *Validity of VHA Policy Document*, June 29, 2016.

<sup>39</sup> *Ibid.*

## Inspection Results

### ***Issue 1: Management of Long-Term Opioid Therapy for Pain***

We substantiated the allegation of poor management of long-term opioid therapy for pain for certain patients. After determining that the 10 patients identified in the complaint had been receiving long-term opioid therapy, we reviewed their EHRs for documentation of providers' assessments of chronic pain conditions. We found documentation of the condition requiring opioid therapy but did not find evaluation of risks when clinically significant changes to a patient's health status occurred.<sup>40</sup>

Below we give three examples of patients with clinically significant changes:<sup>41</sup>

- A patient was admitted to an intensive care unit for overdose on prescription drugs, including morphine, but continued on long-term opioid therapy after discharge without the prescribing provider reassessing the patient until 5 months later.
- A patient had five consecutive positive UDSs for an illicit drug and continued on long-term opioid therapy for pain without a documented discussion of changing the care plan for long-term opioid therapy.
- A patient had a recent suicide attempt with a gun that misfired but continued on long-term opioid therapy for pain without a documented risk assessment.

Because of the clinically significant changes in these patients, the providers should have documented an evaluation of the patients' risks in continuing long-term opioid therapy.

Additionally, the complainant alleged specific opioid management and treatment concerns for:

- A patient who had two short-acting narcotics that were prescribed by the same provider at the same time.
- Lack of knowledge of a PCP when tapering opioids.

We confirmed these issues in the EHR. Both scenarios exemplified clinical practice concerns that could have been rectified with focused provider education. For the case of the prescription of two short-acting narcotics, the provider's treatment plan documented increasing one short-acting narcotic while continuing the other. For the case of tapering opioids, the pain consultant outlined the steps of tapering to the PCP. However, the PCP noted that he/she did not know how to convert or taper the opioid dosages despite the instructions provided by the pain consultant.

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<sup>40</sup> VHA Directive 2009-053.

<sup>41</sup> For this report, we define clinically significant changes or findings to a patient's health status as a clinical scenario or lab result that could potentially alter therapy for a patient and, at the least, would prompt a provider to re-evaluate the status quo of treatment.

## **Issue 2: ORTs**

We substantiated the allegation that opioid prescriptions were written for patients without documentation of an opioid risk stratification tool, such as an ORT. The lack of the use of an ORT was a concern for all 10 patients reviewed.

The Guideline and OSI goals include development of tools to identify high-risk patients. The ORT is included in the OSI toolkit, and using the ORT helps a provider risk stratify patients for initiating or continuing opioid therapy. Further, the ORT can help guide clinicians in determining the frequency of obtaining UDS for patients on long-term opioid therapy for pain. The treatment plan for a patient who is stratified as high risk may impact the frequency of UDS testing, require closer clinical monitoring, and/or preclude the initiation or continuation of opioids.

## **Issue 3. UDS Process**

We substantiated the allegation that some providers did not consistently use UDS, order confirmatory tests to evaluate for diversion, or further evaluate UDS results that were suggestive of urine tampering.

### *Completion of UDS*

We found that 5 of the 10 patients did not have a UDS as recommended.<sup>42</sup> Of the five patients, three had UDS completed within the year but clinical risks required more frequent UDS. According to the Guideline, a UDS is recommended for all patients prior to and during opioid therapy, and the Educational Guide<sup>43</sup> recommends a UDS be completed at least yearly, and more frequently based on a patient's risk.

### *Confirmatory Tests*

We found that 5 of the 10 patients had UDS results that were consistent with the patient not taking the prescribed opioids as ordered, and providers did not order confirmatory testing. The Guideline recommends that the provider understand lab methods for drug testing and reporting are necessary to interpret UDS results and confirmatory testing.<sup>44</sup>

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<sup>42</sup> For this report, we defined an applicable UDS as a UDS completed within the past year for patients with low risk, a UDS completed twice a year for patients with moderate risk, a UDS 3 to 4 times a year or at time of visit for patients with high risk, and a UDS at the time of a clinic visit if the patient had demonstrated aberrant behaviors.

<sup>43</sup> VA Pain Management Opioid Safety, VA Educational Guide (2014).

<sup>44</sup> VA and DoD, VA/DoD Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain, May 2010. Urine drug screens and confirmatory urine or blood drug testing may be useful in detecting illicit drug use, use of drugs not prescribed, and opioid malabsorption. Repeatedly negative opioid test results may strongly suggest diversion. When performed and interpreted properly, urine drug screens and confirmatory urine and blood drug tests can provide accurate and useful information that allows the provider to tailor pain therapy, safeguards, and risk management strategies.

### *Urine Tampering*

We found that 2 of the 10 patients' EHRs we reviewed had UDS results suggestive of urine tampering,<sup>45</sup> as noted by low levels of a substance in the urine known as creatinine. For example, if urine creatinine levels are low, it can mean that the urine has been diluted with water. The provider must be aware of UDS results consistent with dilution and be cautious when relying on the results because of possible patient tampering.

Through interviews with the facility's primary care providers, we found that UDS testing and evaluation did not occur because of various reasons that included:

- The lack of knowledge that blood testing is not the confirmatory test for UDS. Some providers incorporated blood testing as part of their routine process for evaluating UDS.
- The lack of knowledge of how long the facility's laboratory staff holds UDS specimens. Some providers would repeat the UDS on another day instead of utilizing confirmatory testing in the urine already obtained and held by the laboratory.

### ***Issue 4. Missing Signed Informed Consents***

We substantiated the allegation that patients did not have signed informed consents prior to initiating long-term opioid therapy for pain. We found that 5 of the 10 patients' EHRs were missing signed informed consents. Prior to initiating patients' long-term opioid therapy for pain, VHA opioid providers must complete the informed consent process.<sup>46</sup>

We interviewed the facility's PCPs and found there could be issues with the competing priorities of managing patients with complex medical conditions and chronic pain within the follow-up visit. Some providers noted the time constraints in managing patients with chronic diseases and the need to prioritize their time for those conditions.

## **Conclusions**

We substantiated the allegation of poor management of long-term opioid therapy for pain for the 10 patients we reviewed. We found documentation of the condition requiring opioid therapy, but did not find evaluation of risks when clinically significant changes to a patient's health status occurred. We found that a provider lacked knowledge of safe and effective methods for tapering patients' opioids.

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<sup>45</sup> SCI Test Laboratories states that "tampering is a deliberate malicious attempt to subvert the drug test and is an ongoing concern for urine drug testing," <http://scitestlabs.com/Specimen-Validity-Testing/>. Accessed September 28, 2016.

<sup>46</sup> VHA Directive 1005.

We substantiated the allegation that opioid prescriptions were written for patients without documentation of an opioid risk stratification tool, such as the ORT. The OSI provides guidelines to develop tools to identify high-risk patients. Using the ORT helps a provider risk stratify patients for initiating or continuing opioid therapy. The treatment plan for a patient who is stratified as high risk may impact the frequency of UDS testing, require closer clinical monitoring, and/or preclude the initiation or continuation of opioids.

We substantiated the allegation that some providers did not consistently use UDS, order confirmatory tests to evaluate for diversion, or document consideration of these results in the electronic health record.

We substantiated the allegation that some patients did not have informed consents prior to initiating long-term opioid therapy for pain.

## **Recommendations**

1. We recommended that the Facility Director develop processes to ensure that the relevant providers complete timely patient evaluations for continued long-term opioid therapy for pain based on clinically significant changes or findings to a patient's health status.
2. We recommended that the Facility Director ensure that reviews of the cases of the identified patients with clinically significant changes are completed and take action as appropriate.
3. We recommended that the Facility Director ensure that the relevant providers receive education on the concurrent prescribing of dual short acting opioids and tapering of opioids.
4. We recommended that the Facility Director ensure that the relevant providers review Veterans Health Administration recommendations regarding the use of opioid risk stratification tools, such as the Opioid Risk Tool, to identify high-risk patients for long-term opioid therapy for pain.
5. We recommended that the Facility Director ensure that the relevant providers order urine drug screening frequency based on risk assessment and complete urine drug screening at least annually.
6. We recommended that the Facility Director ensure that the relevant providers consistently use urine drug screening confirmatory testing.
7. We recommended that the Facility Director develop processes that minimize the potential for urine drug screening tampering.
8. We recommended that the Facility Director ensure that the relevant providers consistently complete the informed consent process prior to initiating long-term opioid therapy for pain as specified by Veterans Health Administration policy.

## VISN Director Comments

### Department of Veterans Affairs

### Memorandum

**Date:** April 24, 2017

**From:** Director, VA Heartland Network (10N15)

**Subj:** Healthcare Inspection—Opioid Management Practice Concerns,  
John J. Pershing VA Medical Center, Poplar Bluff, Missouri

**To:** Director, Kansas City Office of Healthcare Inspections (54KC)  
Director, Management Review Service (VHA 10E1D MRS Action)

1. We appreciate the effort of the OIG to improve the care of the 10 long term opioid patients that were pre-selected for the review. At the time of the complaint (1<sup>st</sup> Q FY16) there were over 1300 patients that were receiving long term opioid therapy.
2. Poplar Bluff worked throughout 2015 to improve their management of long term opioid therapy patients.
  - A year prior to the OIG on site review (January 2015), there were 1564 patients at Poplar Bluff on long term opioid therapy.
  - 1072 needed a urine drug screen
  - 1195 needed a signed informed consent
3. By the end of first quarter 2016, December 2015 (OIG on site review took place January 2016), there were 1386 patients on long term opioid therapy.
  - 141 needed a urine drug screen (90% had UDS done)
  - 92 needed a signed informed consent (93 percent had signed informed consent)
4. Of the ten patients reviewed in January 2016, seven no longer receive opioid therapy from the VA. One patient has since died. Only two patients remain on opioid therapy and are compliant with recommendations.

## VISN Director Comments

5. The data clearly demonstrate and document that Poplar Bluff identified that their program needed improvement and began the process of improving the program well before the OIG complaint became known. It is also clear from the data that at least 90 percent of all the patients on long term opioid therapy had consents and current urine drug screen at the time of the OIG on-site review. In comparison, the national average for current UDS for 1Q16 was 79.3 percent and the national average for consent completion was 68 percent.
6. Eight of the ten patients reviewed by the OIG had urine drug screens done at least annually. But for three of the patients the OIG recommended that they have UDS more frequently than semi-annually. Those three patients no longer receive opioid therapy from the VA.
7. As an indication of the work that Poplar Bluff has done since 2015, we believe 7 of the 8 recommendations are potentially in compliance. We will evaluate the performance of the 7 providers who prescribed opioid therapy for the 10 preselected patients. We will monitor the overall compliance of the Medical Center in Opioid therapy.



Dr. William P. Patterson, MD, MSS  
Network Director  
VA Heartland Network (VISN 15)

## Facility Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** April 21, 2017  
**From:** Director, John J. Pershing VA Medical Center (657A4/00)  
**Subj:** Healthcare Inspection—Opioid Management Practice Concerns,  
John J. Pershing VA Medical Center, Poplar Bluff, Missouri  
**To:** Director, VA Heartland Network (10N15)

1. I have reviewed the draft report of the Office of Inspector General's review of the opioid management practices at the John J. Pershing VA Medical Center in Poplar Bluff, Missouri. We concur with the findings and recommendations.
2. The John J. Pershing VA Medical Center has made strides toward implementation of the Opioid Safety Initiative prior to receiving the OIG report. A Clinical Pharmacy Specialist was assigned to pain management in April 2016. Education regarding appropriate management of opioid medications has been provided to physicians. The facility has adopted the use of a clinical reminder for urine drug screen testing, an opioid risk tool is available for clinician use, and iMED consents are being obtained for long term opioid therapy. Additionally, the total number of patients (non-oncology) receiving long term opioid therapy has decreased from 1564 in first quarter 2015 to 1100 in first quarter 2017.
3. If you have questions or require additional information, please do not hesitate to contact Ginger Potts, Quality Manager, at 1-573-778-4280 or [ginger.potts@va.gov](mailto:ginger.potts@va.gov).
4. I appreciate the opportunity for this review as a continuing process to improve care to our Veterans.

*(original signed by:)*  
Patricia L. Hall, PhD, FACHE  
Medical Center Director

## Comments to OIG's Report

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

### **OIG Recommendations**

**Recommendation 1.** We recommended that the Facility Director develop processes to ensure that the relevant providers complete timely patient evaluations for continued long-term opioid therapy for pain based on clinically significant changes or findings to a patient's health status.

Concur

Target date for completion: Completed

Facility response: The total number of patients (non-oncology) receiving long term opioid therapy has decreased from 1564 in first quarter 2015 to 1100 in first quarter 2017. Processes have been strengthened to ensure that physicians and other prescribers evaluate the Veteran's condition prior to prescribing an opioid, or upon any clinically significant changes or findings to a patient's health status.

An opioid risk stratification tool (ORT) has been implemented, and is available for provider use in the Computerized Patient Record System (CPRS). The Stratification Tool for Opioid Risk Mitigation (STORM) report is utilized to determine the estimated risk for adverse events, as well as suggested risk mitigation strategies. This report takes recent diagnoses and events into consideration when calculating those risks. It includes a hypothetical risk estimate (includes suicide-related events, overdoses, falls, or accidents for the last 3 years, and/or suicide-related events or overdoses in the last 1 year), contributing factors to the patient's risk (relevant diagnoses (mental health and medical) and relevant medications), how to reduce the patient's risk (risk mitigation strategies and/or non-pharmacological pain treatments), and follow up (recent appointments including primary care, mental health, pain clinic, and other, upcoming appointments, and a listing of care providers). The Opioid Therapy Risk Reduction report is also available to providers as a tool to assist providers in mitigating risk associated with chronic opioid use. Providers are able to review these individualized report for each patient to determine if any clinically significant changes or findings to the patient's health status have occurred which would impact the risk for continued opioid therapy, or initiation of opioid therapy. The care plan for long-term opioid therapy can then be revised, if needed.

Additionally, relationships between the medical center and surrounding healthcare facilities have been strengthened. The Suicide Prevention Coordinator (SPC) has increased correspondence with neighboring hospitals to ensure timely and thorough communication of information regarding any Veteran who is admitted with a suicide attempt. This open line of communication assists the SPC with timely evaluation of the

medical record, and initiation of involvement of the patient's primary care team for evaluation and ongoing treatment.

**Recommendation 2.** We recommended that the Facility Director ensure that reviews of the cases of the identified patients with clinically significant changes are completed and take action as appropriate.

Concur

Target date for completion: Completed

Facility response: A review of the three patients has been completed. Appropriate education of relevant staff has been completed. As mentioned previously, relationships have been strengthened with non-VA medical centers to ensure timely notification of a suicide attempt to the facility's Suicide Prevention Coordinator, so the flag can be placed without delay. For hospitalizations coordinated by the facility, both VA and Non-VA, post hospitalization follow up appointments occur within 2 weeks of discharge. During this visit any clinically significant changes are evaluated, and changes to the treatment plan are made, if needed. Clinical changes are also evaluated by the ordering provider when medication renewals are completed between primary care visits.

**Recommendation 3.** We recommended that the Facility Director ensure that the relevant providers receive education on the concurrent prescribing of dual short acting opioids and tapering of opioids.

Concur

Target date for completion: Completed

Facility response: The relevant providers have received education on dual short acting opioids and tapering of opioids. Safety Initiative Academic Detailing is being provided for all new providers during new provider orientation. Additionally, third quarter 2016, Pharmacy provided in-services educating providers on the Centers for Disease Control's (CDC's) guidelines on prescribing opioids. The medical center also has planned tele involvement with another VISN 15 VA medical center in their Pain Summit, which occurs in spring 2017.

The Chief of Pharmacy Services provided repeat written education regarding prescribing dual short acting opioids in March 2017. Materials related to tapering of opioids, and information on consults that can be placed to assist, were also included. Consults have been developed and made available for Opioid Taper Clinic Consults and Pain Management eConsults. These patients can be evaluated by a Pain Management Clinical Pharmacy Specialist who will assist the provider with the tapering process. There is also guidance available for tapering opioids in the Academic Detailing *Pain Management Opioid Safety: A Quick Reference Guide* which was given to all providers. An electronic link for the quick reference guide was also provided.

Additionally when an order is placed, during the Pharmacy review and verification process, the pharmacist monitors for dual short acting opioids. If it is identified that there are dual short action opioids ordered, the provider will be alerted, and clarification will be requested.

A review was completed of all non-oncology patients receiving long term opioid therapy. Two patients were found with dual short acting opioids, for a compliance rate of 99.8 percent. The two patients who had dual short acting opioids were originally on one, with a new prescription written due to recent clinical changes: one patient was being treated for unilateral kidney stones and given a 30 day supply of an increased strength pain medication, and the other was given a 4 day supply due to increased “suspected cervical radiculopathy pain.” Both have instructions in the medication order “do not take Lortab while taking Percocet.”

**Recommendation 4.** We recommended that the Facility Director ensure that the relevant providers review Veterans Health Administration recommendations regarding the use of opioid risk stratification tools, such as the Opioid Risk Tool, to identify high-risk patients for long-term opioid therapy for pain.

Concur

Target date for completion: Completed

Facility response: The relevant providers have been educated on the Veterans Health Administration recommendations use of opioid risk stratification tools through TMS Course No. 31108 Pain Management and Opioid Safety. Additionally, there has been education on and implementation of the use of the STORM report, as described above in recommendation one. Providers have also received the pocket guide, which includes information on utilization of an opioid risk tool.

**Recommendation 5.** We recommended that the Facility Director ensure that the relevant providers order urine drug screening frequency based on risk assessment and complete urine drug screening at least annually.

Concur

Target date for completion: Completed

Facility response: Strides had been made to improve compliance with annual collection of urine drug screens prior to the on-site OIG review. Patients without annual urine drug screens have decreased from 1,072 patients in first quarter 2015 to 169 patients in first quarter 2017, for a compliance rate of 85.4 percent.

All Primary Care Providers have been given Academic Detailing *Pain Management Opioid Safety: A Quick Reference Guide* educational materials which contains educational information on the following: Urine Drug Test (UDT) Results, UDT Methods, UDT Specimen Validity, UDT Federal Work Place Cut Off Values, and Interpreting UDT.

The Quick Reference Guide also gives guidance on appropriate frequency of urine drug screen based on the patient's risk assessment, no less than annually.

The facility Preventative Ethics Committee has utilized the topic of pain management as part of the facility annual ISSUE Cycle completion. ISSUE cycles related to alternative measures for pain management were completed in FY 2014 and 2016. A Preventative Ethics ISSUE Cycle related to Urine Drug Screen Collection was completed in September of 2016. One of the recommendations was a clinical reminder for UDS to improve compliance with UDS collection. The facility pain management committee has worked toward this goal. The urine drug screen clinical reminder has been developed, approved by clinical leadership, and implemented. Additionally, two in-services were provided regarding interpretation of urine drug screens third quarter of 2017. A TMS training course is also available for urine drug screen interpretation.

**Recommendation 6.** We recommended that the Facility Director ensure that the relevant providers consistently use urine drug screening confirmatory testing.

Concur

Target date for completion: Completed

Facility response: In-services, Academic Detailing education, and training through TMS have been provided to the providers regarding proper confirmatory testing. Laboratory has also initiated a process for auto-verification of any positive amphetamine results which results in automatic reflex confirmatory testing. A written Urine Drug Screen Standard of Practice has been developed, and is presently in the approval process. This standard of practice includes guidance on completing urine drug screening confirmatory testing. For positive UDS results, lab will keep specimen for 7 days for the purpose of ordering confirmatory testing when appropriate. For negative UDS results, lab will keep the specimen for 3 days for the purpose of ordering confirmatory testing when appropriate.

**Recommendation 7.** We recommended that the Facility Director develop processes that minimize the potential for urine drug screening tampering.

Concur

Target date for completion: Completed

Facility response: Education related to urine drug screen tampering has been provided to healthcare providers through in-services, Academic Detailing education, Academic Detailing *Pain Management Opioid Safety: A Quick Reference Guide*, and TMS training. To minimize the potential for urine drug screen tampering a urine creatinine is also run with a UDS to assist with recognizing if tampering has occurred. If creatinine is less than 20, dilution should be suspected, and repeating a UDS should be considered. If creatinine is less than 15, tampering should be suspected, and repeating a UDS should be considered.

**Recommendation 8.** We recommended that the Facility Director ensure that the relevant providers consistently complete the informed consent process prior to initiating long-term opioid therapy for pain as specified by Veterans Health Administration policy.

Concur

Target date for completion: Completed

Facility response: The relevant providers have been educated that the informed consent process for long-term opioid therapy needs to be completed prior to initiation.

The Pain Management Committee monitors Opioid Safety Initiative data, which includes but is not limited to, patients dispensed opioids, opioid-benzo combination therapy, urine drug screening rate, iMED consent, high-dose opioids greater than 100 morphine equivalent daily dose, and overall composite score in comparison to other VA facilities.

**OIG Comment:** The Facility Director considers all recommendations completed; however, we consider all recommendations open until we receive and review written documentation that proposed actions were completed.

## OIG Contact and Staff Acknowledgments

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