

### **Office of Healthcare Inspections**

Report No. 15-02156-346

# **Healthcare Inspection**

# Review of Opioid Prescribing Practices Clement J. Zablocki VA Medical Center Milwaukee, Wisconsin

August 22, 2017

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# **Executive Summary**

The VA Office of Inspector General conducted a healthcare inspection in response to a February 2015 request from Congresswoman Gwen Moore to review the prescribing practices related to controlled substances<sup>1</sup> at the Clement J. Zablocki VA Medical Center (facility), Milwaukee, WI. We also received an allegation that a provider at the facility had questionable opioid prescribing practices. In addition, we received a request from Senator Tammy Baldwin to review prescribing practices at the facility.

To review the overall opioid prescribing practices at the facility, we evaluated whether facility and Veterans Integrated Service Network (VISN) leadership complied with specific goals delineated in the Veterans Health Administration (VHA) Opioid Safety Initiative (OSI) Update. We looked at the facility's implementation of Goals 2, 3, 7, 8, and 9.

- Goal 2 Increase the Use of Urine Drug Screening. We found that the facility met this goal as the number of patients who had an annual urine drug screen increased by nearly twofold from fiscal year (FY) 2014 through the second quarter of FY 2015.
- Goal 3 Facilitate the Use of State Prescription Drug Monitoring Program
   <u>Databases</u>. We determined that facility providers did not access the prescription
   drug monitoring program (PDMP) database prior to the initiation of chronic opioid
   therapy as outlined in facility policy. We recommended that the Facility Director
   ensure facility providers access the PDMP database as required by facility policy
   and monitor compliance.
- Goal 7 Review Treatment Plans for Patients on High Doses of Opioids. We found that miscommunication between the VISN and facility resulted in the facility performing fewer patient reviews than required by the OSI Update. We found that facility staff did not timely review all patients prescribed opioid medications greater than (>) 200 morphine equivalent daily dose (MEDD) for clinical appropriateness and certify the completion of the review as specified by the OSI Update. We recommended that the VISN 12 pain committee strengthen processes to improve communication with the facility to ensure information is relayed timely.
- Goal 8 Offer Complementary and Alternative Medicine Modalities for Chronic Pain at All Facilities. We found that the facility had several Complementary and Alternative Medicine options available to treat chronic pain, including acupuncture, Tai Chi, and biofeedback.
- Goal 9 <u>Develop New Models of Mental Health and Primary Care Collaboration</u> to Manage Prescribing of Opioid and Benzodiazepines in Patients with Chronic

<sup>&</sup>lt;sup>1</sup> We interpreted controlled substances in the context of this request to mean opioid medications rather than all controlled substances listed by the Drug Enforcement Agency.

<u>Pain</u>. In April 2015, the facility did not have an interdisciplinary team approach to the management of patients on chronic opioids. However, based on updated information we received in October 2016, we determined that the facility had established a collaborative model to manage the prescribing of opioids and benzodiazepines for patients with chronic, non-cancer pain as of October 2016.

We substantiated that a provider prescribed opioid medications for some patients in a manner that varied from clinical guidelines and other providers at the facility. We recommended that the VISN Director convene an expert panel to review the subject provider's opioid prescribing practices within the context of the patients whose treatment varied from guidelines described in this report and expand the review as necessary. We found that facility managers did not track patients prescribed Suboxone as part of their monitoring of opioid prescribing. We recommended the VISN Director ensure the monitoring of patients on Suboxone.

At the time of our visit in April 2015, we did not find evidence of opioid diversion, criminal, or illegal activities associated with opioid prescriptions dispensed at the facility.

We recommended that the Veterans Integrated Service Network Director:

- Convene an expert panel knowledgeable in the subspecialties of Pain Medicine and Addiction Medicine to review the subject provider's opioid prescribing practices within the context of the patients whose treatment varied from guidelines as described in this report and ensure that the expert panel expand the review as necessary and submit a report of findings to the Veterans Integrated Service Network and Facility Directors.
- Ensure the monitoring of patients on Suboxone.
- Ensure the Pain Committee strengthens processes to improve communication with the facility to ensure information is relayed timely.

We recommended that the Facility Director:

- Ensure that providers access the Prescription Drug Monitoring Program database as required by facility policy and monitor compliance.
- Ensure adequate resources, such as additional staff or allotted duty time, are allocated for patient reviews for opioid therapy appropriateness.

### **Comments**

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes B and C, pages 31–35 for the Directors' comments.) We consider Recommendation 3 closed and will follow up on the planned actions for the remaining recommendations until they are completed.

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# **Purpose**

The VA Office of Inspector General conducted a healthcare inspection in response to a February 2015 request from Congresswoman Gwen Moore to review the prescribing practices related to controlled substances<sup>2</sup> at the Clement J. Zablocki VA Medical Center (facility), Milwaukee, WI. We also received an allegation that a provider had questionable opioid prescribing practices. In addition, we received a request from Senator Tammy Baldwin to review prescribing practices at the facility.

# **Background**

The facility provides tertiary care through a broad range of inpatient and outpatient medical, surgical, mental health, and specialty care, including pain management and substance abuse treatment. The pain clinic at the facility is managed by anesthesiologists, who primarily treat cancer patients for pain and do not typically manage or prescribe opioid medications (opioids) for chronic pain. The facility has four community based outpatient clinics located throughout Wisconsin and in fiscal year (FY) 2015, reported over 723,000 outpatient visits. The facility is part of Veterans Integrated Service Network (VISN) 12.

### **Pain Management**

Veterans Health Administration (VHA) Directive 2009-053, *Pain Management*<sup>3</sup> (Directive), outlines strategies for effective pain management. These strategies include ensuring that every facility establishes a multidisciplinary<sup>4</sup> pain committee, implements a stepped model of pain care, and monitors patient outcomes as well as the quality of pain management.

The Directive<sup>5</sup> also requires the VISN Director appoint a clinician trained in pain management at the VISN level; establish a VISN level pain committee to develop and maintain pain management standards; and ensure a tertiary interdisciplinary<sup>6</sup> pain rehabilitation program is available to manage complex cases. The Directive further requires safe and effective use of opioid medications<sup>7</sup> when managing pain and consideration of the potential for accidental or intentional overdose of pain medications.

<sup>&</sup>lt;sup>2</sup> We interpreted controlled substances in the context of this request to mean opioid medications rather than all controlled substances listed by the Drug Enforcement Agency.

<sup>&</sup>lt;sup>3</sup> VHA Directive 2009-053, *Pain Management*, October 28, 2009. This VHA Directive expired October 31, 2014 and has not yet been updated.

<sup>&</sup>lt;sup>4</sup> A multidisciplinary team draws on knowledge from different disciplines but stays within their boundaries. The core members of a pain management multidisciplinary team would typically include practitioners from anesthesia, physical medicine and rehabilitation, psychology, occupational therapy, and recreational therapy.

coherent approach.

Opioids are a class of pain medications that have addictive properties.

<sup>&</sup>lt;sup>5</sup> VHA Directive 2009-053.

<sup>&</sup>lt;sup>6</sup> An interdisciplinary team analyzes, synthesizes, and harmonizes care between disciplines into a coordinated and coherent approach.

### **Opioid Therapy**

The use of opioids in the management of pain can be an effective treatment option. Commonly known examples of opioids are codeine, hydrocodone, morphine, and oxycodone. Codeine is frequently used to treat mild pain, hydrocodone is commonly used in injury-related pain, and morphine is used to treat surgical pain. Although opioids are commonly prescribed to reduce and/or alleviate pain, long-term opioid use can be harmful because of the increased risk for accidental overdose, abuse, addiction, and diversion. As a result, clinicians should carefully weigh the benefits of long-term opioid therapy against the potential harmful effects to patients.

In May 2010, VHA and the Department of Defense (DoD) published the Clinical Practice Guideline, *Management of Opioid Therapy for Chronic Pain* (Guideline) to help clinicians improve pain management therapies, as well as the quality of life and care of veterans with chronic non-cancer pain. The Guideline includes criteria to help clinicians determine if opioid therapy is an appropriate treatment option. The Guideline also includes protocols for patient assessment and monitoring, evaluation of a patient's response to opioid therapy, and protocols for adjusting and discontinuing opioid therapy.

### **Opioid Safety Initiative**

In 2013, the VA Principal Deputy Under Secretary for Health informed Congress that more than 50 percent of veterans receiving care at VHA facilities were affected by chronic pain. The Principal Deputy Under Secretary further informed Congress that the management of chronic pain in veteran populations was complex and that VHA developed two system-wide initiatives to improve the safety and management of chronic pain in veterans. The two initiatives were the Opioid Safety Initiative (OSI) and the enabling of VHA providers to participate in state prescription drug monitoring programs (PDMPs).<sup>10</sup> The VA Under Secretary for Health issued a memorandum outlining the OSI framework that included nine goals to all VISN Directors on April 2, 2014.<sup>11</sup>

In a December 10, 2014, "OSI Updates" memorandum, the Acting Deputy Under Secretary for Health provided additional guidance to all VISN directors that included

<sup>&</sup>lt;sup>8</sup>Drug diversion is the illegal distribution or abuse of prescription drugs or their use for purposes not intended by the prescriber. CMS. *Partners in Integrity: What is the Prescriber's Role in Preventing the Diversion of Prescription Drugs?* January 2014.

<sup>&</sup>lt;sup>9</sup>VA/DoD, Clinical Practice Guideline, *Management of Opioid Therapy for Chronic Pain*, May 2010. VA/DoD issued an updated version of the clinical practice guideline *Management of Opioid Therapy for Chronic Pain* in February 2017.

<sup>&</sup>lt;sup>10</sup> PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients.

<sup>&</sup>lt;sup>11</sup> Under Secretary for Health memorandum, *Opioid Safety Initiative Requirements*, April 2, 2014. <u>VHA Memorandum, *Opioid Safety Initiative*, April 2, 2014</u>. One of the nine goals was facilitation of the use of state PDMP databases.

timelines for complying with the nine goals. The OSI Update is appended to this report (Appendix A).<sup>12</sup>

### **Opioid Prescribing and the Risk of Overdose Deaths**

Opioids are associated with serious adverse health effects. Overdose deaths involving prescription opioids have quadrupled since 1999. In 2014, more than 14,000 people died from overdoses involving prescription opioids. With increasing opioid overdose deaths, the emphasis on opioid prescribing has shifted to opioid dose reduction, increased assessment, and monitoring of patients on chronic opioid therapy.

Patients who are prescribed higher doses of opioids are at increased risk of drug overdose deaths. Several studies observed an increase in the risk of drug overdose deaths when patients are prescribed more than 100 morphine equivalent daily dose (MEDD). The Centers for Disease Control and Prevention (CDC) recently published "CDC Guideline for Prescribing Opioids for Chronic Pain" that recommended providers avoid prescribing more than 90 MEDD or carefully justifying a decision to prescribe such dosages.

While MEDD describes the dosage prescribed to a patient, the effect of an opioid medication on a specific patient is influenced by a variety of factors including a patient's other medications and tolerance to opioids. When evaluating the appropriateness of the dosage of an opioid prescription for a specific patient, providers should consider these additional factors.

### **Opioid Dependence/Addiction Treatment**

In addition to pain management, providers also prescribe opioids as part of the management of opioid dependence/addiction. The *Diagnostic and Statistical Manual of Mental Disorders*, 5th Edition (DSM-5), provides diagnostic criteria for opioid misuse disorder that includes cravings to use opioids and persistence in using opioids despite disruptions to functional activities and causing interpersonal problems.<sup>19</sup>

<sup>&</sup>lt;sup>12</sup>Acting Deputy Under Secretary for Health For Operations and Management memorandum, *Opioid Safety Initiative* (OSI) Updates, December 10, 2014.

<sup>&</sup>lt;sup>13</sup> Centers for Disease Control and Prevention, <a href="http://www.cdc.gov/drugoverdose/data/overdose.html">http://www.cdc.gov/drugoverdose/data/overdose.html</a>. Accessed August 23, 2016.

Gwira Baumblatt JA, Wiedeman C, Dunn JR, Schaffner W, Paulozzi LJ, Jones TF. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. *JAMA Intern Med.* 2014 May; 174(5): 796-801.

<sup>&</sup>lt;sup>15</sup> Bohnert AS, Valenstein M, Bair MJ, Ganoczy D, McCarthy JF, Ilgen MA, Blow FC. Association between opioid prescribing patterns and opioid overdose-related deaths. *JAMA*. 2011 Apr 6; 305(13): 1315-21. <sup>16</sup> Paulozzi LJ, Kilbourne EM, Shah NG, Nolte KB, Desai HA, Landen MG, Harvey W, Loring LD. A history of

being prescribed controlled substances and risk of drug overdose death. *Pain Med.* 2012 Jan; 13(1): 87-95. <sup>17</sup> For example, 1 mg of oxycodone is 1.5 morphine equivalents, so a patient taking three 10 mg oxycodone pills a

<sup>&</sup>lt;sup>17</sup> For example, 1 mg of oxycodone is 1.5 morphine equivalents, so a patient taking three 10 mg oxycodone pills a day is taking 45 MEDD (3 pills multiplied by 10 mg multiplied by the 1.5 conversion factor).

<sup>&</sup>lt;sup>18</sup> Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. *JAMA*. 2016;315(15):1624-1645.

<sup>&</sup>lt;sup>19</sup>http://pcssmat.org/wp-content/uploads/2014/02/5B-DSM-5-Opioid-Use-Disorder-Diagnostic-Criteria.pdf. Accessed October 26, 2015.

The course of drug addiction treatment is often characterized by periods of relapse and patients commonly experience difficulty with treatment compliance. Relapse and non-compliance, however, do not necessarily signal treatment failure, and the provider should individually evaluate the circumstances of such events and the patient's behavior with and without treatment. Like other chronic illnesses, relapse may indicate that the current treatment plan needs adjustment rather than being discontinued. For example, a patient who relapses may be monitored more frequently and receive more intense therapy rather than being discontinued from pharmacotherapy.

### **Suboxone®**

Suboxone is a Food and Drug Administration (FDA)-approved opioid medication for the treatment of opioid dependence. Suboxone is a combination medication composed of an opioid (buprenorphine) and another medication (naloxone) that blocks the effects of opioids to prevent the medication from being misused. The particular opioid in Suboxone is in a special class of drugs called a partial-agonist and does not fully activate the opioid receptor. This property gives this opioid different pharmacological properties from traditional opioids and lowers its potential for misuse, increases its safety in cases of overdose, and diminishes the effects of physical dependency to opioids, such as withdrawal symptoms and cravings. In some policies and guidelines, Suboxone may be referred to as either (a) buprenorphine/naloxone, the generic names for its components, or as (b) buprenorphine for the opioid component.

Unlike methadone treatment for opioid addiction, Suboxone treatment can be performed in an office setting rather than a highly structured clinic. As an opioid medication with analgesic properties, physicians can use Suboxone for pain management, but it is not FDA-approved for this indication. The Guideline recommends against using Suboxone for pain management only. However, because physicians can use Suboxone to treat both diagnoses, determining whether a Suboxone prescriber intended to treat a patient for pain or opioid dependence when the patient has both pain and opioid dependence is difficult in the absence of an explicit statement to that effect.<sup>20</sup>

The prescription of Suboxone is more regulated than most other opioid prescribing. Physicians must meet qualifications for a waiver to prescribe Suboxone before the Drug Enforcement Agency will assign a special identification number. The Substance Abuse and Mental Health Services Administration (SAMHSA)<sup>21</sup> reviews and approves waiver applications after verifying the physician's background.<sup>22</sup>

VA has several Suboxone prescribing guidelines:

<sup>&</sup>lt;sup>20</sup> Off-label prescribing is prescribing for an indication not in the approved FDA labelling. The FDA guidance to physicians who prescribe off-label is that they "...be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects." <a href="https://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm">https://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm</a> Accessed January 25, 2016.

<sup>&</sup>lt;sup>21</sup> SAMHSA is a federal agency and the mission of the agency is to reduce the impact of substance abuse and mental illness on America's communities. <a href="http://www.samhsa.gov/about-us">http://www.samhsa.gov/about-us</a>. Accessed May 2, 2016.

<sup>&</sup>lt;sup>22</sup> SAMHSA - How to Qualify for a Physician Waiver. http://www.samhsa.gov/medication-assisted-treatment/buprenorphine-waiver-management/qualify-for-physician-waiver Accessed March 29, 2016

- Suboxone is not recommended as the only therapy when treating opioid dependence. VA Pharmacy Benefits Management Services (PBMS) outlined guidance for providers in August 2014: Suboxone and Buprenorphine for Opioid Dependence Criteria for Use for Office-Based Opioid Treatment (OBOT) Settings recommends that buprenorphine "should be used as part of a complete treatment plan including medical management and, when indicated, other counseling and psychosocial support."
- VA/DoD Clinical Practice Guideline for Management of Patients with Substance Use Disorders (SUD)<sup>23</sup> states that pharmacotherapy, if prescribed, needs to be provided in addition to, and directly linked with, psychosocial treatment and support.
- VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics*, <sup>24</sup> under its OBOT section, states, "...the patient's condition needs to be monitored in an ongoing manner, and care needs to be modified, as appropriate, in response to their change in clinical status."
- The Guideline<sup>25</sup> recommends against the use of buprenorphine for pain management alone and states "[i]f SL [sublingual]<sup>26</sup> buprenorphine was being prescribed solely for pain, then an opioid rotation to a full-agonist opioid<sup>27</sup> should be undertaken if opioid therapy is indicated."
- PBMS' Suboxone and Buprenorphine for Opioid Dependence Criteria for Use for OBOT Settings also recommends against the use of benzodiazepines in patients taking Suboxone given the risk of fatal drug abuse-related overdoses from the combination.

While VHA does not provide specific parameters on the frequency of monitoring patients on Suboxone, SAMHSA has published best-practice guidelines that address this issue: "[v]isits on a monthly basis are considered a reasonable frequency for patients on stable buprenorphine doses who are making appropriate progress toward treatment objectives and in whom toxicology shows no evidence of illicit drugs."<sup>28</sup>

<sup>&</sup>lt;sup>23</sup> VA/DoD Clinical Practice Guideline *Management of Substance Use Disorders*, December 2015.

<sup>&</sup>lt;sup>24</sup> VHA Handbook 1160.01, *Uniformed Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008. This VHA Handbook was scheduled for recertification on or before the last working date of September 2013. The timing for a clinic appointment was amended in November 2015; however, the amendment did not reset the date of recertification.

<sup>&</sup>lt;sup>25</sup> VA/DoD Clinical Practice Guideline, *Management of Opioid Therapy for Chronic Pain*, May 2010.

<sup>&</sup>lt;sup>26</sup> Sublingual means to administer medication under the tongue. (Merriam-Webster Medical Dictionary).

<sup>&</sup>lt;sup>27</sup> The phrase "opioid rotation to a full-agonist opioid" means that the opioid should be switched from a medication like Suboxone to a medication like morphine.

<sup>&</sup>lt;sup>28</sup> Center for Substance Abuse Treatment. *Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction*. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

### **Urine Drug Tests**

According to the Guideline, <sup>29</sup> urine drug tests (UDT)<sup>30</sup> are an important part of the assessment of the patient taking chronic opioids and states that "self-report of drug use has limited validity, and monitoring behavior alone can fail to detect problems revealed by UDTs."31 The Guideline further notes the importance of UDTs:

There is moderate evidence (level II-2 studies) that a substantial percentage of patients on opioid therapy for chronic pain have positive urine drug screens, suggesting that this procedure may be the only way to identify addiction, drug abuse and diversion.

The Guideline<sup>32</sup> also notes that information provided by UDTs extends beyond assessing compliance or detecting substance abuse.

When performed and interpreted properly, urine drug screens and confirmatory urine and blood drug tests can provide accurate and useful information that allows the clinician to tailor pain therapy, safeguards, and risk management strategies.

The Guideline<sup>33</sup> recommends routine and random UDTs for all patients with chronic pain prior to and during opioid therapy.

The recommended frequency of UDTs for patients is currently based in part by the assessed risk of the patient. According to the OSI, pain management patients prescribed more than 120 MEDD should be assessed by a UDT 3-4 times per year. Although VHA does not provide specific guidance on the frequency of UDTs for opioid dependent/addiction patients on Suboxone, SAMHSA does provide guidance. In its Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction,<sup>34</sup> SAMHSA recommends, "during opioid addiction treatment with buprenorphine [Suboxone], toxicology tests for all relevant illicit drugs should be administered at least monthly."

### **Facility Suboxone Prescribing**

VHA Handbook 1160.01, Uniform Mental Health Services in VA Medical Centers and Clinics<sup>35</sup> mandates treatment of patients with opioid dependency. The facility has

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

<sup>&</sup>lt;sup>30</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. We attempted to use these terms consistently with the cited

<sup>&</sup>lt;sup>31</sup> UDTs can identify problems such as when patient are taking other opioids, illegal drugs, or abusable medications. It also can identify when patients are not taking their opioids which could indicate drug diversion.

<sup>&</sup>lt;sup>32</sup> VA/DoD Clinical Practice Guideline, *Management of Opioid Therapy for Chronic Pain*, May 2010.

<sup>&</sup>lt;sup>34</sup> Center for Substance Abuse Treatment, Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004. p. 65 Toxicology Testing for Drugs of Abuse.

<sup>35</sup> VHA Handbook 1160.01, Uniformed Mental Health Services in VA Medical Centers and Clinics, September 11, 2008.

25 physicians authorized to prescribe Suboxone to opioid dependent patients. In calendar year 2014, three addiction specialists prescribed approximately 85 percent of Suboxone at the facility with the remainder of the authorized physicians averaging only a few prescriptions per month.

**Request for Review.** In a February 2015 letter sent to the-then VA OIG Acting Inspector General, Congresswoman Gwen Moore requested a review of the prescribing practices related to controlled substances at the facility. In addition, we received a request from Senator Tammy Baldwin to review prescribing practices at the facility.

**Allegation.** In January 2015, OIG received an allegation that a provider had questionable opioid prescribing practices at the facility. We examined the request for review and the allegation together.

# **Scope and Methodology**

We conducted our review from January 2015 through March 2016. We requested updated information from the facility and VISN in October 2016.

We made a site visit April 20–23, 2015. Prior to our site visit, we interviewed the VISN Chief Pharmacist and Pain Committee members. We collaborated with the OIG Chicago Criminal Investigations Division who interviewed VA staff and members of the Milwaukee Police department.

We interviewed the facility Chief of Staff, primary care and mental health providers, pharmacists, and other staff who were knowledgeable about the issues under review. We also reviewed relevant VA/VHA and facility policies and procedures, and reports from the Corporate Data Warehouse, VISN Data Warehouse, and Pharmacy Benefits Management Cube.

To review the overall opioid prescribing practices at the facility, we evaluated whether facility and VISN leadership complied with specific goals delineated in the OSI Update.<sup>37</sup> We selected goals 2, 3, 7, and 8, listed below, because implementation was expected by March 30, 2015. (See also discussion of goal 9 on next page).

- Goal 2: Increase the use of urine drug screens (UDS)<sup>38</sup> by the end of quarter 2, FY 2015.
- Goal 3: Facilitate the use of state PDMP databases by the end of quarter 2, FY 2015.

<sup>&</sup>lt;sup>36</sup> We interpreted controlled substances in the context of this request to mean opioid medications rather than all controlled substances listed by the Drug Enforcement Agency.

<sup>&</sup>lt;sup>37</sup> VHA Memorandum, *Opioid Safety Initiative Updates*, December 10, 2014.

<sup>&</sup>lt;sup>38</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. We attempted to use these terms consistently with the cited reference.

- Goal 7: Review the appropriateness of therapies of patients on high doses of opioids (greater than (>) 200 MEDD) and certify that the review was completed by March 30, 2015.
- Goal 8: Offer Complementary and Alternative Medicine (CAM) treatment options at all facilities by March 30, 2015.

We also selected Goal 9 with an expected implementation date of September 30, 2015, because it required development of new models of mental health and primary care collaboration to manage prescribing opioids and benzodiazepines in patients with chronic pain, a goal that is also supported by VHA Directive 2009-053, *Pain Management*<sup>39</sup> and the Guideline.<sup>40</sup> The use of opioids and benzodiazepines concurrently increases a patient's risk of adverse outcomes. Accomplishing this goal requires an interdisciplinary approach to pain management.

• Goal 9: Develop new models of mental health and primary care collaboration to manage prescribing of opioids and benzodiazepines in patients with chronic pain.

To evaluate progress on specific goals, we conducted the following:

- For Goal 2, we reviewed facility UDS data from FY 2014, through quarter 2 FY 2015. We also identified the clinics of the providers who prescribed >400 MEDD for FY 2014 through quarter 1, FY 2015.
- For Goal 3, we reviewed facility policy and facility providers' and pharmacists' use of the PDMP.
- For Goal 7, we reviewed VISN 12 Pain Committee meeting minutes from March 2015 through July 2015, and October 2015 through November 2015<sup>41</sup> and interviewed facility Pain Committee members.
- For Goal 8, we reviewed CAM treatment schedules at the facility.
- For Goal 9, we interviewed VISN and facility Pain Committee members.

We also reviewed electronic health records (EHR) of selected patients on >400 MEDD to determine their diagnoses. These patients were identified as a high risk group in documents provided to us by the facility.<sup>42</sup>

<sup>&</sup>lt;sup>39</sup> VHA Directive 2009-053, *Pain Management*, October 28, 2009.

<sup>&</sup>lt;sup>40</sup> VA/DoD Clinical Practice Guideline, *Management of Opioid Therapy for Chronic Pain*, May 2010.

<sup>&</sup>lt;sup>41</sup> The VISN Pain Committee did not provide us with meeting minutes for August and September 2015.

<sup>&</sup>lt;sup>42</sup> As noted in the background of this report, VHA has focused increased attention on opioid prescribing practices with the publication of relevant directives, guidelines, and OSI documents. As VHA-wide attention to prescribing practices has increased, the facility has re-focused its review of patients receiving opioids from those on 400 MEDD to lower MEDD doses.

While different tables of ratios are available to calculate morphine-equivalents to compare opioid dosages, we used the ratios that VHA provided to us in FY 2015 when converting opioid doses to MEDD for this report with the exception of methadone. We used the ratios of 4:1 for doses less than 90 mg of morphine per day and 6:1 for doses 90 mg or greater. VISN staff did not use and could not provide us with a conversion ratio for Suboxone. We excluded tramadol and codeine from our analysis given their low potency.

Our review of the subject provider focused on the provider's patients who were prescribed chronic opioids. <sup>45</sup> We reviewed the EHRs of selected patients. We also reviewed the credentialing and privileging records of the subject provider with a focus on issues related to opioid prescribing.

We reviewed the provider's frequency of completed UDTs. We considered any UDT obtained at the facility as having been considered by the provider even if the test was not ordered by the provider nor explicitly documented in the provider's notes. In our EHR review, in the setting of a significant UDT result such as a positive test for illicit substances, we commented on a lack of documentation in the provider's notes.

While SAMHSA guidelines recommend monthly testing, they also recommend that "...physicians should be sensitive to treatment barriers, such as geographical issues, travel distance to treatment, domestic issues such as child care and work obligations, as well as the cost of care." We looked at the frequency of completed UDTs of similar specialists at the facility for patients on chronic Suboxone who were doing well (on a stable dose of medication, without aberrant behaviors or concerning findings with UDT). To determine the appropriateness of the frequency of UDTs for patients prescribed Suboxone, we applied the criteria of four UDTs per year.

Two policies cited in this report were expired or beyond their recertification dates:

- 1. VHA Directive 2009-053, *Pain Management*, October 28, 2009 (expired October 31, 2014).
- VHA Handbook 1160.01, Uniformed Mental Health Services in VA Medical Centers and Clinics, September 11, 2008 (recertification due date September 30, 2013).

We considered these policies to be in effect, as they 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>46</sup> the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond

<sup>&</sup>lt;sup>43</sup> We made an exception for methadone because its pharmacokinetics are different than most other opioids.

<sup>&</sup>lt;sup>44</sup> We were unable to identify a widely accepted conversion ratio for Suboxone.

<sup>&</sup>lt;sup>45</sup> We have assigned the VHA definition of prescriptions of greater than 90 days in the past year to the term "chronic opioids."

<sup>&</sup>lt;sup>46</sup> VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance." 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."

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.

<sup>&</sup>lt;sup>47</sup> VA Under Secretary for Health Memorandum, *Validity of VHA Policy Document*, June 29, 2016.

<sup>48</sup> Ibid.

# **Inspection Results**

### Issue 1: Facility Opioid Prescribing Practices FY 2014 Through Quarter 2 FY 2015

To review the overall opioid prescribing practices at the facility, we evaluated whether facility and VISN leadership complied with specific goals delineated in the OSI Update.

### Goal 2 - UDS

By March 30, 2015, the OSI Update required facility providers who performed an annual UDS on 26 to 35 percent of long-term opioid therapy patients to increase the number of patients with an annual UDS by 1.25 times. The OSI did not set a specific target but instead specified stratified goals for each medical center. We found the number of patients at the facility who had an annual UDS increased by nearly twofold, from FY 2014 through quarter 2 of FY 2015. Specifically, we determined that, of patients prescribed chronic opioid therapy, 31 percent had an annual UDS by the end of FY 2014, with an increase to 61.7 percent in quarter 2, FY 2015.

### Goal 3 – Use of State PDMP Databases<sup>49</sup>

The OSI Update required facilities to facilitate the use of state PDMP databases by the end of quarter 2, FY 2015. Beginning in June 2014, facility policy<sup>50</sup> required prescribing providers to access the PDMP database prior to the initiation of chronic opioid therapy. We learned that facility managers did not verify whether providers checked the PDMP database prior to the initiation of chronic opioid therapy. Facility managers informed us that the Wisconsin PDMP became available in 2013 and that "VA data was not downloadable until 2014."

An April 2015 facility policy<sup>51</sup> required pharmacists to query the PDMP database for requests for initial name-brand only prescriptions and initial claims of controlled substance delivery problems and/or changes to do-not-mail status. Pharmacists were also required to query the database for requests to replace lost or stolen prescriptions, requests for early refills for travel, and/or the patient runs out of their medication early without a change in directions. Since the PDMP database became available, facility providers' use of the database has trended upwards. We identified that facility providers queried the PDMP database 309 times in FY 2014 and 1,080 times in FY 2015.

### Goal 7 - Review of Treatment Plans

OSI requires that VISN clinicians and facility providers review patients on >200 MEDD for appropriateness of therapies by March 30, 2015. We did not find timely

<sup>&</sup>lt;sup>49</sup> We did not look at the educational component of the program.

<sup>&</sup>lt;sup>50</sup> Clement J. Zablocki VA Medical Center Professional Services Memorandum, PSM, I-9, *Chronic Opioid Use for Non-Cancer Pain*, June 16, 2014.

<sup>&</sup>lt;sup>51</sup> PHCS3, Pharmacy Procedures for Auditing the Wisconsin Drug Monitoring Program, April 2015.

documentation that VISN or facility clinicians reviewed patients on >200 MEDD for clinical appropriateness. We did find that facility and VISN clinicians reviewed patients on >400 MEDD during this time.

The VISN 12 Pain Committee meeting minutes dated March 2, 2015, reflected that committee members voiced "some consternation" regarding completing reviews as outlined in Goal 7. VISN Pain Committee members decided the "facility [will] determine appropriate staff to perform this task, identify pertinent patients, and develop local plans to assess potential options to reduce opioid doses."

In December 2015, we were informed that the facility Pain Committee did not routinely review patients on >200 MEDD. A facility Pain Committee member informed us that quarterly reviews of patients on >400 MEDD were completed by a single person who only looked at UDTs, patient consents, PDMP database access, and whether patients were on benzodiazepines and opioids but not the appropriateness of therapies. Although the reviews of patients on >200 MEDD should have been completed by March 30, 2015, such reviews were only begun in October 2016 due to a misunderstanding between the facility and VISN of the nature of the requirement for patient reviews and who was responsible for complying with it.

In November 2016, we learned that the VISN Pain Committee was planning to change the criteria for patient review and increase the number of required patient reviews. Discussions between the facility and VISN staff regarding these additional reviews are ongoing.

During our site visit in April 2015, several facility providers stated that facility leadership previously did not support the clinical recommendations from the patient reviews and that treating providers would ignore the recommendations. In October 2016, we found that providers were responding to "almost 100 percent" of recommendations resulting from the clinical reviews. Facility leadership reported that in a few cases, recommendations were not ignored but that different providers had legitimate differences in clinical opinions.

We found that, in general, the average daily MEDD for facility prescribers was trending downward. Providers who prescribed >400 MEDD generally practiced in clinics that provide care for patients who would typically require high doses of opioids, such as cancer patients and patients with spinal cord injuries.

### Goal 8 – CAM Modalities

The OSI Update requires that all facilities offer at least one CAM modality to treat chronic pain. Consistent with this goal, several alternative pain management therapies were available at the facility, including acupuncture, Tai Chi,<sup>52</sup> and biofeedback. We

<sup>&</sup>lt;sup>52</sup> Tai Chi is a Chinese exercise program that uses smooth body movements to achieve mental and physical relaxation.

found that the facility routinely offered these therapies Monday through Thursday. Specifically,

- Acupuncture was available by appointment;
- Healing touch therapy, a type of massage therapy, was offered Monday through Thursday;
- Tai Chi was offered Tuesday afternoons; and
- Biofeedback was offered Tuesday, Wednesday, and Thursday.

# <u>Goal 9 – Develop New Models of Mental Health and Primary Care Collaboration To Manage Prescribing of Opioids and Benzodiazepines in Patients With Chronic Pain</u>

In April 2015, we found that facility leaders had not established a collaborative model to manage prescribing of opioids and benzodiazepines for chronic, non-cancer pain. We noted that VISN leaders had not provided guidance to the facility regarding interdisciplinary care models, and VISN Pain Committee meeting minutes reflected that VISN staff were awaiting VHA guidance. In October 2016, we learned that facility and VISN leaders had initiated changes in early 2016 aimed at reducing the number of patients prescribed both medications.

Because facility leaders had not initially developed the interdisciplinary collaboration specified in Goal 9, we looked more broadly at the facility's interdisciplinary approach to pain management. During our onsite visit in April 2015, facility providers informed us that, in general, the management of chronic non-cancer pain had not included an interdisciplinary team and that communication between mental health and pain management providers could be improved. In August 2016, facility managers implemented a "functional restoration clinic," a multidisciplinary clinic that provides pain management services.

### Issue 2: Alleged Questionable Opioid Prescribing Practices of a Provider

We substantiated that a provider had questionable opioid prescribing practices for patients prescribed chronic opioid medications.

We found that the provider prescribed both full and partial agonist opioids<sup>53</sup> and used these medications for treatment of pain as well as management of opioid addiction. In our review of the credentialing and privileging records of the provider, we determined that he was properly credentialed to prescribe opioids.

<sup>&</sup>lt;sup>53</sup> Full-agonist opioids are those that bind and activate the mu-opioid receptor. Examples of full-agonist opioids are hydrocodone, oxycodone, heroin, and morphine. Partial-agonist opioids are defined in the Background section on Suboxone and bind less strongly to the mu-opioid receptor, producing a different set of properties.

### Patients Prescribed Full-Agonist Opioids

For patients of this provider who were prescribed full-agonist opioids, we found that UDTs were performed less frequently than guideline recommendations. In reviewing the EHRS of the patients prescribed full-agonist opioids, we also found several instances where frequency and method of patient monitoring and assessment differed significantly from guidelines.

At the time of our visit in April 2015, the provider was transitioning away from prescribing full-agonist opioids to manage patients' chronic pain. The provider continued to prescribe full-agonist opioids for short periods to patients who were on Suboxone and undergoing surgical and dental procedures to manage their pain during the perioperative period.

We identified 13 patients who had received full-agonist opioids from the provider between October 1, 2013, and March 1, 2015. We reviewed the EHRs back to when the provider initially prescribed opioids. In seven of these cases, we observed that patients were prescribed opioids on a short-term basis and excluded them from further review. <sup>54</sup>

The remaining six patients received prescriptions for chronic full-agonist opioids. One of the six patients had been on 120 MEDD and was tapered to a lower dosage before being transitioned to buprenorphine. The other five patients on chronic full-agonist opioids were on doses high enough to warrant 3–4 UDT per year according to the OSI.

For the five patients for whom the provider prescribed full-agonists for chronic pain, we concluded that UDTs were performed less frequently than recommended by the OSI. The OSI recommendation for these patients was to perform UDT 3-4 times per year since these patients were prescribed >120 MEDD and were, therefore, high-risk. None of the five patients had screening at this frequency in calendar years 2014–2015. Although no specific screening frequency was specified prior to calendar year 2014, we noted that from calendar year 2011 to 2014, none of the five patients met the standard of annual screening, which is the least frequent level of screening recommended by the OSI for the lowest risk patients.

### OIG Review of Select Patients on Full-Agonist Opioids

### Patient A

The patient, with a diagnosis of chronic pain, was transferred to the provider's care after review by a multidisciplinary provider group at the facility $^{55}$  that recommended the

<sup>&</sup>lt;sup>54</sup> We excluded those patients who were prescribed these medications for a few months or where the intention was not long-term treatment.

<sup>&</sup>lt;sup>55</sup>At the time, a multidisciplinary group of pain providers came together for the purpose of evaluating and providing recommendations for patients with challenging pain needs. This group later disbanded as these activities were a collateral duty, and the group members reported that both providers and facility leadership did not support their efforts.

patient taper off opioids. The patient was on approximately150 MEDD at the time the provider took over opioid prescribing in 2010. The provider was the patient's primary opioid prescriber for the next 5 years. During this 5-year period, the patient was prescribed opioid doses >1,600 MEDD and had three UDTs (one in 2010, and two in 2013.

The provider documented inconsistent criteria regarding patient adherence to prescribed medication dosages. In some notes, he documented that he would like the patient to follow prescriptions carefully.

Apparently, [the patient's spouse] was dosing [the patient] more and more as [the patient] was not getting relief and [the patient] ran out of meds early. (!!). I emphasized to [the patient] the danger of that, to which [the patient] said [I] didn't seem to be getting much narcotic effect from the pills anyway, so hadn't thought about it being too much. We will have to address this dangerous breaking of the narcotic agreement.

A year later, the provider followed with another statement consistent with a desire that the patient adhere to prescribed dosages: "It is very concerning that [the patient] isn't sticking to the dose prescribed."

In subsequent notes, the provider documented that he gave the patient considerable leeway over the dosing of opioid medications--an approach to opioid prescribing that does not appear consistent with the diligent monitoring and follow-up described in the clinical guidelines.

ASSESSMENT: Ongoing pain, not addressed very well by meds [the patient] may not be absorbing very well. [The patient] has adequate supply now and doesn't need more yet. I am allowing a great deal of flexibility in [the patient's] dosing, as [the patient] has to repeat it after vomiting sometimes, or has diarrhea, or often the fentanyl patch can stay on only a short time before [the patient's] skin flares up, and [the patient] has to remove it, making up the difference with morphine.

PLAN: [The patient] will let me know when refills are needed.

On occasions when the patient reported episodes of vomiting or removal of medication patches secondary to skin rashes, the provider prescribed additional doses of medication. The provider made significant changes to dosing based on the patient's symptoms with documented episodes where the patient was taking roughly twice the prescribed dosage.

Although the provider reported concerns about the absorption of pain medications and how much medication the patient was effectively taking, the provider did not order laboratory testing, such as blood or serum levels, that could have provided objective data that would have provided a better understanding of this issue.

The patient had two episodes of opioid withdrawal where understanding the nature of the malabsorption would have been particularly helpful. During one of these episodes, the provider noted that the patient was able to absorb tablets of a lower dose of long-acting morphine than higher doses of the same medication. The patient was prescribed >200 MEDD at that time. During the other episode, the provider saw the patient 2 days after running out of pain medications. The provider noted the patient was

off pain medication and although complaining of severe pain, the patient was not having too much withdrawal. The patient was prescribed a range between 270 to 360 MEDD of morphine at that time.

The provider also did not hold the patient accountable for securing medications as recommended in the Guideline. The patient had a prior history of a family member stealing medications. In a 3-year period, the provider wrote replacement prescriptions on five separate occasions for reasons relayed by the patient—three times for medications the patient said were lost or accidentally damaged; once because some of the medication was destroyed by the patient's pet, and once because the medications were thrown away while sleepwalking.

### Patient B

The patient, who was receiving opioids for chronic back pain, presented to the provider requesting substance abuse treatment. The patient was receiving care at an outside pain clinic and requested a transfer to the facility. Although the provider noted that the patient used an illicit drug 10 days prior to the first visit with him, the provider did not document that the patient had two UDTs that were positive for an illicit drug in the year prior to the first visit. The provider also did not document that another VA provider had discontinued prescribing this patient opioids less than a year prior to the initial visit.

Three weeks after the first visit with the provider, the patient was admitted to a residential treatment program and had a UDT positive for an illicit substance. Although the patient had three positive UDTs within one year, the provider did not document the two previous positive UDTs in his clinical notes.

After discharge from residential treatment, the provider saw the patient regularly as an outpatient. He did not order UDTs although he prescribed >250 MEDD of an opioid medication for this patient with a history of multiple recent positive UDTs.

Three days after an outpatient office visit at which time the provider documented the patient was grieving but otherwise doing well, the patient was hospitalized for an overdose of prescribed opioids and a family member's benzodiazepines. The admission UDT was positive for opiates, benzodiazepines, and an illicit substance.

After discharge from the hospital, the patient had several outpatient visits with the provider. During the third visit post-discharge, the patient disclosed the use of illicit substances. A UDT that day demonstrated both an illicit substance and alcohol. The provider noted it as a lapse and continued to prescribe opioids. Another UDT done 6 weeks later was negative for illicit substances. No further UDT was obtained until 4 years and 3 months later when the patient was being transitioned from one addiction medication to another (the transition UDT was positive for an illicit substance).

In a patient with a history of substance abuse with illicit substances, recent hospitalization, and multiple relapses, the provider effectively ceased testing after a single negative test for illicit drugs. The provider did not consistently document facts related to prescribing opioids safely. He did not document aberrant findings in UDT and had a low threshold for discontinuing UDT on a patient with multiple recent episodes of illicit substance abuse.

### OIG Review of Select Patients on Partial-Agonist Opioid (Suboxone)

The provider was the highest volume prescriber of Suboxone at the facility for calendar year 2014. We found during our review of the provider's EHR documentation that he used this medication for pain management and opioid dependence.

To identify those patients who may have had a suboptimal number of UDTs, we reviewed the EHRs of all patients prescribed Suboxone<sup>56</sup> by an addiction specialist at the facility between FY 2013–2015 who had fewer than 12 UDTs (an average of 4 per year). We reviewed the EHRs of the 55 patients who met the criteria. For those patients who had not been treated for the entire 3-year period, we still considered an average of four or more UDT per year as acceptable. For example, a patient prescribed Suboxone for 18 months should have at least six UDTs during that period. We also looked at the interval between UDTs to determine whether testing was performed regularly throughout the time they were prescribed Suboxone.<sup>57</sup> We excluded 37 patients where the number of UDTs met or exceeded the review criteria.

We determined the frequency of UDTs for the remaining 18 patients was below that recommended by the SAMSHA guideline and the practice of the other specialists who prescribed Suboxone at the facility. The subject provider was the primary Suboxone prescriber for 16 of the 18 patients. We found relatively minor lapses in the completion of UDTs; for example, one patient had three rather than four tests in FY 2013, with adequate screening in more recent years. Other lapses were more significant such as patients on chronic Suboxone with less than annual testing.

We noted other concerns with the subject provider's monitoring of patients prescribed Suboxone including infrequent assessments, co-prescription of Suboxone and a benzodiazepine, and failure to enforce consent agreements. We selected two patients (see Patients C and D below) to illustrate some of these concerns.

### Patient C

At the time of our review in 2015, the provider was ordering chronic opioids for a patient with a history of mental health issues, and chronic pain. In 2013, the provider switched the patient to Suboxone for pain management, obtained a UDT, and ordered a Physical Medicine and Rehabilitation consult for complaints of chronic low back pain. The

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<sup>&</sup>lt;sup>56</sup> We included both buprenorphine and Suboxone in our original search. Buprenorphine only prescriptions were less than one-quarter of one percent of the prescriptions and none were considered problematic. For simplicity, when we refer to Suboxone in this section this includes both buprenorphine and buprenorphine/naloxone.

<sup>&</sup>lt;sup>57</sup> A patient with eight UDTs in the first year they were prescribed Suboxone, two UDTs in the following year, and two UDTs in the year after that would have had an average of four tests per year over the entire time period. However, such a patient would have only averaged two tests per year in the last 2 years. We considered this pattern of testing as inconsistent with the intent of the guideline recommendations.

consult occurred one week after starting Suboxone; the consulting provider made several recommendations about the management of the patient's chronic low back pain. The patient had follow-up visits with the provider at 1 and 2 weeks after starting Suboxone. The provider documented in the EHR that the patient had a good response to Suboxone and was encouraged by the Physical Medicine and Rehabilitation visit.

In the year prior to the change to Suboxone therapy, we found that the provider saw the patient three times in person and communicated once by phone. In the  $2\frac{1}{2}$  year period after starting Suboxone, we found no My HealtheVet <sup>58</sup> or EHR documentation of UDTs or office visits. During this time, the provider had two telephone contacts with the patient.

In 2014, almost 1½ years after starting the patient on Suboxone, the provider wrote in the patient's EHR, "I am intentionally not seeing [the patient] very often because it seems the more I attempt greater engagement, the more resistance [the patient] generates (unconsciously)."

In 2015, almost 2 years after starting Suboxone, the provider wrote:

Will continue to prescribe meds as long as patient is not letting me know of problems...I have found that [the patient] does best if I do not attempt to cause change...[t]his sets up resistance, and the patient gets more dysfunctional. So, for now, will continue on current meds and see on prn [as needed] basis.

VHA Handbook 1160.01, *Uniform Mental Health Services in VA Medical Centers and Clinics* states that a "patient's condition needs to be monitored in an ongoing manner, and care needs to be modified, as appropriate, in response to changes in their clinical status." We found the provider's reliance on the patient to self-report problems with taking his/her pain medications differed significantly from VHA policy. Best practice guidelines from SAMHSA's Center for Substance Abuse Treatment recommend monthly follow up and toxicology testing for patients who are doing well in treatment. The provider's treatment differed from another recommendation that Suboxone should be used as part of a complete treatment plan.

Prior to switching to Suboxone, the provider also prescribed the patient a benzodiazepine, a medication that has the potential for severe interactions with Suboxone. The provider continued the benzodiazepine after the switch. The *Risk Evaluation and Mitigation Strategy for Suboxone* states that "[s]ignificant respiratory depression and death have occurred in association with buprenorphine, particularly when taken by the intravenous (IV) route in combination with benzodiazepines or other

<sup>&</sup>lt;sup>58</sup> My HealtheVet is the VA's personal health record that allows a veteran to communicate securely with his/her health care team. Some of the information in My HealtheVet may not be stored in the medical record.

<sup>&</sup>lt;sup>59</sup> VHA Handbook 1160.01, *Uniformed Mental Health Services in VA Medical Centers and Clinics*, September 11, 2008.

<sup>&</sup>lt;sup>60</sup> Center for Substance Abuse Treatment. Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction. Treatment Improvement Protocol (TIP) Series 40. DHHS Publication No. (SMA) 04-3939. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2004.

CNS [central nervous system] depressants (including alcohol)."<sup>61</sup> Other addiction specialists we interviewed at the facility reported that they would not prescribe Suboxone and a benzodiazepine concurrently.

### Patient D

The provider was treating a patient with diagnoses of polysubstance abuse, depression with prior suicide attempts, and chronic pain who had been treated with Suboxone for polysubstance abuse from FY 2013 through FY 2015. While being treated with Suboxone for opioid addiction, the patient admitted to the use of illicit drugs during treatment to the provider. The provider documented the following in the patient's EHR:

ASSESSMENT: Given [the patient's] honesty, and the fact that [this illicit drug] is not dangerous with suboxone [buprenorphine], I'll not cut [the patient] off. [The patient] has made progress in general, then has setbacks.

PLAN: Renew current meds as above and see in 2 to 4 weeks.

After the patient admitted to illicit drug use, the provider saw him in the office twice, approximately one month apart, and a UDT was negative for the illicit drug. The patient had a prescription for Suboxone filled approximately 2 months later, although no office visits, telephone calls, or UDT was completed for the next 3 months until the patient was admitted to the facility following a motor vehicle accident.

Given that the provider considered the patient was making progress, continuing the prescription for Suboxone was justifiable despite the use of illicit drugs. However, in that setting, we would expect to see more frequent monitoring or an increase in intensity of the treatment plan to address such behavior. We noted that when necessary, other facility addiction specialists increased the frequency of patient visits (perhaps weekly) and/or UDTs and/or more intensive therapy. We also noted that the EHR did not include documentation that the provider counseled the patient to avoid illicit drugs while being treated for opioid addiction.

We found that the notation in the patient's EHR that the illicit drug was not dangerous with Suboxone misrepresents the dangers in taking this combination of substances. The illicit drug can cause cardiovascular problems placing patients at risk of sudden death. In addition, studies in the medical literature have shown that the illicit drug at issue can lower the level of buprenorphine in the blood and could potentially lead to undesirable therapeutic outcomes. <sup>62</sup>

The patient was also prescribed a benzodiazepine while being prescribed Suboxone, which placed the patient at higher risk for a drug overdose death (see discussion above regarding concurrent use of benzodiazepine and Suboxone).

<sup>&</sup>lt;sup>61</sup> REMS for Suboxone. See p. 29 under C. Warnings and Precautions.

<sup>&</sup>lt;sup>62</sup> Guo AY, Ma JD, Best BM, Atayee RS. Urine Specimen Detection of Concurrent Nonprescribed Medicinal and Illicit Drug Use in Patients Prescribed Buprenorphine. *Journal of Analytical Toxicology* 2013;37:636–641.

In summary, the concern raised by this patient's case includes the frequency of monitoring of this patient with known recent illicit substance use. Documentation is not present in the patient's EHR concerning a decrease in illicit drug use. The statement about the illicit drug "is not dangerous with Suboxone" may have represented a poorly worded explanation of how Suboxone is less risky than full-agonist opioids or even that Suboxone may be effective in reducing illicit drug use. However, in combination with infrequent assessments as well as the lack of a documented plan to address the illicit drug use, the statement gives the impression of an inattentive prescriber.

### Consistency of Patient Care Between Providers and Cross-Coverage

In our EHR reviews and interviews with other facility staff, we found that other providers were resistant to covering the subject provider's patients because they were uncomfortable with the pain medication regimen being prescribed. The provider reported to us difficulties with cross-coverage for his patients on full-agonist opioids. Multiple staff members knowledgeable about opioid prescribing identified the provider as an outlier with regard to opioid prescribing.

### Issue 3: Other Issues Regarding Opioid Prescribing at the Facility

### Facility/VISN Monitoring of Suboxone Patients

During our review of the physician who prescribed both full-agonist opioids and a partial-agonist opioid (Suboxone), we requested the facility and VISN tracking data. We found that the facility tracked monitoring of patients on chronic opioids as part of the OSI; however, the data provided to us by the VISN for OSI monitoring only included patients on full-agonist opioids. The monitoring of patients taking Suboxone was not tracked; such monitoring was not required by the OSI.

### Review of Drug Diversion

The Guideline<sup>63</sup> advises providers to be aware of the potential for illegal, criminal, or unsafe and dangerous behavior related to chronic opioid therapy. Specifically, providers are instructed to interact with regulating authorities inside and outside the medical system when they suspect patients are engaging in illegal or criminal behaviors such as diverting prescription opioids.<sup>64</sup>

The OIG Chicago Criminal Investigations Division interviewed VA staff and members of the Milwaukee Police department. At the time of our visit in April 2015, there were no reported incidents or "red flags" suggesting patterns of opioid diversion, criminal, or illegal activities associated with opioid prescriptions dispensed at the facility.

<sup>&</sup>lt;sup>63</sup> VA/DoD Clinical Practice Guideline, *Management of Opioid Therapy for Chronic Pain*, dated May, 2010.

<sup>&</sup>lt;sup>64</sup> Drug diversion is the illegal distribution or abuse of prescription drugs or their use for unintended purposes.

### **Conclusions**

To review the overall opioid prescribing practices at the facility, we evaluated whether facility and VISN leadership complied with specific goals delineated in the OSI Update. We looked at the implementation of Goals 2, 3, 7, 8, and 9.

We found that the facility was compliant with Goal 2 and of the patients prescribed chronic opioid therapy; the percentage who had an annual UDS was 31 percent by the end of FY 2014 and 61.7 percent in quarter 2, FY 2015.

We learned that facility managers did not verify whether providers checked the PDMP database prior to the initiation of chronic opioid therapy. However, we determined that facility providers queried the PDMP databases 309 times in FY 2014 and 1,080 times in FY 2015.

According to the OSI Update, Goal 7, facility and VISN level providers were to complete clinical reviews on patients that were prescribed opioids >200 MEDD by March 30, 2015. We found that such reviews were not completed and certified by March 30, 2015 as specified by the OSI Update; however, as of October 2016, facility providers were completing these reviews and discussing them with the VISN Pain Committee. Miscommunication between the VISN and facility resulted in the facility performing fewer patient reviews than required by the OSI Update. As of November 2016, the VISN was implementing a program that would increase the number of required patient reviews.

Consistent with Goal 8, we found the facility had several CAM pain management therapies available, including acupuncture, Tai Chi, and biofeedback.

We found in April 2015 that the facility had not established the collaborative model of mental health and primary care as described in Goal 9 to manage prescribing of opioids and benzodiazepines with chronic, non-cancer pain. VISN leadership told us that as of October 2016, the VISN was implementing a new system at the facility to establish a collaborative model.

We substantiated that a provider's opioid prescribing practices were questionable and identified concerns related to assessments of pain management and opioid addiction patients for whom the provider prescribed chronic opioids. We found several cases where the frequency of the provider's patient assessments differed significantly from guideline recommendations.

We also had concerns that for a subset of the provider's patients, the opioid prescribing practice was not consistent with other opioid prescribers at this facility, particularly with regard to the quality of the monitoring of his patients. Given the range of diseases and conditions that cause pain as well as different approaches to pain management, variability in how clinicians prescribe opioids is expected. However, when the degree of variance in practice affects the continuity of care provided to patients, better coordination of opioid prescribing practices systematically seems to be warranted.

The provider's practice contained a clinically challenging population of patients diagnosed with both chronic pain and opioid dependence. A practitioner may opt to continue to prescribe opioids despite aberrant behaviors or relapse if the patient's overall condition is better with opioid treatment than without opioid treatment. While a patient with opioid dependence would ideally be able to discontinue opioids, such a patient may need to be on opioids indefinitely.

We found clinical care that we considered at variance from clinical guidelines, and we recommended additional review of these cases. We also found care that was not covered by current clinical guidelines, specifically the treatment of chronic pain with buprenorphine. However, neither care at variance from clinical guidelines nor off-label prescribing without clinical guidelines equate to problematic care. The Institute of Medicine noted "interdisciplinary assessment and treatment may produce the best results for people with the most severe and persistent pain problems," and that an interdisciplinary assessment and review of these cases will provide the best judgement. For the provider's practice, an interdisciplinary assessment by board certified experts in the subspecialties of Pain Medicine and Addiction Medicine would be appropriate. Such a review can account for the individual circumstances of the cases, identify corrective action(s) if necessary, and identify systematic issues.

We also noted that Suboxone was not included in the opioid prescription monitoring reports that we reviewed. Providers primarily used Suboxone for the treatment of opioid addiction and high-risk patients cannot be readily identified by dosage. Patients on Suboxone for opioid addiction with chronic pain can be especially challenging clinically because both diagnoses can put patients at higher risk for overdose and death. Most of the elements of OSI prescription monitoring are important for patients prescribed Suboxone such as the frequency of UDS and the rate of co-administration of benzodiazepines.

We found no reports or patterns suggesting drug diversion in April 2015.

## Recommendations

- 1. We recommended that the Veterans Integrated Service Network Director convene an expert panel knowledgeable in the subspecialties of Pain Medicine and Addiction Medicine to review the subject provider's opioid prescribing practices within the context of the patients whose treatment varied from guidelines as described in this report, ensure that the expert panel expand the review as necessary, and submit a report of findings to the Veterans Integrated Service Network and Facility Directors.
- **2.** We recommended that the Veterans Integrated Service Network Director ensure the monitoring of patients on Suboxone.

<sup>&</sup>lt;sup>65</sup> Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research. <a href="http://iom.nationalacademies.org/reports/2011/relieving-pain-in-america-a-blueprint-for-transforming-prevention-care-education-research.aspx#sthash.DXBHbBqk.dpuf">http://iom.nationalacademies.org/reports/2011/relieving-pain-in-america-a-blueprint-for-transforming-prevention-care-education-research.aspx#sthash.DXBHbBqk.dpuf</a>.

- 3. We recommended that the Veterans Integrated Service Network Director ensure the Pain Committee strengthens processes to improve communication with the facility to ensure information is relayed timely.
- 4. We recommended that the Facility Director ensure that providers access the Prescription Drug Monitoring Program database as required by facility policy and monitor compliance.
- 5. We recommended that the Facility Director ensure adequate resources, such as additional staff or allotted duty time, are allocated for patient reviews for opioid therapy appropriateness.

### Department of Veterans Affairs

### Memorandum

Date: DEC 1 0 2014

From: Acting Deputy Under Secretary for Health For Operations and Management (10N)

subj: Opioid Safety Initiative (OSI) Updates

To: VISN Directors (10N1-23)

Assistant Deputy Under Secretary for Health for Clinical Operations Deputy Under Secretary for Health for Policy and Services (10P)

- 1. On April 22, 2014, the Under Secretary for Health reviewed and concurred with the Office of Inspector General (OIG) Report, VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy (Project No. 2014-00895-HI-0378) (VAIQ 7462279) (Attachment 1).
- 2. The OIG report highlights the nine goals of the Opioid Safety Initiative (OSI). Based on the other recommendations contained in the OIG report, the purpose of this memorandum is to provide updated guidance on the nine goals of the OSI. The updated guidance clarifies and revises the April 2, 2014 memorandum issued by the Under Secretary for Health (Attachment 2).
- 3. An OSI Toolkit Curriculum has been developed and is available on the OSI SharePoint at <a href="http://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/10NC/OSI/default.aspx">http://vaww.vha.vaco.portal.va.gov/sites/DUSHOM/10NC/OSI/default.aspx</a> and on the VA National Pain Program office website (<a href="http://vaww.va.gov/painmanagement/">http://vaww.va.gov/painmanagement/</a>). A table of contents from this toolkit is attached for your reference (Attachment 3).
- 4. Updated guidance is below:
  - a. Goal 1: Educate prescribers of opioid medication regarding effective use of urine drug screening
    - VISNs will establish a Network-wide standardized education system by December 31<sup>st</sup>, 2014.
    - ii. Educational tools for pain management that include information to support use of urine drug screening by prescribers can be found in the OSI Toolkit curriculum. Additional tools will be added to the Toolkit as they are developed in the field and appropriately peerreviewed by relevant subject matter experts.

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### b. Goal 2: Increase the use of urine drug screening

- i. After agreeing with the OIG Report, VHA set an internal goal of increasing the number of patients on long-term opioid therapy who currently receive urine drug screening by10% by Quarter 2 (Q2) of fiscal year (FY) 2015. This goal has been acheieved however, remains in effect to reduce practice variation at the medical centers.
- ii. Many medical centers began increasing the frequency of urine drug screen testing prior to the release of the April 2<sup>nd</sup> OSI memo. In order to achieve the national goal by the end of Quarter 2, Fiscal Year 2015, and to recognize the medical centers that were early adopters of this initiative, goals have been stratified for medical centers. Specifically, facilities that, at the end of FY14Q1, drug screened:
  - 1. less than 15% of chronic opioid therapy patients should attempt to double the number of patients.
  - 2. between 15% and 20%, should screen 1.75 times as many patients
  - 3. between 21 and 25% should screen 1.5 times as many patients
  - 4. between 26 and 35% should screen 1.25 times as many patients
  - 5. between 36 and 40% should screen 1.2 times as many patients
  - 6. between 41 and 50% should screen 1.1 times as many patients
  - facilities over 50% should maintain and increase screening as appropriate
- iii. For example, a facility with a 17% screening rate (i.e. in the group between 15% and 20%) that conducted annual screening on 100 patients per the FY14Q1 OSI report should conduct annual screening on 175 patients by the FY15Q2 OSI report. Attachment 4 provides facility rates of urine drug screening of patients on chronic opioid therapy as of December 31, 2013.

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iv. These initial efforts occurred during FY 14 will provide an infrastructure for on-going implementation and improvement in use of drug screening for chronic opioid therapy in future years.

# c. Goal 3: Facilitate the use of state prescription drug monitoring program (PDMP) databases

- i. VISNs must certify by the end of Quarter 2, Fiscal Year 2015 that medical centers have an education program in place that consists of training and/or educational materials that are made available to providers. VISNs and medical centers are encouraged to customize the training/educational materials from the specific state PDMPs.
- ii. VA Office of General Counsel has provided initial guidance on access to state PDMPs. They will support efforts to improve access to state PDMP databases by providing further guidance as needed within the initial timeline.
- d. Goal 4: Establish safe and effective VISN tapering programs for patients using the combination of benzodiazepines and opioids.
  - i. Significant progress has been made on Goal 4. Comparing FY12Q4 and FY14Q2, 14,475 fewer patients were receiving these drugs at the same time.
  - ii. The focus of this goal is to address risks related to the combined use of benzodiazepines and opioids, not to encourage administrative discontinuation of opioid or benzodiazepine treatments. The slow tapering of opioids and benzodiazepines should only occur when clinically indicated, and should be carried out with sufficient monitoring to ensure patient safety. Tapering patients who have been treated chronically with opioid and benzodiazepine medications may be complicated due to development of physical dependence. In these cases, both treatment maintenance and treatment taper may pose risks, and will require careful balancing of overall risks and benefits for the individual patient.
  - iii. Initial objectives to reduce population risks should focus on minimizing new starts of combined opioids and benzodiazepines. Providers should carefully evaluate new starts of combined opioid and benzodiazepine prescriptions for safety and clinical appropriateness, and adjust treatment plans as needed. This includes new starts of benzodiazepines in patients on opioids, new

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- starts of opioids in patients on benzodiazepines, and concurrent starts of medications from the two classes. Preventing initiation of these prescriptions or adjusting treatment plans before combined use becomes chronic can make a rapid impact on population risk related to opioid/benzodiazepine combinations.
- iv. Deputy Under Secretary for Health for Operations and Mangement (10N) approved materials to assure a common standard for tapering opioids and benzodiazepines when clinically indicated. These materials are included in the OSI Toolkit Curriculum entitled "Clinical considerations when caring for patients on Opioids and Benzodiazepines", "Helping patients Taper Benzodiazepines – Clinician Handout", and "Helping patients Taper Benzodiazepines – Patient Handout".
- v. VISNs need to develop local tapering protocols and plans to resource their implementation. VISN protocols must ensure that patients can be monitored regularly during dosage changes as medications are slowly tapered. These protocols should include guidance about dose decreases and about self-help and clinical resources that could address needs and symptoms that emerge during tapering.
- vi. Trends in prescribing of combined opioid and benzodiazepine medications are promising. These numbers will continue to be monitored with an overall goal of reducing the combined use of these medications; however, the September 15, 2014 deadline for a 10% decrease will be suspended to ensure that adjustments to treatment plans are conducted in a patient-centered fashion and tapers are conducted at a slow pace to reduce safety risks related to withdrawal.

### e. Goal 5: Develop tools to identify higher risk patients

- i. An Opioid Risk Stratification (ORS) Toolkit is being developed collaboratively by 10NC and 10P.
- ii. The ORS Toolkit will help to identify patients who are at higher risk of adverse events with opioid medication. The goal is to facilitate the targeting of patients who will require more intensive monitoring of opioid therapy, or more intensive consideration of non-opioid treatment plans as outlined in the clinical guidance recommendations and the VA/DOD Clinical Practice Guideline for Opioid Therapy for Chronic Pain (http://www.healthquality.va.gov/guidelines/Pain/cot/). This ORS

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Toolkit is part of the response to the OIG report recommendation 3 on timely follow-up for patients on take-home opioids.

iii. Initial recommendations for risk stratification of patients are included in the OSI Toolkit Curriculum in the documents entitled "Pain Management Opioid Safety – Education Guide" and "Pain Management Opioid Safety – Quick Reference Guide". These guidelines will be reviewed quarterly and updated annually based on statistical modeling, clinical policy, and best practices by the National Pain Program office in consultation with other relevant PCS and 10NC offices.

# f. Goal 6: Improve prescribing practices around long-acting opioid formulations

- i. The focus of this goal is to ensure that protocols and resources are available for addressing clinical risks related to high-dose, and long-acting opioid prescribing, and for tapering patients on long-acting opioid medications when clinically indicated. There are risks related to use of all opioid medications. Patients receiving high-dose or long-acting opioids in VA have higher rates of documented opioid poisoning than patients receiving lower dose or chronic short-acting opioids. Thus more intensive monitoring of patients on high-dose or long-acting opioids is warranted. However, providers should not taper patients on specific long-acting opioid formulations or initiate opioid rotations when these treatment modifications are not clinically indicated.
- ii. Each VISN will develop local opioid tapering protocols and plans to resource their implementation to ensure that tapers can be conducted safely when they are clinically appropriate. VISN protocols must ensure that patients can be monitored regularly during dosage changes as medications are slowly tapered. Guidance on opioid tapering is included in the OSI Toolkit Curriculum entitled "Opioid Dose Reduction –Fact Sheet".
- iii. Tapering protocols and plans will be approved by VHA Central Office (National Pain Program office and 10N).
- iv. All high-dose opioids regardless of opioid formulation used, such as morphine, oxycodone, hydromorphone and methadone, increase risk of adverse events. The initial objectives for this goal have been combined with Goal 7 to focus on review of patients prescribed greater than 200 MEDD. The objective to reduce use of methadone and sustained action oxycodone and hydromorphone,

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specifically will not be monitored. Providers are instead encouraged to review all existing high-dose prescribing, consider treatment options during decisions regarding dose escalations, and adjust treatment plans for safety as appropriate

# g. Goal 7: Review treatment plans for patients on high doses of opioids

- i. All VHA facilities will identify patients on greater than 200 morphine equivalent daily dose (MEDD).
- Through a VHA Central Office (10N) directed program, VISNs will be provided patient and provider data for all patients on greater than 200 MEDD by facility.
- iii. VISN and facilities will review the appropriateness of these therapies and consult with prescribers and veterans regarding cases deemed unsafe and/or ineffective.
- iv. VHA's initial objective is for each VISN to review all patients on greater than 200 MEDD for clinical appropriateness and certify the review has been completed by the end of Quarter 2, FY 2015 (March 30, 2015).

# h. Goal 8: Offer Complementary and Alternative Medicine (CAM) modalities for chronic pain at all facilities

- i. All facilities will provide at least two evidence-based behavioral/psychological treatments or CAM modalities in the treatment of chronic pain. The focus of Goal 8 is to ensure the availability of chronic pain treatments beyond the use of standard medical modalities. Facilities should consider providing evidencebased behavioral and psychological treatments (e.g. Cognitive Behavioral Therapy for pain, relaxation practices) as well as CAM modalities. Evidence-based behavioral/psychological treatments, may count as one of the two Goal 8 modalities; At least one CAM modality must be offered. Evidence-based options should be given priority for implementation.
- iii. CAM expands provider options beyond the use of standard modalities (e.g. interventional pain medicine, physical therapy, occupational therapy, and non-opioid medication therapies). Recommended modalities(e.g., acupuncture/acupressure, yoga, progressive relaxation) are listed at the in National Pain

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Management Intranet site. http://vaww.va.gov/PAINMANAGEMENT.

- iii. VHA's initial objective remains evidence of at least two evidencebased behavioral/psychological treatments or approved CAM modalities per facility by the end of Quarter 2, FY 2015 (March 30, 2015).
- i. Goal 9: Develop new models of mental health and primary care collaboration to manage prescribing of opioid and benzodiazepines in patients with chronic pain.
  - i. Because the Behavioral Health Interdisciplinary Program (BHIP) Model is not fully implemented within general mental health programs, facilities should utilize available psychiatric and behavioral health resources, such as the Primary Care Mental Health staff working in the Patient Aligned Care Team, to provide mental health support for the safer and evidence-based use of opioids, and benzodiazepines in patients with chronic pain syndromes. Those Veterans whose mental health needs exceed what can be provided in the extended PACT shall be referred to general or specialty mental health services for further assessment and care, which must be closely coordinated with ongoing PACT
  - iii. Mental Health Services, the Office of Mental Health Operations, Office of Primary Care Operations and Primary Care Services will work collaboratively with the National Pain Program office to provide guidance to mental health, primary care, and pain teams. By end of Quarter 3, FY 2015 (September 30, 2015) these offices will identify strong practices that can be operationalized across the VHA Health Care system.
  - iii. A request for proposals will be released to the field by VHA Central Office (10N) to establish model interdisciplinary teams and strategies for management and tapering of opioid and/or benzodiazepine medications for field trials at three medical centers.

5. VISNs should submit materials for approval at to VHA CO 10NC Front Office HSSs < VHACO10NCFOHSSs@va.gov>.

Philip Matkovsky

# **VISN Director Comments**

# **Department of Veterans Affairs**

# **Memorandum**

Date: July 6, 2017

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

Healthcare Inspection—Review of Opioid Prescribing Practices, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

Director, Chicago Office of Healthcare Inspections (54CH)
Director, Management Review Service (VHA 10E1D MRS Action)

- 1. Thank you for the opportunity to view the draft report of the Clement J. Zablocki Veterans Affairs Medical Center inspection. I have reviewed the document and concur with the recommendations.
- Corrective action plans have been established, as detailed in the attached report. If additional information is needed, please contact my office at (708) 492-3900.

(original signature on file:) Renee Oshinski

# **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 Veterans Integrated Service Network Director convene an expert panel knowledgeable in the subspecialties of Pain Medicine and Addiction Medicine to review the subject provider's opioid prescribing practices within the context of the patients whose treatment varied from guidelines as described in this report, ensure that the expert panel expand the review as necessary, and submit a report of findings to the Veterans Integrated Service Network and Facility Directors.

### Concur

Target date for completion: September 30, 2017

VISN response: In 2015, the subject provider's opioid prescribing practices were reviewed. Feedback including strategies to improve clinical monitoring was provided. The VISN director will convene an expert panel to formally review the subject provider's opioid prescribing practices as described in the report. The panel will include a board-certified pain specialist physician, a board-certified addictions specialist and a clinical pharmacy specialist. The findings of the report will be submitted to the VISN and Facility Director.

**Recommendation 2.** We recommended that the Veterans Integrated Service Network Director ensure the monitoring patients on Suboxone.

### Concur

Target date for completion: September 30, 2017

VISN response: The VISN will initiate a monitoring system for urine drug screening for chronic patients on Suboxone. 80% of chronic patients on Suboxone will have urine drug screening monitoring in place.

**Recommendation 3.** We recommended that the Veterans Integrated Service Network Director ensure the Pain Committee strengthens processes to improve communication with the facility to ensure information is relayed timely.

### Concur

Target date for completion: May 31, 2017

VISN response: Significant changes have occurred since this review was conducted in 2015. In FY 16, VISN 12 hired four Academic Detail (AD) pharmacists who are dedicated to the VISN 12 Opioid Safety Initiative (OSI) efforts. These pharmacists

participate and play an instrumental role on the VISN 12 VISN Pain/Opioid Safety Committee (OSC). Together with the VISN 12 Pain/OSI Lead, the AD pharmacists meet quarterly with facility OSI teams helping them analyze outcome data and overcome identified barriers. VISN 12 has an active VISN Pain/Opioid Safety Committee (OSC) with each VISN 12 facility Opioid Safety Initiative (OSI) lead represented. VISN 12 Pain/OSC meets quarterly to review and analyze facility and VISN level data. VISN 12 has added a mental health representation to VISN Pain/OSI meetings to provide expertise on complex mental health cases.

OIG Comment: Based on information received from the VISN, we consider this recommendation closed.

# **Facility Director Comments**

# **Department of Veterans Affairs**

# **Memorandum**

Date: July 7, 2017

From: Director, Clement J. Zablocki VA Medical Center (695/00)

Healthcare Inspection—Review of Opioid Prescribing Practices, Clement J. Zablocki VA Medical Center, Milwaukee, Wisconsin

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

- I have reviewed the draft report of Office of Inspector General's review of the Opioid Prescribing Practices at the Clement J. Zablocki VA Medical Center. We concur with all recommendations.
- 2. Please see the attached response to the recommendations identified in the review.
- 3. I appreciate the opportunity for this review as a continuing process to improve care to our Veterans.

(original signature on file:)
Daniel S. Zomchek, PhD, FACHE

# **Comments to OIG's Report**

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

### **OIG Recommendations**

**Recommendation 4.** We recommended that the Facility Director ensure that providers access the Prescription Drug Monitoring Program database as required by facility policy and monitor compliance.

### Concur

Target date for completion: September 30, 2017

Facility response: In accordance with the publication of VHA Directive 1306 in October 2016, VISN 12 initiated annual monitoring, provided Prescription Drug Monitoring Program (PDMP) education and implemented a standardized note title to document the results of queries in the VA medical record. Beginning April 1, 2017, physicians and other prescribers in the state of Wisconsin have been required to review patient records from the electronic PDMP database before issuing a prescription order for a controlled substance. This state requirement is more stringent than VHA Directive 1306. In May 2017, a tool was developed to assist providers in identifying when a PDMP is required prior to prescription renewal. Milwaukee VAMC will augment the existing tool to include a compliance monitoring mechanism.

**Recommendation 5.** We recommended that the Facility Director ensure adequate resources, such as additional staff or allotted duty time, are allocated for patient reviews for opioid therapy appropriateness.

### Concur

Target date for completion: August 31, 2017

Facility response: Since 2015, the facility Pain Management Team (PMT) has evolved and increased multidisciplinary support for the pain committee and patient care reviews. The facility has completed an assessment of the current workload and staff dedicated to the patient reviews for opioid therapy appropriateness. Distribution of patient reviews and/or reassignment of clinical staff to complete the reviews will be directed to ensure timely patient reviews for opioid therapy appropriateness.

Appendix D

# **OIG Contact and Staff Acknowledgments**

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