



DEPARTMENT OF VETERANS AFFAIRS
WASHINGTON DC 20420

November 18, 2015

The Honorable Carolyn N. Lerner
Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW, Suite 300
Washington, DC 20036

RE: OSC File No. DI-14-3745

Dear Ms. Lerner:

I am responding to your letter regarding allegations made by a whistleblower at the Sam Rayburn Memorial Veterans Center in Bonham, Texas, operated by the VA North Texas Health Care System, Dallas, Texas (the Medical Center). The whistleblower alleged that practitioners there improperly dispensed opioid medications without suitable monitoring and follow up, and without use of the Texas Department of Public Safety online prescription monitoring program, and that these practices constitute a violation of law, VA directives, and a substantial and specific danger to public health. The Secretary has delegated to me the authority to sign the enclosed report and take any actions deemed necessary as referenced in 5 United States Code § 1213(d)(5).

When this referral was received, the Interim Under Secretary for Health was assigned to review this matter and prepare a report in compliance with § 1213(d)(5) requirements. She, in turn, directed the Office of the Medical Inspector to assemble and lead a VA team to conduct an investigation. The report does not substantiate the allegations but makes three recommendations to the Medical Center. We will send your office follow-up information describing actions that have been taken by the Medical Center and other entities to implement these recommendations.

Thank you for the opportunity to respond.

Sincerely,

A handwritten signature in black ink, which appears to read "Robert L. Nabors II".

Robert L. Nabors II
Chief of Staff

Enclosure

**DEPARTMENT OF VETERANS AFFAIRS
Washington, DC**

**Report to the
Office of Special Counsel
OSC File Number DI-14-3745**

**Department of Veterans Affairs
North Texas Health Care System
Dallas, Texas**



Report Date: October 20, 2015

TRIM 2015-D-4459

Executive Summary

The Interim Under Secretary for Health (I/USH) requested that Office of the Medical Inspector (OMI) investigate allegations lodged with the Office of Special Counsel (OSC) of inappropriate opioid management at the Department of Veterans Affairs (VA) North Texas Health Care System (VANTHCS) in Dallas, Texas (hereafter, the Medical Center), and at the Sam Rayburn Memorial Veterans Center (the Bonham Center) in Bonham, Texas. The whistleblower alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health. The VA team conducted a site visit to the Medical Center and the Bonham Center on May 18–22, 2015.

Allegation

The whistleblower alleged that:

Narcotic prescriptions are routinely refilled automatically without following proper procedures, including a reevaluation of the patient's continued need, completion by the patient of a Controlled Pain Medication (Opioid) Agreement, urine toxicology screening, and use of the Texas Department of Public Safety online prescription monitoring program.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and a law, rule or regulation was violated or there was a substantial and specific threat to public health and safety. We **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA **confirmed** a whistleblower observation when we agreed with the facts, findings, or data, but did not agree the facts or findings violated a law, rule, or VA policy or were a substantial and specific threat to public health and safety. We **did not confirm** a whistleblower observation when we did not agree with the facts, findings, or data.

After careful review of findings, VA makes the following conclusions and recommendations.

Conclusions

Opioid Management

- Although VA found some evidence of provider deviation from the recommendations in the VA/Department of Defense (DoD) Guideline, VA **does not substantiate** a violation of law, rule, regulation or a substantial and specific danger to public health and safety with regard to the clinical management of long-term opioid therapy for pain at the Bonham Center. The following paragraphs place the deviations we found at the Bonham Center in context with national Veterans Health Administration (VHA) and Medical Center performance in the metrics we evaluated.

- VA **confirmed** that VHA providers nationally did not fully implement the recommendation in the VA/DoD Guideline that all patients chronically medicated with opioids be offered "routine and random" urine drug tests (UDT). Adherence to this recommendation is not compulsory. While the recommendation may serve to help inform a provider's treatment process and clinical decision-making, whether to conduct such testing is a clinical determination left to the medical judgment of the treating provider and is dependent on the consent of the patient. Using the Opioid Safety Initiative (OSI) Dashboard data, we found that nationally, less than 70 percent of such patients had a UDT at least every year. This conclusion is consistent with the findings and conclusions presented in the Office of the Inspector General (OIG) study published in 2014. In the OSI Dashboard metrics VA reviewed, VHA has shown recent improvement in complying with this recommendation. The VA/DoD Guideline recommends all patients chronically medicated with opioids have a follow-up encounter at least every 6 months. VHA providers nearly met this goal: more than 96 percent of their patients had a documented follow-up encounter within 6 months. In addition, although there is no VA/DoD Guideline recommendation regarding the appropriate percentage of patients who are prescribed a Morphine Equivalent Daily Dose (MEDD) of 100 mg or more or who are prescribed opioids and benzodiazepines concomitantly, the performance of VHA providers showed a slight reduction over the period reviewed in these opioid-patient management metrics.
- VA **confirmed** that Medical Center providers performed, as well as or better than the national VHA providers in the four opioid management metrics we reviewed. VA **confirmed** that the Bonham providers performed, as well as or better than the national VHA providers in three of the four metrics. However, the percentage of patients taking opioids and benzodiazepines concomitantly at the Bonham Center was greater than the national percentage. Although the Bonham providers showed deviation from the national VHA providers in this metric, our assessment did not include the variability in individual provider patient population and provider position responsibilities that might explain this deviation. In other words, the data do not establish or address whether the concomitant use of the medications was clinically appropriate or inappropriate in any particular case; the data establish only the number of cases where both medications were prescribed, to identify trends.
- VA **confirmed** that Provider 1 performed, as well as or better than the national provider performance in three of the four opioid management metrics we reviewed. The percentage of Provider 1's patients taking opioids and benzodiazepines concomitantly; however, was greater than the national percentage. Although this Provider showed deviation from the national VHA providers in this metric, our assessment did not include the variability in the provider's patient population and the provider's position responsibilities that might explain this deviation.
- VA **confirmed** that Provider 2 performed, as well as or better than the national provider performance in all four opioid management metrics we reviewed.

- VA **confirmed** that Provider 3 performed, as well as or better than the national provider performance in all four opioid management metrics we reviewed.
- VA **confirmed** that Provider 4 performed as well as or better than the national provider performance in three of the four opioid management metrics we reviewed. The percentage of Provider 4's patients taking opioids and benzodiazepines concomitantly; however, was greater than the national percentage. Although this Provider showed deviation from the national VHA providers in this metric, our assessment did not include the variability in the provider's patient population and the provider's position responsibilities that might explain this deviation.
- VA **confirmed** that the percentage of long-term, opioid-treated patients having a VANTHCS Opioid Agreement did not meet the standard set by the Medical Center, which is that all patients treated long-term with opioids have such an agreement in the electronic health record (EHR). Provider 1 had 85 percent success at meeting this standard, and Provider 2 achieved a 62 percent success rate. Because VHA has never had a requirement for the documentation of such an agreement, we found no violation of agency policy.
- VANTHCS MEMORANDUM 112A-06, *Chronic Opioid Use*, February 26, 2014, does not conform with VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 6, 2014, in that the VANTHCS MEMORANDUM requires the placement of a locally approved Opioid Pain Care Agreement (OPCA). VHA Directive 1005 requires such locally developed OPCAs be supplanted by signature consents by May 6, 2015.
- The Medical Center does not communicate individual provider's performance with regard to opioid prescribing practices in an easily understandable fashion to the Bonham Center providers.

Medical Record Reviews

- Although VA found some evidence of provider deviation from the recommendations in the VA/DoD Guideline, VA **does not substantiate** a violation of law, rule, regulation or a substantial and specific danger to public health and safety with regard to VA providers' clinical management of long-term opioid therapy in the five patient cases identified by the whistleblower.
- VA **confirmed** 5 of the 10 separate allegations arising from our review of the 5 individual Veteran EHRs.
 - For Veteran 1, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we did **not confirm** that the Veteran's EHR had no VANTHCS Opioid Agreement.

- For Veteran 2, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we did **not confirm** that the Veteran's EHR had no VANTHCS Opioid Agreement. We **confirmed** the allegation that the Veteran had no UDT within 1 year of the represcribing of his opioid medication, although there is no VHA or Medical Center requirement for the provider to have obtained one within that timeframe.
- For Veteran 3, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we **confirmed** that there was no VANTHCS Opioid Agreement in the Veteran's EHR. Absence of this document violated the Medical Center policy at that time. The allegation that the Veteran's UDTs were positive for benzodiazepine is confirmed, but the implication that he was taking this medication illicitly is **not confirmed**, since this medication was prescribed by the patient's primary care physician (PCP). Although the allegation that the Veteran was consuming cannabis is **confirmed** and other providers might have discontinued opioids in such a patient who repeatedly used cannabis, the decision to discontinue opioids for this reason is properly a clinical determination left to the judgment of the treating physician. In this case, the Veteran's PCP, in the exercise of clinical judgment, elected to continue prescribing his opioid medications.
- For Veteran 4, the allegation that the Veteran's UDTs were recently and repeatedly positive for cannabis is **not confirmed**.
- For Veteran 5, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we **confirmed** that there was no VANTHCS Opioid Agreement in the Veteran's EHRs at the time the medical officer of the day (MOD) accessed this Veteran's EHR. Absence of this agreement at that time violated local Medical Center policy. However, this agreement was subsequently executed on February 18, 2015. The allegation that the Veteran's UDTs were positive for benzodiazepine and opioids, suggesting that he was taking these medications illicitly, is **not confirmed** because each of those medications had been prescribed by the Veteran's PCP. However, the allegation that there was no appropriate testing for fentanyl within 1 year of the represcribing of this medication is **confirmed**, but we note there is no VHA or Medical Center requirement to test for it.
- VA found only one provider at the Bonham Center who frequently accessed the Texas Prescription Drug Monitoring Programs (PDMP) Web site prior to prescribing opioids. However, no VHA or local Medical Center requirement existed, or exists now, that directs VA providers to access this or similar sites in their clinical decision-making process related to opioid prescribing, even though VHA recommends providers access PDMP Web sites when available.

- **Recommendations to the Medical Center**

1. Review patients of Provider 1 and Provider 4 who were concomitantly prescribed opioids and benzodiazepines to determine if the continued opioid therapy was clinically appropriate. Depending on the results of this review, take appropriate action.
2. Continue to develop a comprehensive pain management and long-term opioid use program that includes an opioid oversight process using OSI Dashboard data.
3. Revise VANTHCS MEMORANDUM 112A-06 to conform with VHA Directive 1005.

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I. Introduction

The I/USH requested that OMI investigate allegations lodged with OSC of inappropriate opioid management at the VA North Texas Health Care System (VANTHCS) in Dallas, Texas (hereafter, the Medical Center) and at the Sam Rayburn Memorial Veterans Center (the Bonham Center) in Bonham, Texas. The whistleblower alleged that employees are engaging in conduct that may constitute violations of laws, rules or regulations, and gross mismanagement, which may lead to a substantial and specific danger to public health.

II. Facility Profile

The Medical Center, part of Veterans Integrated Service Network (VISN) 17, operates an 853-bed system including a Spinal Cord Injury Center, Domiciliary Care Program and Community Living Center with a dedicated hospice unit. The Medical Center provides oversight to nine community-based outpatient clinics (CBOC) and other VA clinics including the Sam Rayburn Memorial Veterans Center (the Bonham Center) in Bonham, Texas. The Bonham Center provides primary and geriatric care, as well as outpatient mental health services to Veterans in North Texas and Southern Oklahoma. The 78-acre campus includes a 136-bed Community Living Center for extended care, including skilled nursing care, assisted care unit, specialized dementia unit, palliative and respite care. The Bonham Center also has a 224-bed Domiciliary for rehabilitative care.

III. Allegation

The whistleblower alleged that:

Narcotic prescriptions are routinely refilled automatically without following proper procedures, including a reevaluation of the patient's continued need, completion by the patient of a Controlled Pain Medication (Opioid) Agreement, urine toxicology screening, and use of the Texas Department of Public Safety online prescription monitoring program.

IV. Conduct of Investigation

The VA team conducting the investigation consisted of **Team Member 1**, MD, Deputy Medical Inspector for National Assessments; **Team Member**, MSN, RN, CPUR, Clinical Program Manager; and **Team Member**, PhD, Statistician. The team reviewed relevant policies, procedures, professional standards, reports, memorandums, and other documents listed in Attachment A.

VA interviewed the whistleblower by telephone on May 14, 2015, and conducted a site visit to the Medical Center and the Bonham Center on May 18–22, 2015, holding an entrance briefing with Medical Center leadership, including the acting Chief of Staff (CoS) as the senior Medical Center representative. We held a face-to-face interview

with the whistleblower at the Bonham Center on May 19. We also interviewed the following Medical Center employees:

1. Employee 1 [REDACTED], MD, Acting CoS;
2. Employee 2 [REDACTED], MD, Assistant CoS, Primary Care for Outlying Clinics;
3. Employee 3 [REDACTED], MD, Assistant Chief, Ambulatory Care;
4. Employee 4 [REDACTED], Chief, Ambulatory Care; Opioid Safety Initiative (OSI) Point of Contact
5. Employee 5 [REDACTED], DO, Primary Care Physician (PCP), Domiciliary, Bonham Center;
6. Employee 6 [REDACTED], PA, Community Living Center (CLC) Physician Assistant (PA), Bonham Center;
7. Employee 7 [REDACTED], NP, Primary Care Nurse Practitioner, Domiciliary, Bonham Center;
8. Employee 8 [REDACTED], MD, PCP, Bonham Center;
9. Employee 9 [REDACTED] PA, PCP, Bonham Center;
10. Employee 10 [REDACTED], MD, CLC Physician, Bonham Center;
11. Employee 11 [REDACTED], MD, PCP, Bonham Center;
12. Employee 12 [REDACTED], MD, PCP, Bonham Center;
13. Employee 13 [REDACTED], MD, Primary Care and Employee Health Physician, Bonham Center
14. Employee 14 [REDACTED], PA, CLC, Bonham Center;
15. Employee 15 [REDACTED], DO, PCP, Bonham Center;
16. Employee 16 [REDACTED], MD, PCP, Bonham Center;
17. Employee 17 [REDACTED], MD, PCP, Bonham Center;
18. Employee [REDACTED], MD, PCP, Bonham Center;
19. Employee 19 [REDACTED], MD, contract PCP, Bonham Center; and
20. Employee 20 [REDACTED], MD, Chief, Pain Management and Chair, Pain Management Committee.

We held an exit briefing on May 22, 2015, with the acting CoS attending as the senior Medical Center representative.

VA **substantiated allegations** when the facts and findings supported that the alleged events or actions took place and a law, rule or regulation was violated or there was a substantial and specific threat to public health and safety. We **did not substantiate allegations** when the facts and findings showed the allegations were unfounded. VA **confirmed** a whistleblower observation when we agreed with the facts, findings, or data, but did not agree the facts or findings violated a law, rule, or VA policy or were a substantial and specific threat to public health and safety. We did **not confirm** a whistleblower observation when we did not agree with the facts, findings, or data.

V. Findings, Conclusions, and Recommendations

Allegation

Narcotics prescriptions are routinely refilled automatically without following proper procedures, including a reevaluation of the patient's continued need, completion by the patient of a Controlled Pain Medication (Opioid) Agreement,

urine toxicology screening, and use of the Texas Department of Public Safety online prescription monitoring program.

Background

In October 2009, VHA published VHA Directive 2009-053, *Pain Management*, to provide policy and implementation procedures for the improvement of pain management. The standards in that Directive include the use of opioid therapy when clinically appropriate.¹

In addition, the Under Secretary for Health (USH) chartered the Opioid Safety Initiative (OSI) in 2012 to ensure opioid pain medications are used safely, effectively, and judiciously. The OSI notwithstanding, VHA does not have a policy regarding the prescription of opioids, but instead relies on comprehensive guidelines for best current evaluation and therapeutic options. Such guidelines help to inform providers what the standard of care is and assists them in arriving at a therapeutic plan that reflects expert opinion of current best practice. One such guideline developed for the management of opioids in the VA and the Department of Defense (DoD) is the VA/DoD Guideline. Clinical leaders chosen by the two Departments defined the scope of this guideline and identified a group of clinical experts from VA and DoD to be members of the Departments' joint Opioid Therapy for Chronic Pain Working Group (WG), which completed the guideline. The WG participants were clinical experts drawn from the fields of primary care, pain management, physical medicine and rehabilitation (PM&R), anesthesiology, internal medicine, rheumatology, neurology, psychiatry, pharmacy, nursing, social work, and addiction specialists from diverse geographic regions and both VA and DoD health care systems.

Among other recommendations, the VA/DoD Guideline suggests that patients on chronic opioids undergo routine and random urine drug tests (UDT) "to confirm adherence to the opioid treatment plan and have follow-up contact with a provider "at least once every 1–6 months for the duration of the therapy." UDTs are useful for detecting illicit drug use, assisting in the diagnosis of substance use disorders, and identifying instances of opioid diversion. Further, appropriately timed follow-up contact helps patients achieve the goal of stable pain relief, facilitates effective management of adverse effects, and enables providers to regularly reevaluate the patient's continued need for opioid therapy.

The VA/DoD Guideline also suggests the establishment of a written OPCA which should include "a discussion of the risks and benefits of therapy, as well as conditions under which opioids will be prescribed." In addition to a discussion of the risks and benefits of opioid therapy, OPCAs often document a contract between the patient and the provider outlining the terms under which therapy will be given or continued. Terms of continuation might include agreement on the patient's part to undergo scheduled and random UDTs. However, VHA never required such agreements to be used or

¹ An opioid is any chemical that resembles morphine most often used therapeutically to treat severe pain. Important side effects include sedation and respiratory depression. Dependence can develop subsequent to chronic use.

documented as a matter of national policy, although VHA Directive 2009-053 encouraged their use and recognized they may be mandated at the facility level.

On February 26, 2014, the Medical Center published VANTHCS MEMORANDUM 112A-06, *Chronic Opioid Use*. This memorandum stipulates that “opioid consents/agreements in the Computerized Patient Record System (CPRS) must be used for chronic (greater than 90 days) opioid therapy.” This local requirement for an opioid consent/contract was based on the OPCA recommendation in the VA/DoD guideline and was also consistent with Directive 2009-053. The facility memorandum provides a “Controlled Pain Medication (Opioid) Agreement” form (hereafter referred to as VANTHCS Opioid Agreement) that was to be used to document the opioid consent/agreement. Effective February 26, 2014, local Medical Center policy required a VANTHCS Opioid Agreement to be completed and documented in CPRS for all long-term, opioid-treated patients prescribed at VANTHCS.

In May 2014, VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, was published; it superseded the guidance in Directive 2009-053 which encouraged the use of written OPCAs. In the place of most OPCAs, the new Directive requires signature consent from patients treated with opioid therapy for chronic pain.² In fact, the Directive requires local OPCAs that have not been approved nationally be removed and replaced by the nationally standardized consent form by May 6, 2015. The VA team evaluated the presence of OPCAs rather than the presence of signature consent because of the proximity of the May 6, 2015, compliance deadline for the placement of the informed consents.

In May 2014, the Office of Health Care Inspections (OIG) issued a study that summarizes opioid dispensing patterns and other data relevant to best opioid prescribing practice across VHA facilities for fiscal year (FY) 2012. Its metrics included the percentage of VA patients who were prescribed opioids, the length of time these patients were on opioids during the year, the types and dosages for opioid prescriptions, and concurrent prescriptions for certain drugs, such as benzodiazepines.³ In addition, the OIG study evaluated opioid patient-monitoring metrics such as UDT and follow-up contact with a provider.

In August 2013, the Pharmacy Benefits Management Service (PBM), in collaboration with Specialty Care Services, Mental Health Services, and Clinical Operations, implemented the OSI system-wide after pilot trials were conducted in four VISNs. An OSI Dashboard developed by PBM tracks system-wide trends in opioid prescribing and consumption. The OSI Task Force is a multidisciplinary group that defined business rules for the four key metrics to be measured on this dashboard: 1) the number of

² Informed consent is the permission granted by a patient to a procedure or treatment with full knowledge of the risks and the benefits of the procedure or treatment. Informed consent may be given orally or documented in writing. Per VHA Handbook 1004.01, the term “signature consent” refers to the patient’s (or surrogate’s) signature on a VA-authorized consent form.

³ Benzodiazepines are drugs that possess sedative, antianxiety, anticonvulsant, muscle relaxant, and other actions, which may be useful in augmenting the pain relief properties of opioids. However, the combination of opioid and benzodiazepine medications increases the risk of respiratory depression.

pharmacy users dispensed an opioid, 2) the number of pharmacy users on long-term opioids who receive a UDT, 3) the number of pharmacy users receiving an opioid and a benzodiazepine concomitantly, and 4) the number of pharmacy users dispensed a MEDD of 100 mg or more of opioids.⁴ Quarterly data are available nationally, by VISN, by medical center, and by individual provider. Data for the CBOCs are embedded in the data of their respective medical centers, but generally are not available by individual CBOC.

The state-administered Prescription Drug Monitoring Programs (PDMP) track the prescribing and dispensing of drugs within the state's borders, allowing providers and other users to identify patients who accidentally or intentionally misuse controlled substances. Users typically access the program via a state-administered, password-protected Web site. PDMPs also identify providers who may be prescribing large quantities of opioids or generating large numbers of opioid prescriptions.

Veteran's health care information in the Federal government's possession is protected by the following statutes: 38 U.S.C. § 5701; 38 U.S.C. § 7332; 5 U.S.C. § 552a (Privacy Act); and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as codified at 42 U.S.C. § 1320d-6. Generally, disclosure to non-Federal entities without patient consent is prohibited by those statutes, but exceptions within the statutes and/or their respective implementing regulations provide authority for VA providers to participate in state-administered PDMPs. Specifically, § 1.515 to Title 38 of the Code of Federal Regulations (C.F.R.), which (along with 38 C.F.R. § 1.483) implements the state-PDMP exemption found at 38 U.S.C. § 5701(l), permits VA to disclose to State PDMPs certain information concerning the prescription of controlled substances, including patient demographics and prescriber information. Similarly, 38 U.S.C. § 7332(b)(2)(G) contains an exception for state PDMPs. Furthermore, because VA promulgated Routine Use Disclosure Statement #59 in the system of records, "Patient Medical Records-VA" (24VA10P2), the exception for routine uses in subsection (b)(3) of the Privacy Act also permits VA to disclose relevant information to state PDMPs. Moreover, the HIPAA Privacy Rule, at 45 C.F.R. § 164.512 (b)(1)(i), permits the disclosure of information to State PDMPs for the purpose of preventing or controlling disease, injury, or disability and the conduct of public health surveillance, investigations, or interventions. Though VHA has not published a national policy on querying and reporting to State PDMPs, VHA has legal authority to perform both actions, as described above. This report considers only VA provider PDMP querying.

Requirements for provider participation in PDMPs vary from state to state, as outlined in VHA Fact Sheet, *Prescription Drug Monitoring Program (PDMP) Participation*, February 12, 2013. VHA is developing national provider guidance on the use of PDMPs, but presently does not require VA providers to consult PDMPs prior to making clinical decisions.

⁴ The MEDD is the dose of morphine that produces an equal therapeutic effect when compared to other opioids. The MEDD is a convenient, standard measure to compare doses of different opioid compounds.

A particular challenge for VHA is that state programs differ in their terms, such that, in addition to the national guidance, local facilities would likely need to identify the specific requirements of the PDMPs for the states in which such facilities are located. For instance, the online Texas PDMP is used by medical practitioners and pharmacists to assist them in the prevention of patient diversion of controlled substances.⁵ Created in 1982, it monitors Schedule II controlled substance prescriptions written for all Texas patients. In 2008, it was expanded to include Schedule III through Schedule V controlled substance prescriptions. Although VHA providers and pharmacists are able to provide care within their defined scope of practice as long as they hold a license to practice from any state or United States territory, access to the Texas PDMP is limited to providers and pharmacists who are licensed in the State of Texas. According to Texas Department of Public Safety, Regulatory Services Division Information Sheet, *Texas Prescription Program: Information Sheet*, this restricted access is available to Texas-licensed practitioners and pharmacists to search their own prescribing or dispensing history and the prescription history of their patients.⁶ Also, according to the *Information Sheet*, a person who knowingly gives, permits, or obtains unauthorized access to this information is subject to criminal penalty. In short, VA has not, and does not, require its providers to access PDMPs, specifically here the Texas Department of Public Safety online prescription monitoring program, before prescribing long-term opioid therapy to patients receiving pain management care within the VA health care system.

Findings

Medical Center Opioid Prescribing Practice

To evaluate the opioid prescribing practices at the Bonham Center and of the four providers specifically identified in the OSC referral letter, we compared OSI Dashboard data for seven groups of opioid prescribing providers: national (all VA providers at all medical centers combined), providers at the Medical Center, providers at the Bonham Center, and Providers 1 through 4 (Provider 1 [REDACTED], Provider 2 [REDACTED], Provider 3 [REDACTED], and Provider 4 [REDACTED], respectively). We evaluated four opioid prescribing practice metrics for each group.

1. long-term, opioid-treated pharmacy users who had a UDT within 1 year of the most recent opioid prescription fill date in the quarter,
2. opioid-treated pharmacy users who had a benzodiazepine dispensed in the quarter,
3. opioid-treated pharmacy users who were dispensed MEDD of 100 mg or more in the quarter, and
4. long-term, opioid-treated pharmacy users who had a follow-up encounter within 6 months of the most recent opioid prescription fill date in the quarter.

⁵ See <http://dps.texas.gov/RSD/PrescriptionProgram/index.htm>. Accessed on July 27, 2015.

⁶ See <https://www.txdps.state.tx.us/RSD/PrescriptionProgram/documents/infoSheet.pdf>. Accessed August 11, 2015.

Data for the first three metrics are from tables of the OSI dashboard, and the fourth metric combines OSI Dashboard data with data from the VA Corporate Data Warehouse (CDW: see *Attachment D*). A detailed explanation of how we collected and analyzed the data used in this report is outlined in *Attachment B*. The opioid prescribing data for Providers 3 and 4 do not span the entire time period under consideration because Provider 3 retired and Provider 4 accepted an assignment that did not require her to prescribe enough opioids to allow comparison. See *Attachment B* for a detailed explanation. *Attachment C* lists the providers whose data were combined to determine the Bonham Center results.

The VA/DoD Guideline recommends that all long-term opioid patients undergo routine and random UDTs. The OIG study found that the percentage of such patients who received a UDT fell short of this recommendation. The OSI Dashboard shows that the Medical Center, the Bonham Center, Provider 2, Provider 3, and Provider 4 had UDT percentages greater than or equal to the national percentage in every quarter (*Figures 1b, 1c, and 1d of Attachment D*). Although the percentages for four fiscal quarters for Provider 1 were less than the national percentages, the confidence intervals for all quarters for this provider included the national percentage, indicating that the provider may have equaled the national performance in every quarter (*Figure 1a of Attachment D*). In addition, these data show the performance nationally, at the Medical Center, at the Bonham Center, and by the four providers continued to improve over the period reviewed.

The VA/DoD Guideline recommends that providers carefully monitor patients who are co-administered opioids and drugs such as benzodiazepines that increase the incidence of side effects, including profound sedation and death. This heightened risk notwithstanding, the prescription of opioid and benzodiazepines concomitantly may be appropriate and necessary for individual patients, as discussed above. The OSI Dashboard; however, allows providers and medical managers to monitor the percentage of Veterans with active outpatient prescriptions for opioids and benzodiazepines in the same fiscal quarter. Specifically, the Dashboard tracks the percentage of the patients dispensed at least one opioid prescription in a quarter that were also dispensed at least one benzodiazepine prescription in the same quarter. If the patient is prescribed an opioid and benzodiazepine by different providers, the patient is assigned to the provider who prescribed the opioid in the Dashboard report. The percentages of such patients at the Medical Center are similar to the national percentages for all quarters, while the percentages at the Bonham Center are greater. The percentages for Providers 1 and 4 are greater than the national and Medical Center percentages, but similar to the Bonham Center percentages (*Figure 2a and 2d of Attachment B*). The percentages for Providers 2 and 3 were less than or similar to the Bonham Center percentages and similar to the national and the Medical Center percentages for each quarter (*Figure 2b and 2c of Attachment D*). These data show that the performance nationally, at the Medical Center, at Bonham, and by Providers 1 through 4 are either improving slightly or unchanged over the period reviewed. Although Providers 1 and 4 did not equal the national performance, our assessment did

not consider the variability in individual provider patient population and provider position responsibilities.

When an opioid provides less than satisfactory pain reduction despite an increase in dosage, the VA/DoD Guideline recommends trying to maintain a “reasonable” opioid dose. However, what is an appropriate opioid dose varies from patient to patient with there being no standard, reasonable dose. The OSI Dashboard shows that the percentages of patients dispensed an MEDD of 100 mg or more was less than 11 percent for all quarters nationally, at the Medical Center, at the Bonham Center, and by Providers 1 through 4 (*Figure 3a, 3b, 3c, and 3d of Attachment D*). The Medical Center, Provider 2, and Provider 3 had percentages less than or equivalent to the national percentages for all quarters, as were those of the Bonham Center. The percentages for Provider 1 were variable and generally greater than the national percentages; however, since all confidence intervals contained the national percentages, this provider may have equaled the national performance for every quarter.

The VA/DoD Guideline recommends that providers schedule follow-up appointments with long-term opioid-treated patients “at least once every 1 to 6 months for the duration of therapy.” VA found that the percentages of long-term, opioid-treated patients who were dispensed at least one opioid prescription in a selected quarter, and had follow-up contact with a provider within 6 months after the last opioid prescription was dispensed, were similar to or greater than 96 percent for all quarters nationally, at the Medical Center, at the Bonham Center, and by Providers 1 through 3 (*Figures 4a, 4b, and 4c of Attachment D*). This finding is consistent with those presented in the OIG study. Although variable, the performances for all three providers were generally better or equal to the national performance. The performance of Provider 4 was not evaluated for this metric, because the provider did not prescribe opioids for a sufficient amount of time to enable performance estimates to be calculated. See *Attachment B* for details. Details of the identification of the patient cohorts and the determination of the follow-up encounters are described in *Attachment E*.⁷

During VA interviews with the Bonham Center providers, we found that all were acquainted with the OSI Dashboard and at least some of the data contained there. We found; however, that a regular report of each provider’s performance based on OSI Dashboard metrics was not being communicated to them by senior medical managers in a way that they could easily and quickly understand, although there is no express requirement for the Medical Center to do so.

The Bonham Center VANTHCS Opioid Agreement Documentation Practice

To document that the Veteran has executed a VANTHCS Opioid Agreement in accordance with VANTHSC MEMORANDUM 112A-06, providers are required to obtain a signed VANTHCS Opioid Agreement between the provider and patient.

⁷ We extracted the data in the first three graphs directly from the OSI Dashboard. Because the OSI Dashboard does not track the percentages of patients with an encounter within the last 6 months of the last opioid prescription, we combined data from the OSI Dashboard with encounter data from the VHA CDW according to the details of Attachment E.

At the Bonham Center, the VANTHCS Opioid Agreement is completed on a paper form and scanned into the patient's EHR. The note in the EHR containing the link to the scanned appropriate documentation may be identified by at least four unique note titles. We searched EHR for notes written from October 1, 2009 through May 1, 2015, to identify the long-term, opioid-treated patients who had been dispensed opioids in Quarter 2 of FY 2015 by Provider 1 and Provider 2. Providers 3 and 4 did not dispense opioids in 2015, and, consequently, were not included in this analysis.

Provider 1 dispensed opioids to 48 long-term, opioid pharmacy users in Quarter 2 of FY 2015, and 85 percent of these patients had appropriate documentation in their EHRs. Provider 2 dispensed opioids to 158 long-term opioid pharmacy users in the same quarter, and 62 percent had appropriate documentation. Although Providers 1 and 2 did not appear to achieve the local policy goal, we caution that it is possible the necessary documentation was present but beyond the parameters of our review, because the agreements were executed and entered into the record prior to October 1, 2009 (the starting date of our data review) or else was scanned in using nonstandard note titles that would have not have been captured in the data we accessed.

Medical Record Reviews

VA also reviewed five cases in which the whistleblower alleges that opioid management was inadequate.

Veteran 1

Allegation: No opioid-treatment agreement was documented in the EHR.

More specifically, the whistleblower who was serving as the MOD at the Bonham Center alleged that on May 23, 2014, this Veteran requested him to renew his prescription for Lortab®, 120 tablets per month.^{8,9} The whistleblower, who has a Texas license, reviewed the Texas PDMP Web site and found that the Veteran was also receiving a monthly prescription for 180 Lortab tablets from a private physician. The whistleblower declined to fill the prescription because of his determination that the Veteran may have been multi-sourcing.¹⁰ In addition, the whistleblower told the VA team at the interview they had with him on May 19, 2015, that while he was reviewing the Veteran's EHR, he found that the appropriate documentation of a VANTHCS Opioid Agreement had not been completed by the Veteran's PCP.

⁸ Lortab is a proprietary combination of acetaminophen and hydrocodone.

⁹ At the Bonham Center, the MOD is a rotating additional duty for ambulatory care physicians. One of the MOD's responsibilities is to rewrite prescriptions including ones for opioids for patients whose PCP is away. If asked to rewrite an opioid prescription, the MOD should review the patient's EHR to ensure the medication is indicated and, if it is, to ensure the prescription is appropriately written.

¹⁰ "Multi-sourcing" refers to the patient's obtaining opioids or other controlled substances from more than one provider. Usually, this refers to a VA provider and a private physician.

Findings:

We reviewed the Veteran's medical record and found the locally required VANTHCS Opioid Agreement signed by the Veteran and his PCP on March 28, 2014. We found no evidence in the EHR that the PCP had accessed the Texas PDMP while prescribing or considering to prescribe opioids to this Veteran.

Conclusion:

The allegation that there was no VANTHCS Opioid Agreement in the Veteran's EHR is **not confirmed**.

Veteran 2

Allegation: No opioid-treatment agreement or recent UDT was documented in the EHR.

More specifically, the whistleblower alleged that on May 23, 2014, while he was serving as MOD, this Veteran requested him to renew his Lortab medication. On review of the Texas PDMP Web site, the whistleblower found that the Veteran was also receiving Lortab medication from a private physician and noticed that the Veteran's EHR did not have appropriate documentation of a VANTHCS Opioid Agreement or documentation of a UDT since August 22, 2012, despite having been repeatedly prescribed opioids. The whistleblower declined to re-prescribe the Veteran's Lortab medication; subsequently, on May 29, 2014, he noticed that another staff physician had re-prescribed the Lortab medication, without addressing the lack of appropriate documentation and a UDT.

Findings:

On review of the Veteran's EHR, we found appropriate documentation of a VANTHCS Opioid Agreement signed by the Veteran and his PCP, dated February 13, 2014. However, we also found that the last UDT documented in the EHR had been on August 22, 2012, even though the Veteran continued to receive prescriptions for the Lortab medication by different providers. We found no evidence in the EHR that the PCP had accessed the Texas PDMP while prescribing opioids to this Veteran.

Conclusion:

The allegation that there was no VANTHCS Opioid Agreement in the Veteran's EHR is **not confirmed**. However, the allegation that there was no UDT within 1 year of the re-prescribing of the Veteran's opioid medication **is confirmed** although there is no VHA or Medical Center requirement for the provider to have obtained one within that timeframe.

Veteran 3

Allegation: No opioid-treatment agreement was documented in the EHR. Also, the Veteran's PCP continued prescribing opioids despite repeat UDTs that indicated he was using cannabis and benzodiazepines, implying he was taking the benzodiazepine illicitly.

Specifically, the whistleblower alleged that while he was serving as MOD, this Veteran asked him to re-prescribe his opioid medication. The whistleblower alleged that the Veteran's EHR did not have appropriate documentation of a VANTHCS Opioid Agreement despite his PCP's repeated opioid renewals. In addition, the whistleblower alleged that the patient tested positive for both cannabis and benzodiazepines during routine UDTs on June 4, 2013, December 12, 2013, and June 9, 2014, during which period the patient's PCP continued to prescribe opioids.

Findings:

In our review of this Veteran's EHR, we did not find evidence of the then locally required VANTHCS Opioid Agreement. Further, we confirmed the patient's UDTs were positive for benzodiazepines and cannabis on those three identified occasions. However, we also found that the Veteran's PCP had prescribed benzodiazepines for anxiety and insomnia during this period.

Conclusion:

The allegation that there was no VANTHCS Opioid Agreement in the Veteran's EHR **is confirmed**. Absence of this document violated the then applicable Medical Center policy. The allegation that the Veteran's UDTs were positive for benzodiazepine is confirmed but the implication that he was taking this medication illicitly is **not confirmed** since this medication was prescribed by the patient's PCP. Although the allegation that the Veteran was consuming cannabis **is confirmed** and other providers might have discontinued opioids in such a patient who repeatedly used cannabis, the decision to discontinue opioids for this reason is properly a clinical determination left to the clinical judgment of the treating physician. In this case, the Veteran's PCP, in the exercise of clinical judgment, elected to continue prescribing his opioid medications.

Veteran 4

Allegation: This Veteran's PCP continued prescribing opioids despite repeat UDTs that indicated he was using cannabis, as well as receiving controlled substances from a private physician at the same time he was receiving them from VA providers.

More specifically, the whistleblower alleged that when the Veteran asked that the controlled substance prescriptions previously prescribed by a VA physician, Lortab and alprazolam, be rewritten, the whistleblower reviewed this Veteran's prescription history in the Texas PDMP and found that he had been simultaneously prescribed methadone,

diazepam, Lortab, and oxycodone by a private provider.¹¹ In addition, his UDTs revealed cannabis usage.

Findings:

The Veteran is deceased. His EHR reflects that his PCP initiated treatment with benzodiazepines for insomnia and anxiety in December 1998. In 2003, Lortab was added to his medications for pain. Attempts to manage his pain disorders with other non-pharmacological treatment modalities were unsuccessful; therefore, he continued to receive the combination of benzodiazepines and opioids prescribed by VA providers. All of his UDTs between 2009 and 2011 were positive for benzodiazepines and opioids. He also had three UDTs that were negative for cannabis in 2007, 2009, and 2011, and one UDT that was positive for cannabis in 2004. We found a VANTHCS Opioid Agreement signed by the Veteran and his PCP dated May 12, 2014, and saw no evidence that his PCP had accessed the Texas PDMP while prescribing opioids to this Veteran. The VA team confirmed this patient died outside of the VHA health care system; however, we are unaware of any evidence that VHA's clinical management of his opioid therapy contributed to the death.

Conclusion:

The allegation that the Veteran's UDTs were recently and repeatedly positive for cannabis is **not confirmed**. We found no evidence in the EHR to suggest that this Veteran's death outside the VA system was due to or related to his clinically indicated use of long-term use of opioids and benzodiazepines. As explained above, concomitant use of opioids and benzodiazepines is not contraindicated for all patients. Neither is it uniformly indicative of a breach of the standard of care or applicable guidelines. Nor is the continuation of opioid therapy invariably contraindicated in the face of a single UDT positive for cannabis. As previously explained, a provider must take into account the totality of clinical facts, including UDT results, and other relevant factors when determining whether to continue long-term opioid therapy for pain.

Veteran 5

Allegation: No opioid-treatment agreement was documented in the EHR, nor was there documentation of a recent UDT or special testing for fentanyl.¹² The Veteran's PCP continued to prescribe opioids despite the patient's also receiving controlled substances from a private physician, implying these alleged lapses on the part of his VA providers constituted a danger to the patient's safety.

¹¹ Alprazolam is a benzodiazepine indicated for the treatment of anxiety. Methadone is a synthetic opiate used to treat chronic pain and the detoxification of opiate addiction. Diazepam is another benzodiazepine while oxycodone is an opiate used to treat chronic pain.

¹² Fentanyl is a synthetic opioid that is nearly 100 times as potent as morphine. It is used intravenously in anesthesia and by dermal patch for chronic pain. Fentanyl monitoring is by blood sample rather than urine testing, so, if a measurement of fentanyl in a patient prescribed that medication is desired, an additional order other than the routine one for a UDT must be given.

More specifically, the whistleblower alleged that on January 23, 2015, he reviewed the Veteran's EHR because the Veteran requested renewal of his controlled medications. The whistleblower did not find that the Veteran had completed the appropriate documentation of a VANTHCS Opioid Agreement or had had routine UDTs or the special screening required for fentanyl since November 2013. On his review of the Texas PDMP, the whistleblower alleges he found the Veteran was receiving benzodiazepines and opioids that were prescribed by private providers, implying the patient was taking those additional medications illicitly.

Findings:

The VA team found the locally-required VANTHCS Opioid Agreement in the patient's record; it was signed on February 18, 2015, after the whistleblower reviewed the patient's EHR and failed to find the Agreement. His UDTs of November 2007, June 2008, February and August 2009, August 2011, May and November 2013, and February 2015, were positive for benzodiazepine and opioids that had been prescribed by his PCP. The Veteran's EHR also reflects that he had a fentanyl screening test done in 2009, and again on February 18, 2015 after the whistleblower review. On May 18, 2015, the Veteran's PCP noted in the EHR that on his review of the Texas PDMP he found that the Veteran did not have additional prescriptions for controlled substances written by private providers in 2015. We did not find evidence that the PCP had accessed the Texas PDMP prior to the May 18, 2015 note documenting that access.

Conclusion:

The allegation that there was no VANTHCS Opioid Agreement in the Veteran's EHR at the time the MOD accessed this Veteran's EHR **is confirmed**. Absence of this agreement at that time violated local Medical Center policy. However, the locally required agreement was subsequently executed on February 18, 2015. The allegation that the Veteran's UDTs were positive for benzodiazepine and opioids, indicating that he was taking these medications illicitly, is **not confirmed** because each of those medications was prescribed by the Veteran's PCP. However, the allegation that there was no appropriate testing for fentanyl within 1 year of the re-prescribing of this medication **is confirmed**, but we note there is no VHA or Medical Center requirement to test for it. Instead, testing for use of fentanyl would have been a clinical matter left to the judgment of the treating provider. Because the PCP was licensed in the State of Texas, we note that he did not violate the terms of the Texas PDMP by accessing the database. However, he was under no obligation to review that database when determining whether to continue the patient's opioid therapy within the VA health care system.

Conclusions

Opioid Management

- Although VA found some evidence of provider deviation from the recommendations in the VA/DoD Guideline, VA **does not substantiate** a violation of law, rule, regulation or a substantial and specific danger to public health and safety with regard to the clinical management of long-term opioid therapy for pain at the Bonham Center. The following paragraphs place the deviations we found at the Bonham Center in context with national VHA and Medical Center performance in the metrics we evaluated.
 - VA **confirmed** that VHA providers nationally did not fully implement the recommendation in the VA/DoD Guideline that all patients chronically medicated with opioids be offered "routine and random" UDTs. Adherence to this recommendation is not compulsory. While the recommendation may serve to help inform a provider's treatment process and clinical decision-making, whether to conduct such testing is a clinical determination left to the medical judgment of the treating provider and is dependent on the consent of the patient. Using the OSI Dashboard data, we found that nationally, less than 70 percent of such patients had a UDT at least every year. This conclusion is consistent with the findings and conclusions presented in the OIG study published in 2014. In the OSI Dashboard metrics VA reviewed, VHA has shown recent improvement in complying with this recommendation. The VA/DoD Guideline recommends all patients chronically medicated with opioids have a follow-up encounter at least every 6 months. VHA providers nearly met this goal: more than 96 percent of their patients had a documented follow-up encounter within 6 months. In addition, although there is no VA/DoD Guideline recommendation regarding the appropriate percentage of patients who are prescribed an MEDD of 100 mg or more or who are prescribed opioids and benzodiazepines concomitantly, the performance of VHA providers showed a slight reduction over the period reviewed in these opioid-patient management metrics.
 - VA **confirmed** that Medical Center providers performed as well as or better than the national VHA providers in the four opioid management metrics we reviewed. VA **confirmed** that the Bonham providers performed, as well as or better than the national VHA providers in three of the four metrics. However, the percentage of patients taking opioids and benzodiazepines concomitantly at the Bonham Center was greater than the national percentage. Although the Bonham providers showed deviation from the national VHA providers in this metric, our assessment did not include the variability in individual provider patient population and provider position responsibilities that might explain this deviation. In other words, the data do not establish or address whether the concomitant use of the medications was clinically appropriate or inappropriate in any particular case; the data establish only the number of cases where both medications were prescribed, to identify trends.

- VA **confirmed** that Provider 1 performed, as well as or better than the national provider performance in three of the four opioid management metrics we reviewed. The percentage of Provider 1's patients taking opioids and benzodiazepines concomitantly; however, was greater than the national percentage. Although this Provider showed deviation from the national VHA providers in this metric, our assessment did not include the variability in the provider's patient population and the provider's position responsibilities that might explain this deviation.
- VA **confirmed** that Provider 2 performed, as well as or better than the national provider performance in all four opioid management metrics we reviewed.
- VA **confirmed** that Provider 3 performed, as well as or better than the national provider performance in all four opioid management metrics we reviewed.
- VA **confirmed** that Provider 4 performed, as well as or better than the national provider performance in three of the four opioid management metrics we reviewed. The percentage of Provider 4's patients taking opioids and benzodiazepines concomitantly; however, was greater than the national percentage. Although this Provider showed deviation from the national VHA providers in this metric, our assessment did not include the variability in the provider's patient population and the provider's position responsibilities that might explain this deviation.
- VA **confirmed** that the percentage of long-term, opioid-treated patients having a VANTHCS Opioid Agreement did not meet the standard set by the Medical Center, which is that all patients treated long-term with opioids have such an agreement in the EHR. Provider 1 had 85 percent success at meeting this standard, and Provider 2 achieved a 62 percent success rate. Because VHA has never had a requirement for the documentation of such an agreement, we found no violation of agency policy.
- VANTHCS MEMORANDUM 112A-06, *Chronic Opioid Use*, February 26, 2014, does not conform with VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 6, 2014 in that the VANTHCS MEMORANDUM requires the placement of a locally approved OPCA. VHA Directive 1005 requires such locally developed OPCAs be supplanted by signature consents by May 6, 2015.
- The Medical Center does not communicate individual provider's performance with regard to opioid prescribing practices in an easily understandable fashion to the Bonham Center providers.

Medical Record Reviews

- Although VA found some evidence of provider deviation from the recommendations in the VA/DoD Guideline, VA **does not substantiate** a violation of law, rule, regulation or a substantial and specific danger to public health and safety with regard to VA providers' clinical management of long-term opioid therapy in the five patient cases identified by the whistleblower.
 - VA **confirmed** 5 of the 10 separate allegations arising from our review of the 5 individual Veteran EHRs.
 - For Veteran 1, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we did **not confirm** that the Veteran's EHR had no VANTHCS Opioid Agreement.
 - For Veteran 2, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we did **not confirm** that the Veteran's EHR had no VANTHCS Opioid Agreement. We **confirmed** the allegation that the Veteran had no UDT within 1 year of the re-prescribing of his opioid medication, although there is no VHA or Medical Center requirement for the provider to have obtained one within that timeframe.
 - For Veteran 3, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we **confirmed** that there was no VANTHCS Opioid Agreement in the Veteran's EHR. Absence of this document violated the Medical Center policy at that time. The allegation that the Veteran's UDTs were positive for benzodiazepine is confirmed but the implication that he was taking this medication illicitly is **not confirmed**, since this medication was prescribed by the patient's PCP. Although the allegation that the Veteran was consuming cannabis **is confirmed** and other providers might have discontinued opioids in such a patient who repeatedly used cannabis, the decision to discontinue opioids for this reason is properly a clinical determination left to the judgment of the treating physician. In this case, the Veteran's PCP, in the exercise of clinical judgment, elected to continue prescribing his opioid medications.
 - For Veteran 4, the allegation that the Veteran's UDTs were recently and repeatedly positive for cannabis is **not confirmed**.
 - For Veteran 5, in addressing the allegation that the patient may have been multi-sourcing opioid or other controlled substances, we **confirmed** that there was no VANTHCS Opioid Agreement in the Veteran's EHRs at the time the MOD accessed this Veteran's EHR. Absence of this agreement at that time violated local Medical Center policy. However, this agreement was subsequently executed on

February 18, 2015. The allegation that the Veteran's UDTs were positive for benzodiazepine and opioids, suggesting that he was taking these medications illicitly, is **not confirmed** because each of those medications was prescribed by the Veteran's PCP. However, the allegation that there was no appropriate testing for fentanyl within 1 year of the represcribing of this medication **is confirmed**, but we note there is no VHA or Medical Center requirement to test for it.

- VA found only one provider at the Bonham Center who frequently accessed the Texas PDMP website prior to prescribing opioids. However, no VHA or local Medical Center requirement existed, or exists now, that directs VA providers to access this or similar sites in their clinical decision-making process related to opioid prescribing, even though VHA recommends providers access PDMP Web sites when available.

Recommendations to the Medical Center

1. Review patients of Provider 1 and Provider 4 who were concomitantly prescribed opioids and benzodiazepines to determine if the continued opioid therapy was clinically appropriate. Depending on the results of this review, take appropriate action.
2. Continue to develop a comprehensive pain management and long-term opioid use program that includes an opioid oversight process using OSI Dashboard data.
3. Revise VANTHCS MEMORANDUM 112A-06 to conform with VHA Directive 1005.

Attachment A
Documents Reviewed by the VA team

1. 38 CFR § 1.515 and 1.483
2. VAOIG-14-00895-163, DIG-Healthcare Inspection, VA *Patterns of Dispensing Take Home Opioids and Monitoring Patients on Opioid Therapy*. May 14, 2014.
3. VHA Directive 2009-053, *Pain Management*.
4. VHA Handbook 1108.1 Controlled Substances.
5. VA/DoD Clinical Practice Guidelines, *Management of Opioid Therapy (OT) for Chronic Pain* (2010).
6. VHA Fact Sheet, *Prescription Drug Monitoring Program (PDMP) Participation*, February 12, 2013.
7. VANTHCS MEMORANDUM 112A-06, *Chronic Opioid Use*, February 26, 2014.
8. Texas Department of Public Safety, Regulatory Services Division Information Sheet, *Texas Prescription Program: Information Sheet*.
9. VHA Directive 1005, *Informed Consent for Long-Term Opioid Therapy for Pain*, May 6, 2014.
10. Department of Veterans Affairs, Veterans Health Administration, VHA Handbook 1108.01, *Controlled Substances (Pharmacy Stock)*, November 16, 2010.

Attachment B OSI Dashboard and Other Data Treatment

For four opioid prescribing metrics, we used data from 11 consecutive fiscal quarters, from the fourth quarter of FY 2012 through the second quarter of FY 2015, to evaluate the performance of providers 1 through 4, the Bonham Center, the Medical Center, and nationally. Performance on the opioid prescribing practice metrics were defined as the percentage of

1. long-term, opioid-treated pharmacy users who had a UDT within 1 year of the most recent opioid prescription fill date in the quarter,
2. opioid-treated pharmacy users who had a benzodiazepine dispensed in the quarter,
3. opioid-treated pharmacy users who were dispensed MEDD of 100 mg or more in the quarter, and
4. long-term, opioid-treated pharmacy users who had a follow-up encounter within 6 months of the most recent opioid prescription fill date in the quarter.

The data nationally, for the Medical Center, and for providers 1 through 4 were obtained directly from their respective tables on the OSI Dashboard for metrics 1 – 3 and from a combination of OSI Dashboard data and data from the CDW for metric 4 (see *Attachment D* for details). We obtained data for the Bonham Center by combining the data for 17 providers (listed in *Attachment C*) that practiced at the Bonham Center at some time during these 11 quarters. For each provider and metric, we plotted the percentage and the 95 per cent confidence interval bounds for the percentage for each fiscal quarter. The confidence intervals were adjusted using the Bonferroni multiple comparisons adjustment to allow for simultaneous review of data for 11 fiscal quarters. We used the confidence intervals to compare the provider's percentages on the metric to the corresponding national percentages. When the confidence interval for a provider's percentage for a quarter does not contain the national percentage, we conclude that the provider's percentage may be different than the national percentage, and when the confidence interval contains the national percentage, we conclude that the providers percentage may not be different than the national percentage. A profile of percentages for a metric is defined as the percentages for all quarters over the period reviewed. Providers overall performance on a metric compared to the national performance was evaluated by comparing the provider's profile of percentages to the national profile of percentages. If a provider's percentage was different than the national percentage for two consecutive quarters or for any three quarters, we conclude that the provider's performance on the metric overall may be different than the national performance. Alternatively, if a provider's percentage on a metric is different than the national percentage for two or fewer nonconsecutive quarters, then we conclude that the provider's performance on the metric overall may not be different than the national performance. This assessment does not consider variability in individual provider patient population or provider position responsibilities. Consequently, when VA determines that a provider's performance may be different than the national performance for a metric, we will recommend that the provider's practice be scrutinized

to determine possible reasons why his/her performance on the metric appeared to be different than the national performance on the metric.

Provider 3 retired on January 11, 2014. Consequently, summaries of the opioid prescribing practices for this provider are not provided for any quarters after the first quarter of FY 2014. Provider 4 worked in the Bonham Center CLC until February 10, 2014, and during this time the provider had a negligible number of opioid prescriptions. Starting on February 10, 2014 and through May 2, 2014, Provider 4 worked in the Bonham Center Ambulatory Care section. Consequently, summaries of the opioid prescribing practices for Provider 4 are provided only for the second and third quarters of FY 2014. Furthermore, since Provider 4 did not practice at the Bonham Center Ambulatory Care section for a full 6 months after the second quarter of FY 2014, VA could not evaluate that provider's encounters for opioid-treated patients prescribed opioids.

Attachment C
Providers at the Bonham Center

The 17 providers listed below were used to determine the UDT, benzodiazepine, MEDD, and encounter data summaries for the Bonham Center. Each practices primarily at the Bonham Center. For each quarter summarized, the provider data, when available, for each of these providers were combined to create a value for the Bonham Center.

1. Provider 5 [REDACTED], MD
2. Provider 4 [REDACTED], MD
3. Provider 6 [REDACTED], DO
4. Provider 7 [REDACTED], MD
5. Provider 15 [REDACTED], MD
6. Provider 3 [REDACTED], MD
7. Provider 2 [REDACTED], MD
8. Provider 8 [REDACTED], NP
9. Provider 9 [REDACTED], MD
10. Provider 10 [REDACTED], PA
11. Provider 11 [REDACTED], MD
12. Provider 12 [REDACTED], DO
13. Provider 13 [REDACTED], MD
14. Provider 14 [REDACTED], MD
15. Provider 1 [REDACTED], MD,
16. Provider 16 [REDACTED], PA,
17. Provider 17 [REDACTED], PA,

Attachment D Opioid Patient Management Plots

Figure 1a: Percentage of long-term, opioid-treated patients who had a UDT within 1 year of the most recent opioid prescription in the fiscal quarter for Provider 1

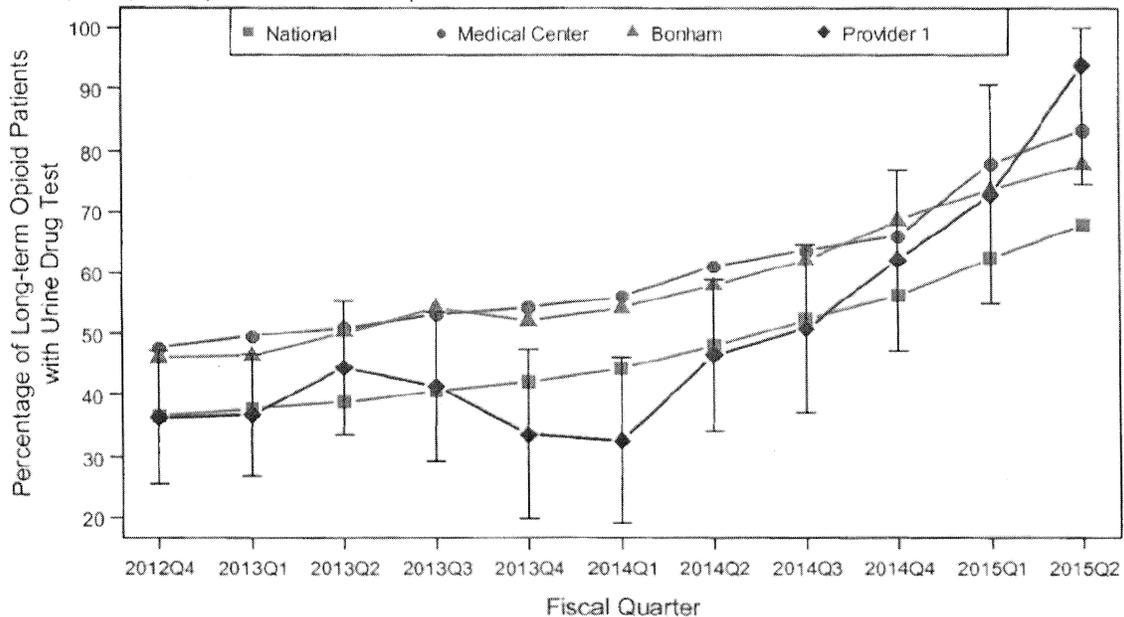


Figure 1b: Percentage of long-term, opioid-treated patients who had a UDT within 1 year of the most recent opioid prescription in the fiscal quarter for Provider 2

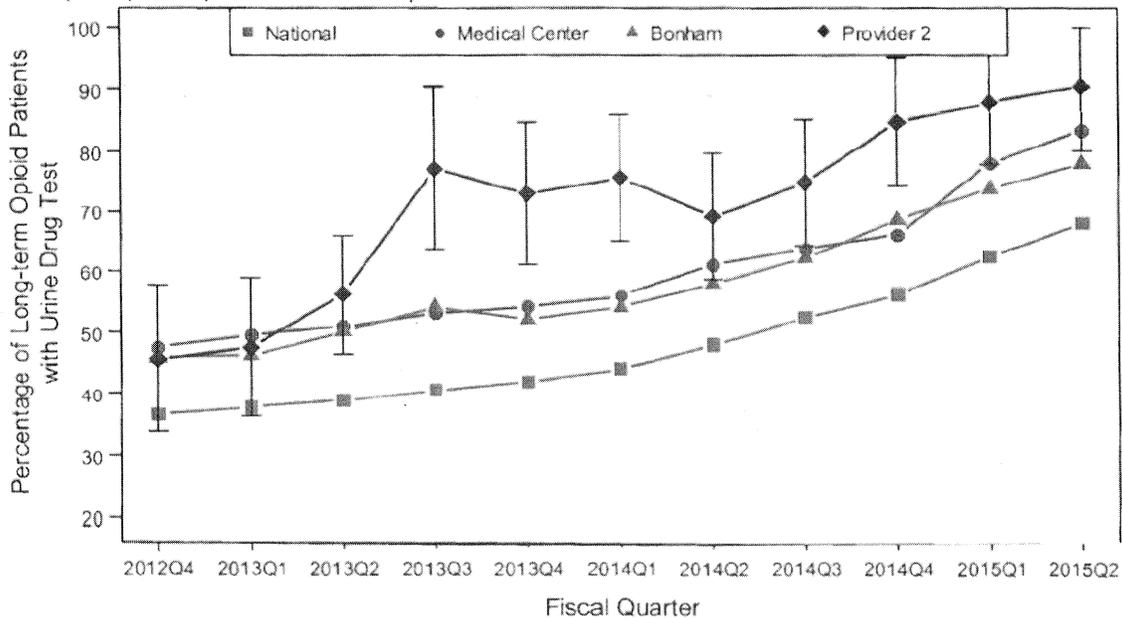


Figure 1c: Percentage of long-term, opioid-treated patients who had a UDT within 1 year of the most recent opioid prescription in the fiscal quarter for Provider 3

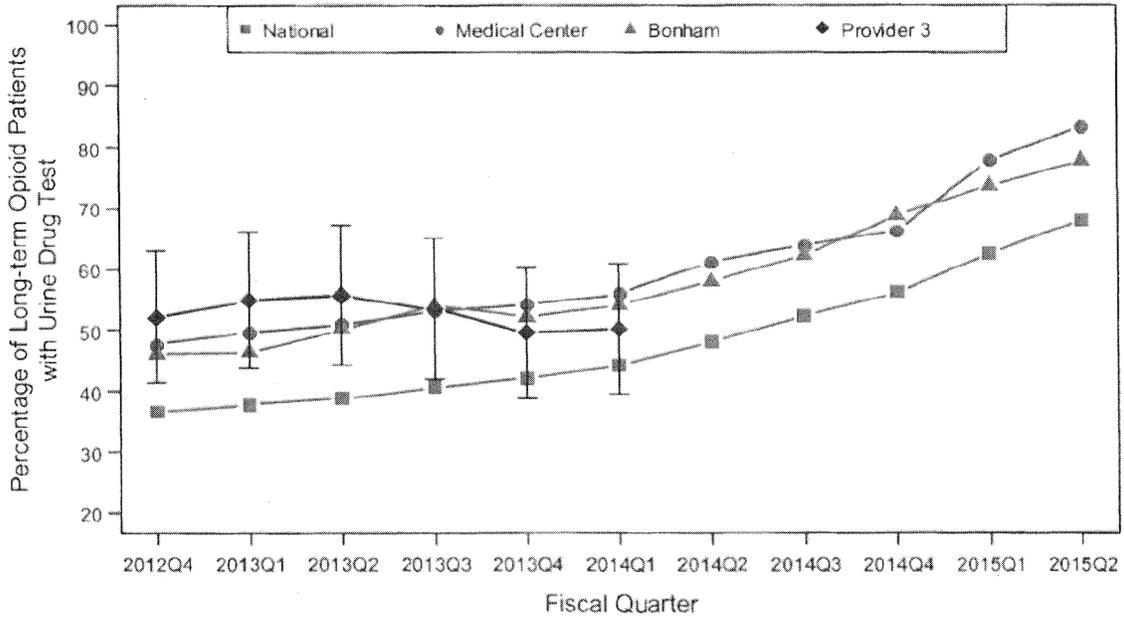


Figure 1d: Percentage of long-term, opioid-treated patients who had a UDT within 1 year of the most recent opioid prescription in the fiscal quarter for Provider 4

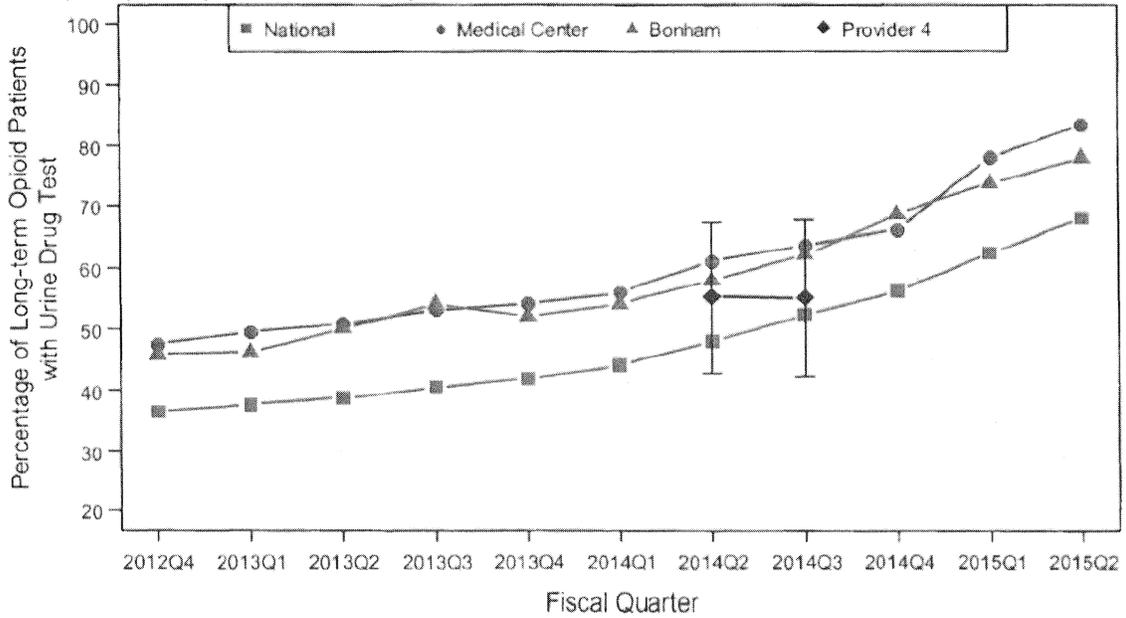


Figure 2a: Percentage of opioid-treated patients who had a benzodiazepine dispensed in the fiscal quarter for Provider 1.

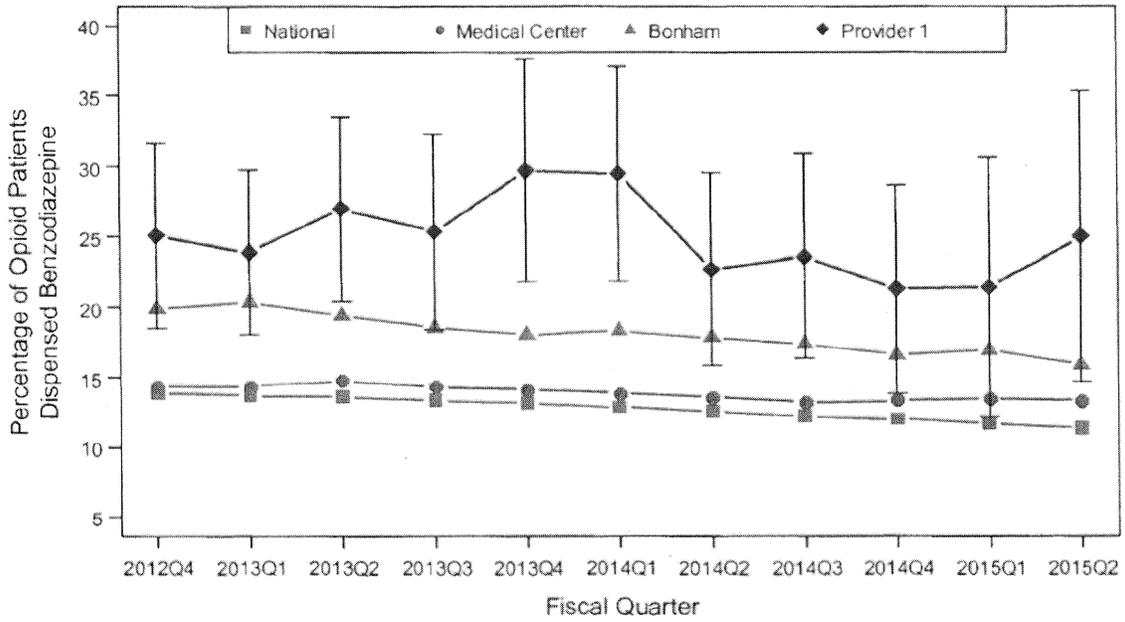


Figure 2b: Percentage of opioid-treated patients who had a benzodiazepine dispensed in the fiscal quarter for Provider 2.

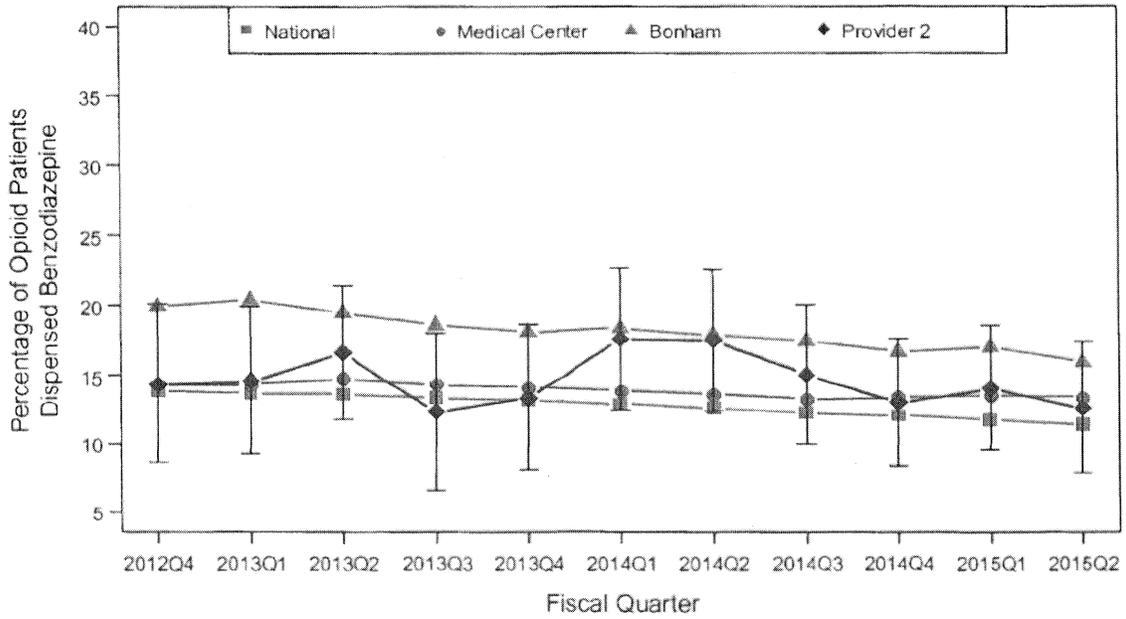


Figure 2c: Percentage of opioid treated patients who had a benzodiazepine dispensed in the fiscal quarter for Provider 3.

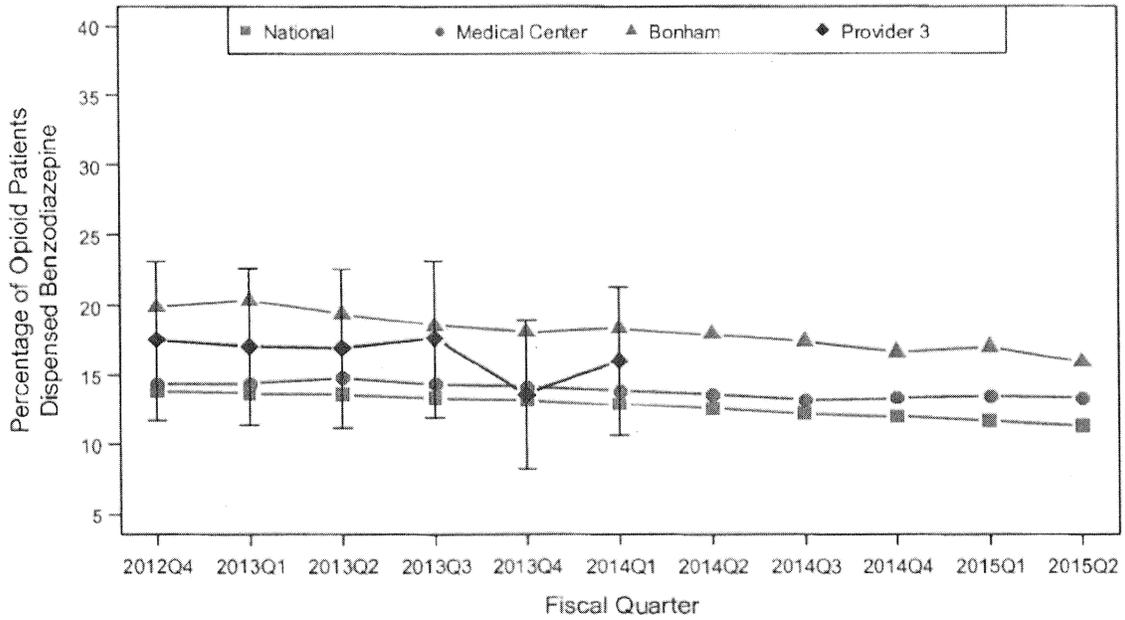


Figure 2d: Percentage of opioid treated patients who had a benzodiazepine dispensed in the fiscal quarter for Provider 4.

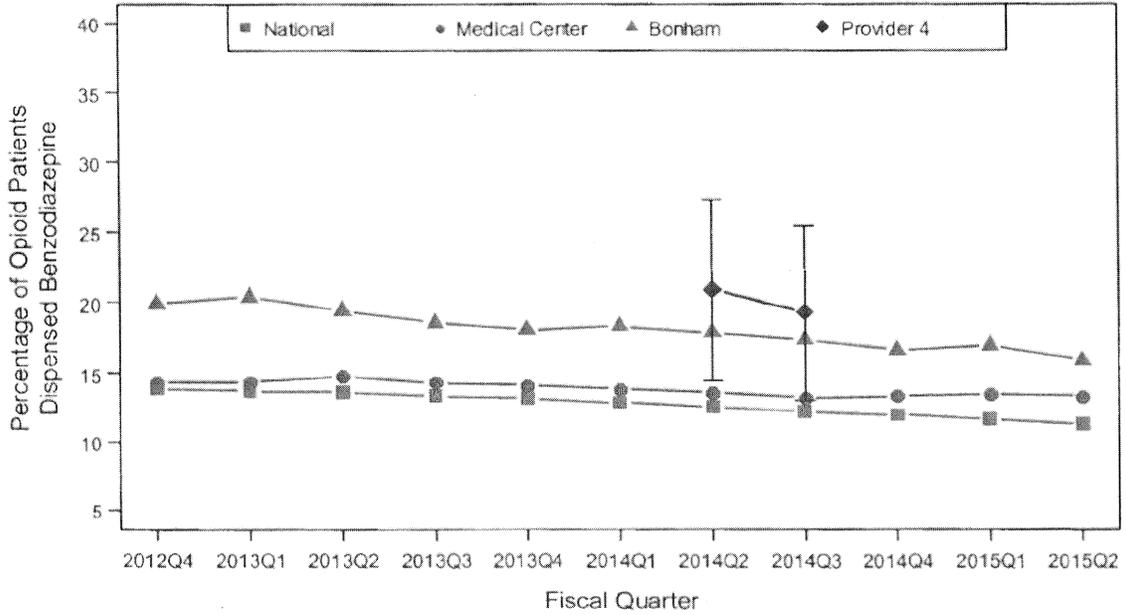


Figure 3a: Percentage of opioid treated patients dispensed a MEDD of 100 mg or more in the quarter for Provider 1.

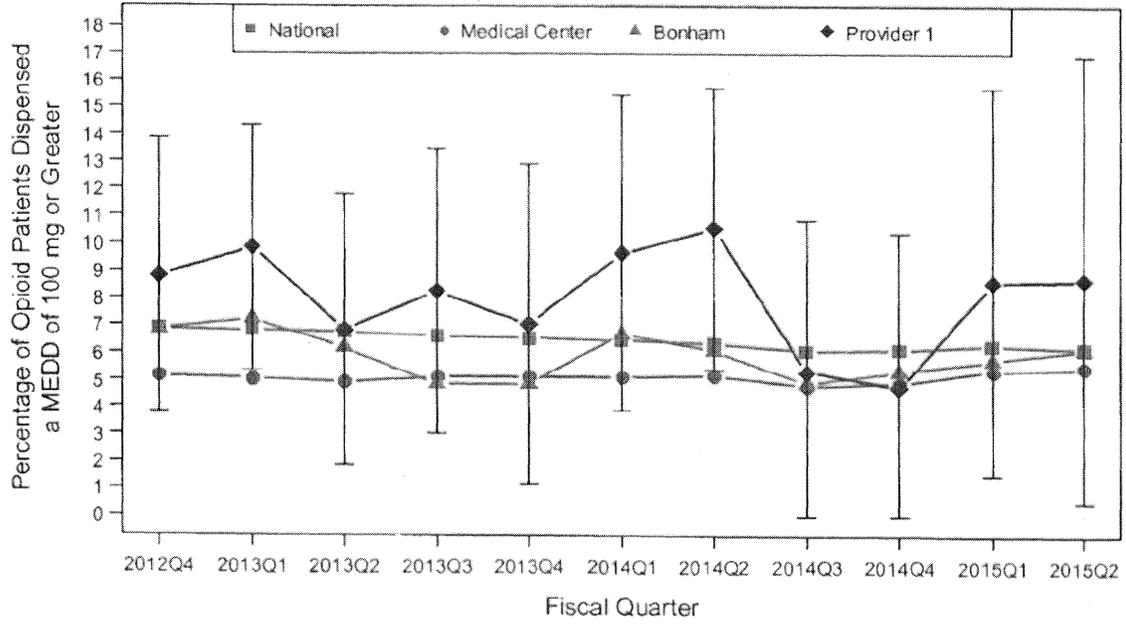


Figure 3b: Percentage of opioid treated patients dispensed a MEDD of 100 mg or more in the quarter for Provider 2.

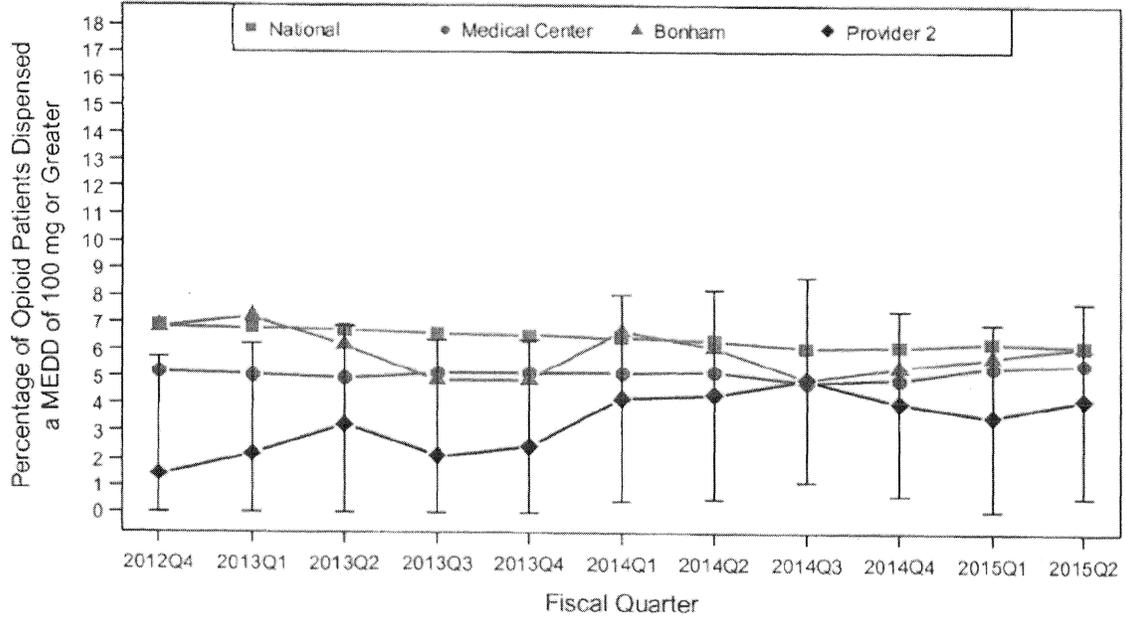


Figure 3c: Percentage of opioid treated patients dispensed a MEDD of 100 mg or more in the quarter for Provider 3.

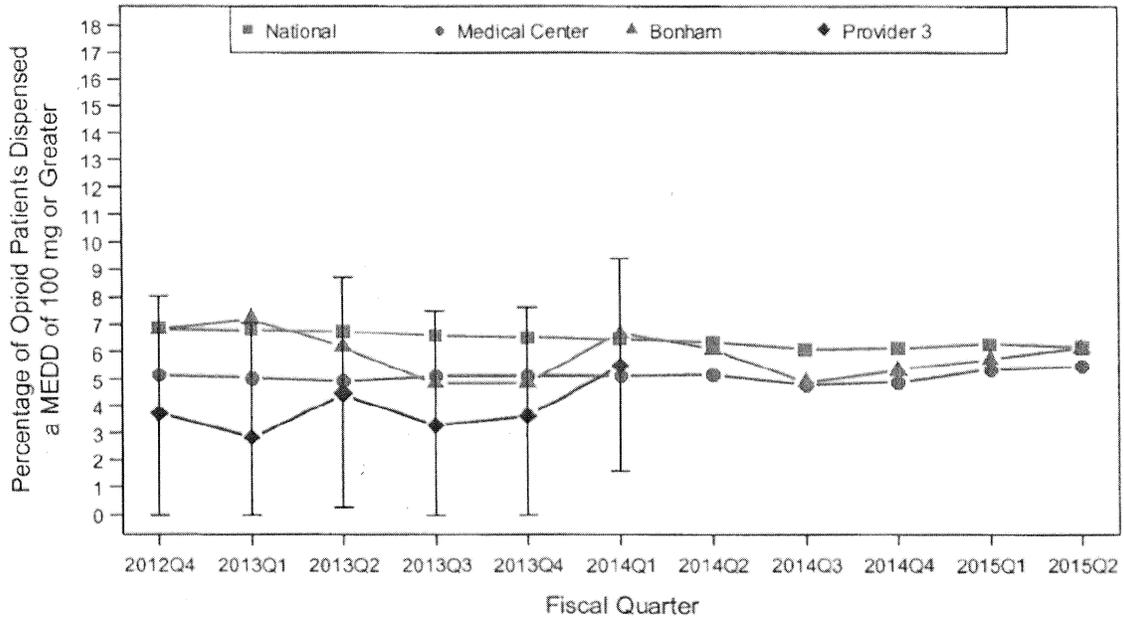


Figure 3d: Percentage of opioid treated patients dispensed a MEDD of 100 mg or more in the quarter for Provider 4.

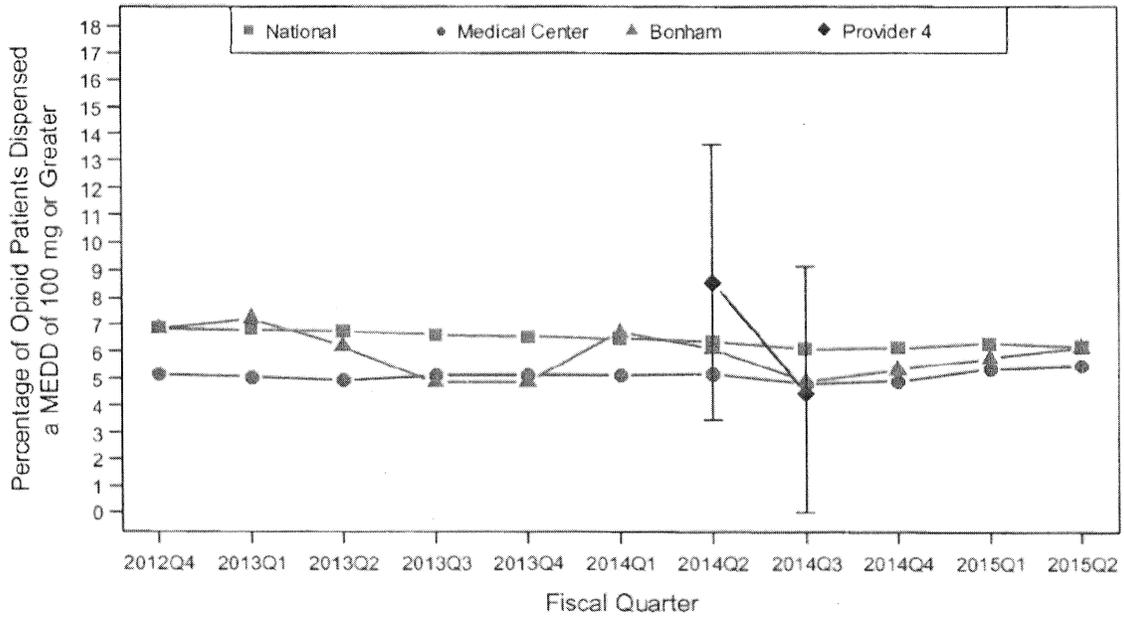


Figure 4a: Percentage of long-term, opioid-treated patients who had an encounter within 6 months of their most recent opioid prescription each quarter for Provider 1.

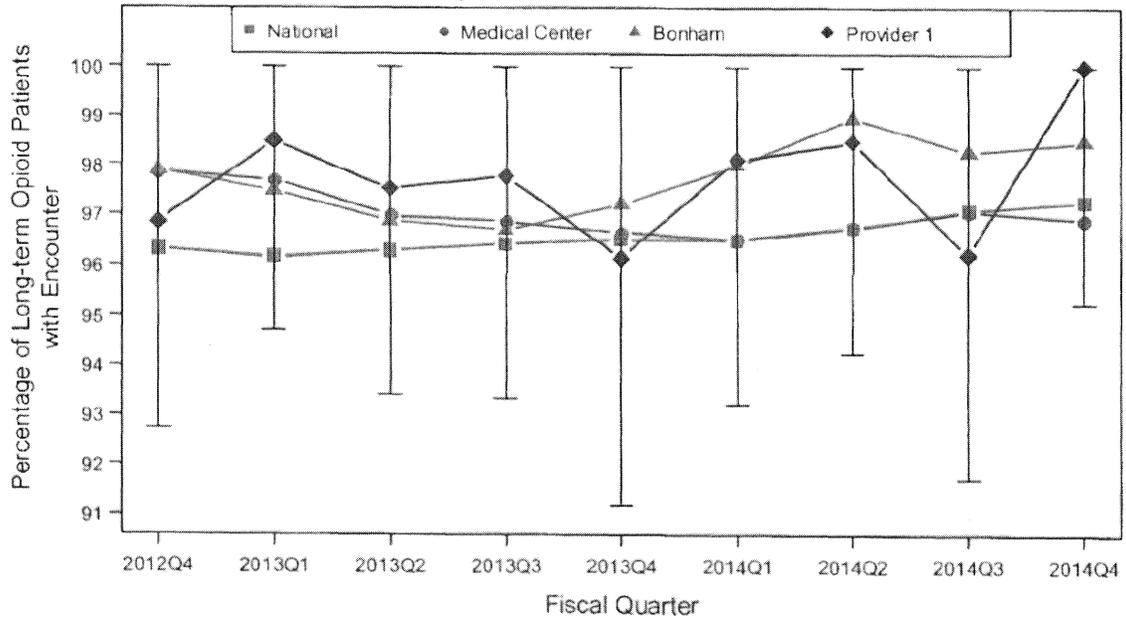


Figure 4b: Percentage of long-term, opioid-treated patients who had an encounter within 6 months of their most recent opioid prescription each quarter for Provider 2.

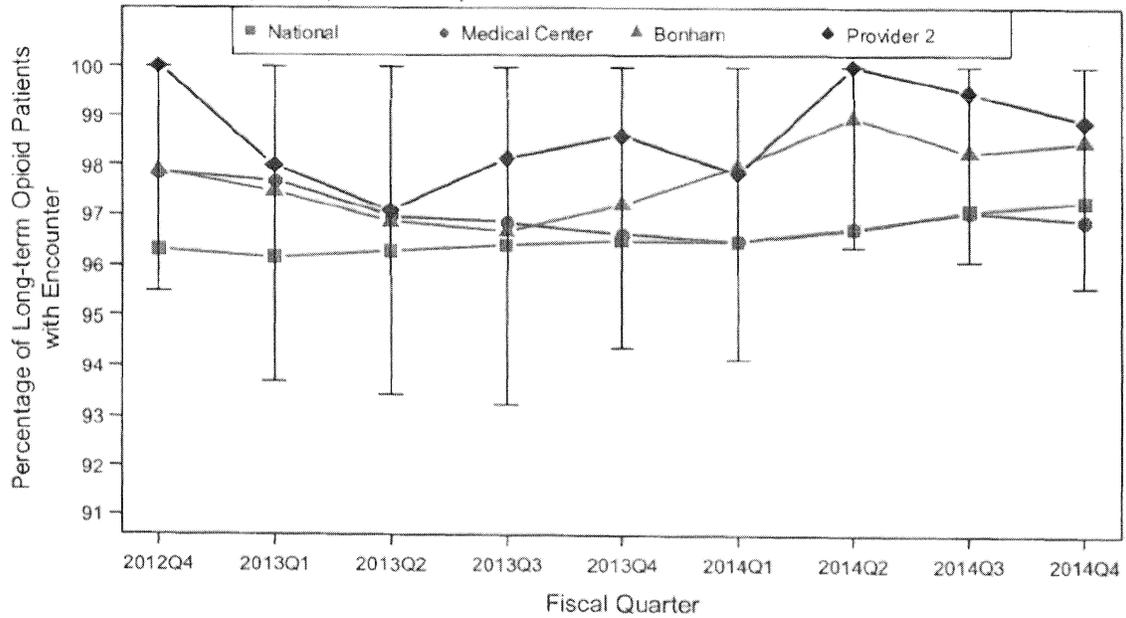
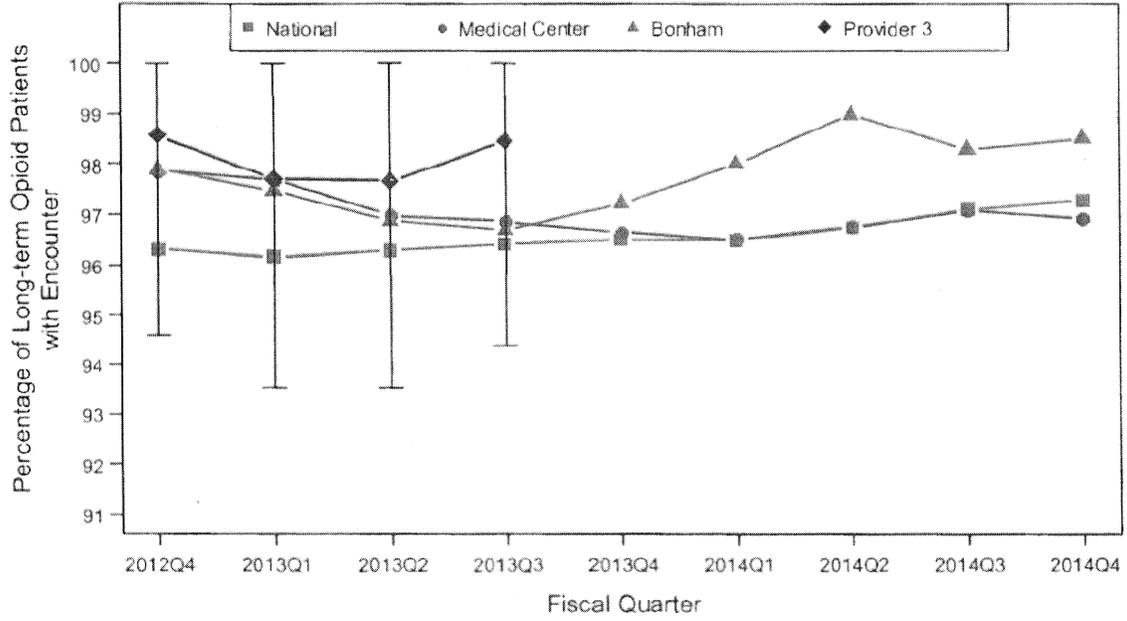


Figure 4c: Percentage of long-term, opioid-treated patients who had an encounter within 6 months of their most recent opioid prescription each quarter for Provider 3.



Attachment E

Chronic Opioid Patients and Encounters

The provider contact percentages calculated for each quarter and shown in Figures 4a – c of Appendix D are the percentages of long-term, opioid-treated pharmacy users who were dispensed at least one opioid prescription in the selected quarter and had follow-up contact with a provider within 6 months of the last opioid prescription release date for the quarter. This metric is not tracked in the OSI Dashboard tables. The cohorts of long-term, opioid-treated pharmacy users for each quarter are the same collections of pharmacy users used for the UDT tables of the OSI Dashboard. For each long-term, opioid-treated pharmacy user, the most recent prescription release date in the selected quarter was used as a marker for the prescription date. This is the date used to determine UDT compliance in the OSI Dashboard table. Follow-up contact and the corresponding dates were identified by the same algorithm the OIG used for their report "Healthcare Inspection - VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy" (Report No. 14-00895-163). Specifically, follow-up contacts were outpatient encounters and inpatient admissions obtained from the CDW. Outpatient encounters in the emergency department and nontraditional outpatient encounters were not eligible to serve as a follow-up appointment; all other outpatient encounters and all inpatient admissions were eligible. The follow-up contact date for each prescription was the closest outpatient encounter date or an inpatient admission date to the prescription date.