



U.S. OFFICE OF SPECIAL COUNSEL

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The Special Counsel

December 8, 2016

The President  
The White House  
Washington, D.C. 20500

Re: OSC File No. DI-14-3745

Dear Mr. President:

Pursuant to my duties as Special Counsel, I am forwarding to you reports provided in response to a disclosure received from an employee of the Department of Veterans Affairs, VA North Texas Health Care System (VANTHCS), Sam Rayburn Memorial Veterans Center (Bonham Center), Bonham, Texas. The whistleblower, Dr. John Bonchak, is an internist in the Ambulatory Care Department of the Bonham Center and consented to the release of his name. Dr. Bonchak alleged that Bonham Center healthcare providers routinely prescribed and refilled narcotics prescriptions without following proper procedures, including reevaluating the patient's continued need, requiring the patient to complete a Controlled Pain Medication Agreement (Opioid Agreement) and submit to urine toxicology screenings, and using the Texas Department of Public Safety online prescription monitoring program as a means of preventing multi-sourcing. I have reviewed the VA reports and, in accordance with 5 U.S.C. § 1213(e), provide the following summary of the agency investigation, Dr. Bonchak's comments, and my findings.<sup>1</sup>

OSC referred Dr. Bonchak's allegations to the Honorable Robert McDonald, VA Secretary, for investigation and a report pursuant to 5 U.S.C. § 1213(c) and (d). Secretary McDonald assigned responsibility to review the matter and prepare a report to then-Interim Under Secretary for Health Carolyn M. Clancy, who directed the Office of the

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<sup>1</sup> The Office of Special Counsel (OSC) is authorized by law to receive disclosures of information from federal employees alleging violations of law, rule, or regulation; gross mismanagement; a gross waste of funds; an abuse of authority; or a substantial and specific danger to public health and safety. 5 U.S.C. § 1213(a) and (b). OSC does not have the authority to investigate a whistleblower's disclosure; rather, if the Special Counsel determines that there is a substantial likelihood that one of the aforementioned conditions exists, she is required to advise the appropriate agency head of her determination, and the agency head is required to conduct an investigation of the allegations and submit a written report. 5 U.S.C. § 1213(c). Upon receipt, I review the agency report to determine whether it contains all of the information required by statute and that the findings of the head of the agency appear to be reasonable. 5 U.S.C. § 1213(e)(2). I will determine that the agency's investigative findings and conclusions appear reasonable if they are credible, consistent, and complete based upon the facts in the disclosure, the agency report, and the comments offered by the whistleblower under 5 U.S.C. § 1213(e)(1).

The President  
December 8, 2016  
Page 2 of 6

Medical Inspector (OMI) to conduct an investigation. Then-Chief of Staff Robert L. Nabors II submitted the report to OSC on November 18, 2015. On December 17, 2015, OSC requested supplemental information regarding actions taken to implement three recommendations set forth in the report. The Honorable David J. Shulkin, M.D., Under Secretary for Health, submitted a supplemental report to OSC on February 1, 2016. OSC received Dr. Bonchak's comments on the reports on February 29, 2016.

## **I. The Allegations and the Agency Investigation**

The OMI investigation did not substantiate Dr. Bonchak's allegations regarding improprieties in the opioid therapy program at the Bonham Center. Although the investigation found some deviations from the recommendations for long-term opioid prescription for pain management contained in VA guidelines, these deviations, according to the report, did not rise to the level of a violation of law, rule, regulation, or a substantial and specific danger to public health and safety.

In arriving at this conclusion, the investigators compared data for the following groups of opioid prescribing providers:

- 1) National (all VA providers at all medical centers combined);
- 2) VANTHCS providers;
- 3) Bonham Center providers; and
- 4) Four Bonham Center providers specifically identified by Dr. Bonchak in his disclosure as having engaged in wrongdoing.

The investigators evaluated the following four opioid prescribing practice metrics for each provider group:

- 1) Long-term, opioid-treated pharmacy users who had a urine drug test (UDT) within one 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 Morphine Equivalent Daily Dose of 100 mg or more in the quarter; and
- 4) Long-term, opioid-treated pharmacy users who had a follow-up encounter within six months of the most recent opioid prescription fill date in the quarter.

The investigation found that Bonham Center providers performed as well as or better than providers nationally in three of the four metrics. The only metric in which Bonham Center providers performed below the national provider percentage was the second metric pertaining to patients prescribed opioids concomitantly with benzodiazepines.

The President  
December 8, 2016  
Page 3 of 6

Two of the four individual Bonham Center providers identified by Dr. Bonchak performed below the national providers in this same metric. The report noted, however, that the assessment did not take into consideration patient population and provider position responsibilities that may explain the deviation. The two other Bonham Center providers identified by Dr. Bonchak performed as well as or better than the national provider population in all four metrics.

With respect to Dr. Bonchak's allegation that long-term opioid-prescribed patients were not subject to "routine and random" UDTs, the report determined that nationally, providers do not fully implement the UDT recommendation found in the VA guidelines. The report concluded, however, that the UDT recommendation is not compulsory and the decision as to "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." While the report indicated that less than 70 percent of long-term opioid-prescribed patients had a UDT at least once a year, more than 96 percent of patients had "a follow-up encounter" every six months, as recommended by the VA guidelines.

With respect to Dr. Bonchak's allegation regarding Opioid Agreements, the investigation acknowledged that a local VANTHCS standard mandating that all long-term opioid-prescribed patients have such an agreement in their electronic health record (EHR) was not met. One of the Bonham Center providers identified by Dr. Bonchak had an 85 percent compliance rate while another's compliance rate was 62 percent. However, the report noted that because VHA does not have an Opioid Agreement requirement, the absence of these agreements is not a violation of agency policy. With respect to Opioid Agreements, the report further determined that VHA Directive 1005, which requires only completion of a signature consent form by May 6, 2015, has "supplanted" a VANTHCS memorandum entitled "Chronic Opioid Use" requiring a locally approved Opioid Pain Care Agreement.

In his original disclosure to OSC, Dr. Bonchak cited irregularities with respect to five specific long-term opioid-prescribed patients. During the course of the investigation, OMI reviewed these individual patients' EHRs and confirmed five of ten separate allegations. In those instances in which the investigation confirmed Dr. Bonchak's allegation that the patient's EHR did not contain an Opioid Agreement, the report found that the absence of the agreements violated local VANTHCS standards that, as noted above, the VHA directive mandating signature consent has since supplanted. The investigation confirmed that a veteran identified by Dr. Bonchak had not had a UDT within one year of the refill of his opioid prescription, but found that no such requirement exists. Finally, the report did not confirm Dr. Bonchak's allegation that those patients who tested positively for other narcotics had taken them illicitly, because these medications were prescribed by the veterans' primary care physicians. With regard to two veterans who Dr. Bonchak alleged tested positive for cannabis, the report concluded, in one case, that the allegation was not confirmed and, in the other case, that the patient's

The President  
December 8, 2016  
Page 4 of 6

primary care physician exercised his “clinical judgment” and elected to continue prescribing the opioid despite this information. Finally, the investigation confirmed Dr. Bonchak’s allegation that a long-term opioid-prescribed veteran was not tested for fentanyl. The report found, however, that there is no VHA or VANTHCS requirement that necessitates the administration of such a test.

As a result of the investigative findings, OMI made three recommendations. First, it recommended a review of the EHRs of the patients of the two Bonham Center providers who prescribed opioids and benzodiazepines concomitantly at a higher percentage than VA providers nationally to determine whether continued opioid therapy was clinically appropriate in those cases. Second, it recommended the development of a comprehensive pain management and long-term opioid use program that includes an opioid oversight process using Opioid Safety Initiative Dashboard data. Third, it recommended the revision of the VANTHCS memorandum, which requires placement of a locally approved Opioid Pain Care Agreement in the patients’ EHR, so that it conforms to the VHA directive requiring completion of a signature consent form by May 6, 2015.

## **II. Agency Supplemental Report**

In a supplemental report dated February 1, 2016, Under Secretary for Health Shulkin indicated that, as of that date, VANTHCS has implemented two of the three recommendations. The Bonham Center’s Assistant Chief of Staff for Primary Care reviewed the EHRs of the patients concomitantly prescribed opioids and benzodiazepines by the two identified providers. This review determined that in every case, “the reviewer found that the management of opioids and benzodiazepines was clinically appropriate....” With regard to the recommendation that the VANTHCS memorandum be revised to conform to the VHA directive, the supplemental report indicated that the Bonham Center adopted a nationally standardized patient information guide and informed consent form to comply with the directive. Bonham Center leadership approved revisions to the memorandum on December 23, 2015. Finally, as of the date of the supplemental report, VANTHCS has initiated but not yet completed the recommendation regarding the development of a comprehensive pain management and long-term opioid use program that includes an opioid oversight process using Opioid Safety Initiative Dashboard data.

## **III. Dr. Bonchak’s Comments**

Dr. Bonchak asserted that the VHA should have a uniform and enforceable national policy regarding opioid prescription protocols establishing requirements rather than suggestions or recommendations. Dr. Bonchak stated, for example, that the VHA should mandate that all VA providers considering prescribing controlled medications access their state’s Prescription Drug Monitoring Program (PDMP) database to prevent multi-sourcing, potentially harmful drug interactions, and/or potential addiction. Further, Dr. Bonchak asserted that the VA should register controlled medications dispensed by the

The President  
December 8, 2016  
Page 5 of 6

VA pharmacy on its state's PDMP database to ensure that private sector physicians have access to this information. He also asserted that all physicians should have access to any state's PDMP databases to prevent patients from crossing state lines to obtain narcotics.

Dr. Bonchak contends that UDTs for long-term opioid patients should be compulsory. He objects to the report's finding that if a patient tests positive for cannabis, the decision to continue opioid therapy should be left to the treating physician. Dr. Bonchak argues that patients who use illegal drugs should not receive opioid medications and that leaving this decision to individual physicians, "can destabilize VA guidelines and policy." With respect to the investigative finding that fentanyl screening is not required for long-term opioid patients, Dr. Bonchak advocated that the VA should have a clear and definitive policy about the use of this particular drug. He notes that fentanyl is becoming the most overused and abused opioid and that it has led to "dramatic increases in overdose and deaths nationwide."

Dr. Bonchak questioned the practice of leaving the decision of chronic opioid medication usage up to medical providers who are not trained or certified as pain management specialists. He suggests that pain specialists evaluate patients requiring chronic opioid medication at least annually and manage the care of patients requiring a certain level of narcotics. Finally, Dr. Bonchak asserted that the VHA needs to ensure that the doctors working within the VA system comply with the requirements of their respective state medical licensing boards regarding the prescribing of controlled medications.

#### **IV. Agency Updates on Recommended Actions**

On October 17, 2016, the agency provided an update regarding the recommendation concerning the development of an opioid oversight process using Opioid Safety Initiative (OSI) Dashboard data. According to the update, the agency has been collecting data on a quarterly basis for the purpose of developing feedback to providers and providing monitoring reports to the service chiefs. While this data is available to providers and supervisors and can be used to identify opiate usage outliers, VANTHCS programmers are still in the process of developing software to make the data more accessible and user friendly. The new software, once available, will display data longitudinally and by specific provider. Full implementation and automation of the new software, according to the update, is expected by April 2017.

#### **V. The Special Counsel's Findings and Conclusions**

I have reviewed the original disclosure, the agency reports, and Dr. Bonchak's comments and have determined that the report contains all of the information required by statute and that the findings appear reasonable. I thank Dr. Bonchak for raising these important and timely issues. As noted by the Centers for Disease Control and Prevention,

**The Special Counsel**

The President  
December 8, 2016  
Page 6 of 6

the United States is experiencing an epidemic of drug overdose deaths, including, since 2000, a 200 percent increase in the rate of overdose deaths involving opioids. Although Dr. Bonchak's allegations were not substantiated, the investigation prompted by his disclosures resulted in significant corrective action. I commend Dr. Bonchak for providing specific suggestions for enhancing opioid prescription safety in his comments. While the policies and procedures regarding opioid prescriptions are a matter of agency discretion, I encourage the agency to consider his suggestions as they move forward in addressing the opioid abuse issue.

As required by 5 U.S.C. § 1213(e)(3), I have sent a copy of this letter, the agency reports, and Dr. Bonchak's comments to the Chairmen and Ranking Members of the Senate and House Committees on Veterans' Affairs. I have also filed a copy of this letter, the redacted agency report, the supplemental report, Dr. Bonchak's comments in OSC's public file, which is available online at [www.osc.gov](http://www.osc.gov). This matter is now closed.

Respectfully,



Carolyn N. Lerner

Enclosures