

Department of Veterans Affairs Office of Inspector General

ADMINISTRATIVE SUMMARY Opioid Purchases VA Northern Indiana Health Care System Marion, Indiana

1. Why the inspection was initiated:

The VA Office of Inspector General (OIG) conducted an inspection to evaluate the merit of a concern submitted by the Drug Enforcement Administration (DEA)¹ regarding the Marion Division of the VA Northern Indiana Health Care System (VANIHCS). The DEA reported a large opioid² purchase increase by VANIHCS Marion Division in fiscal year (FY) 2015 when compared to FY 2014 and to local Marion non-VA hospitals.

2. How the inspection was conducted:

• **Onsite Visit:** April 5–7, 2016

 Interviews Conducted: We interviewed VANIHCS's Acting Director; Acting Chief of Staff; Assistant Director; Associate Director; Associate Chief of Staff for Primary Care; Chief of Pharmacy; Chief of Quality Management; Primary Care Nurse Manager; Patient Aligned Care Team providers and registered nurses; pharmacy staff; patient advocate; Customer Service Manager; Controlled Substance Coordinator; Pain Committee Chairperson; and Interventional Pain Anesthesiologist.

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.

¹ The mission of the DEA is to enforce the controlled substance laws and regulations of the United States and bring to the criminal and civil justice system of the United States, or any other competent jurisdiction, those organizations and principal members of organizations, involved in the growing, manufacturing, or distribution of controlled substances appearing in or destined for illicit traffic in the United States; and to recommend and support non-enforcement programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets. https://www.dea.gov/about/mission.shtml. Accessed February 28, 2017.

² Opioids are medications that relieve mild to severe pain and include codeine, hydrocodone, oxycodone, and morphine.

3. Summary of our findings:

<u>Background</u>

VANIHCS consists of two campuses, one located in Fort Wayne and the other in Marion, IN. It is part of Veterans Integrated Service Network (VISN) 10. The Marion Division pharmacy purchases medications for patients in the Marion catchment area and for VANIHCS's four community based outpatient clinics. The clinics are located in Goshen, Muncie, Peru, and South Bend, IN.³

On October 6, 2014, the U.S. Drug Enforcement Administration rescheduled hydrocodone from Schedule III⁴ to Schedule III⁵ of the Controlled Substances Act. Because of the change, VA's Consolidated Mail Order Pharmacy (CMOP)⁶ no longer prepared and delivered hydrocodone prescriptions to patients' homes. Consequently, the VANIHCS pharmacies increased hydrocodone purchasing because patients were required either to pick up the medication at the local VA pharmacy or arrange for the local VA pharmacy to mail the medication.

In November 2015, after becoming aware of increased hydrocodone purchases by the Marion Division and increased purchases of other opioids such as oxycodone when compared to Marion non-VA hospitals, the DEA obtained a warrant to inspect the Marion Division. In January 2016, the DEA contacted OIG with concerns related to drug purchasing data at the Marion Division.

Results

We met with DEA investigation staff to discuss their concerns and share information on February 23, 2016.

We suspended our inspection. We based our decision to suspend the review on the following:

 Because the Marion Division pharmacy purchases medications for patients in the Marion catchment area and for VANIHCS's four community based outpatient clinics, we determined that comparing the Marion Division pharmacy purchases

³ https://www.northernindiana.va.gov/locations/SouthBend.asp Accessed March 9, 2017.

⁴ "Substances in this schedule have a potential for abuse less than substances in Schedules I and II and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples of Schedule III narcotics include: products containing not more than 90 milligrams of codeine per dosage unit...and buprenorphine..." http://www.deadiversion.usdoj.gov/schedules/ Accessed April 14, 2016.

⁵ "Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence. Examples of Schedule II narcotics include: hydromorphone... methadone... [and] oxycodone..." http://www.deadiversion.usdoj.gov/schedules/, Accessed April 14, 2016.

⁶ In 1994, the CMOP at Leavenworth, Kansas began the processing of high volume mail prescription workloads using an integrated, automated dispensing system. Since that time the VA has expanded the program to include a total of seven CMOP facilities. https://www.va.gov/cbo/wfm/cmop.asp. Accessed February 28, 2017.

to a local hospital's pharmacy purchases was not an equal comparison to the population size or type served.

- Regulatory changes that occurred in October 2014 and re-categorized hydrocodone from a Schedule III to a Schedule II drug required the Marion Division pharmacy to begin purchasing and dispensing hydrocodone, which patients had previously obtained via mail order from a Consolidated Mail Outpatient Pharmacy. Therefore, it would be expected that the Marion Division pharmacy would be purchasing and dispensing larger numbers of hydrocodone.
- The DEA did not have evidence of specific patient harm regarding opioid prescribing practices at the Marion Division.
- Our preliminary onsite interviews at the Marion Division did not reveal evidence of patient harm or drug diversion.

4. Conclusion:

We suspended our inspection after determining there was a rationale for the increase in purchases of hydrocodone in the Marion Division.

We made no recommendations.

The Veterans Integrated Service Network and VANIHCS Directors concurred with the administrative summary report. (See Appendixes A and B, pages 4–5 for the Directors' comments.) No further action is required.

JOHN D. DAIGH, JR., M.D. Assistant Inspector General for Healthcare Inspections

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Appendix A

VISN Director Comments

Department of Veterans Affairs

Memorandum

Date: July 11, 2017

From: Network Director, VISN 10 (10N10)

Administrative Summary: Opioid Purchases, VA Northern Indiana Health Care System, Marion, Indiana

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

- 1. Thank you for this comprehensive investigation. I concur with the facility's response and appreciate the thoroughness of this report.
- 2. It is crucial to note that the OIG suspended this inspection based on the following:
 - The Marion Division pharmacy purchases medications for patients in the Marion catchment area and for VANIHCS's four community based outpatient clinics, the OIG determined that comparing the Marion Division pharmacy purchases to a local hospital's pharmacy purchases was not an equal comparison to the population size or type served.
 - The re-categorization of hydrocodone from a Schedule III to a Schedule II
 drug required the Marion Division pharmacy to begin purchasing and
 dispensing hydrocodone, which patients have previously obtained via mail
 order from a Consolidated Mail.
 - No patient harm identified.
- 3. Thank you for the opportunity to respond to this report.

Robert P.

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Robert P. McDivitt, FACHE

System Director Comments

Department of Veterans Affairs

Memorandum

- Date: June 27, 2017
- From: Director, VA Northern Indiana Healthcare System (610/00)
- Administrative Summary: Opioid Purchases, VA Northern Indiana Health Care System, Marion, Indiana
 - To: Director, VA Healthcare System (10N10)
 - 1. VA Northern Indiana Health Care System leaders have reviewed the draft Administrative Summary: Opioid Purchases conducted by the VA Office of the Inspector General (OIG). We are in agreement with the findings of the OIG to recommend the suspension of their inspection of VA Northern Indiana Health Care System upon the OIG determining there was a rationale for the increase in purchases of Hydrocodone at the Marion Campus and concluding there were no recommendations as a result of the review.
 - 2. We appreciate the completeness of the Review that was conducted.

Jay H. Miller

Associate Director Acting on Behalf of:

Michael E. Hershman, MHA, FACHE

Director

Appendix C

OIG Contact and Staff Acknowledgments

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