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DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
HEARING ON
"OPIATE PRESCRIPTION POLICIES OF THE DEPARTMENT OF VETERANS
AFFAIRS AND EFFORTS IN COMBATING OVERMEDICATION"**

March 26, 2015

Mr. Chairman and Members of the Committee, thank you for the opportunity to discuss the Office of Inspector General's (OIG) work concerning VA's opioid prescription policies and practices. My statement will focus on a national review issued on May 14, 2014, *Healthcare Inspection - VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy*, as well as other reviews that we have conducted since 2011. A listing of those reports is included in Appendix A.

BACKGROUND

Adequate management of pain has become a tenant of the compassionate delivery of health care. Subjective pain levels are now considered to be the fifth vital sign in medicine in addition to body temperature, pulse rate, respiration rate, and blood pressure. It has been estimated that pain affects 100 million adults in the United States. More than 50 percent of veterans enrolled and receiving VA care are affected by chronic pain. Service members come to VA with a combination of health care conditions: pain resulting from injuries during military service, mental health disorders including post-traumatic stress disorder (PTSD), and substance use disorders that involve alcohol and/or narcotic medications.

In 1998, the Veterans Health Administration (VHA) initiated a National Pain Management Strategy to establish pain management as a national priority. In 2009, VHA issued a directive for the improvement of pain management consistent with VHA's National Pain Management Strategy.¹

In 2003, VA and the Department of Defense (DoD) published the first *Clinical Practice Guideline for Management of Opioid Therapy for Chronic Pain* (Clinical Practice Guideline) to improve management, quality of life, and quality of care for veterans and service members. It was last updated in 2010.²

¹ VHA Directive 2009-053, *Pain Management*, October 28, 2009.

² *Clinical Practice Guideline Management of Opioid Therapy for Chronic Pain*, May 2010, http://www.healthquality.va.gov/guidelines/Pain/cot/COT_312_Full-er.pdf.

Opioid therapy is intended for patients who suffer from moderate to severe chronic pain and who have been previously assessed and treated with non-opioid or non-pharmacological therapy with no response or limited success or response, and who may benefit from opioid therapy for pain control. Opioids are powerful medications that can help manage pain when prescribed for the right condition and when used properly. However, if prescribed inappropriately or if used improperly, they can cause serious harm, including overdose and death. Patient adherence with the proper use of opioids is crucial in the delivery of appropriate opioid therapy. Patient assessments, follow-up evaluations, and urine drug tests (UDTs) are recommended monitoring tools for safe and effective use of opioids.

VA PATTERNS OF DISPENSING TAKE-HOME OPIOIDS AND MONITORING PATIENTS ON OPIOID THERAPY

As requested by the United States Senate Committee on Veterans' Affairs, the OIG conducted a study to assess the provision of VA outpatient (take-home) opioids and monitoring of patients on opioid therapy (hereinafter referred to as opioid patients). The objectives of the study were to:

- Describe both the prevalence of VA patients who filled any take-home opioid prescriptions at VA in fiscal year (FY) 2012 and their baseline characteristics.
- Evaluate VA dispensing patterns of take-home opioids, including concurrent (filled) benzodiazepines, filled acetaminophen, and early refills of opioids.
- Assess the extent to which VA screens and monitors opioid patients in alignment with measures adapted from selected recommendations in the Clinical Practice Guideline.
- Define VA patterns of providing psychosocial treatment for pain, pain clinic service, and medication management/pharmacy reconciliation for take-home opioid patients.
- Determine the prevalence of six selected serious clinical adverse effects among VA take-home opioid patients that may reasonably be expected to relate to opioid therapy.

In our May 14, 2014, report, we made six recommendations, and the Under Secretary of Health agreed to the findings and recommendations and provided an improvement plan. As of March 20, 2015, four recommendations are closed:

- We recommended that the Under Secretary for Health ensure that the practice of prescribing acetaminophen is in compliance with acceptable standards.
- We recommended that the Under Secretary for Health ensure that follow-up evaluations of patients on take-home opioids are performed timely.
- We recommended that the Under Secretary for Health ensure that opioid patients with active (not in remission) substance use receive treatment for substance use concurrently with urine drug tests.
- We recommended that the Under Secretary for Health ensure that VA's practice of prescribing and dispensing benzodiazepines concurrently with opioids is in alignment with acceptable standards.

As of March 20, 2015, only two recommendations remain open:

- Recommendation 2: We recommended that the Under Secretary for Health ensure that VA's practice of routine and random urine drug tests prior to initiating and during take-home opioid therapy to confirm the appropriate use of opioids is in alignment with acceptable standards.

VA management provided an estimated implementation date of February 28, 2015. In its most recent status update dated December 30, 2014, VA indicated that actions to implement this recommendation remain in progress. VA is scheduled to provide another status update to the OIG by March 31, 2015.

- Recommendation 6: We recommended that the Under Secretary for Health ensure that medication reconciliation is performed to prevent adverse drug interactions.

VA management provided an estimated implementation date of December 31, 2014. However, VA indicated in its most recent status update dated December 30, 2014, that actions to implement the recommendation remain in progress. VA did not provide an updated implementation date estimate. VA is scheduled to provide another status update to the OIG by March 31, 2015.

Findings

We integrated and analyzed VA administrative files, as well as the Death Master Files of the Social Security Administration, for the population of nearly half a million VA patients who filled at least one oral or transdermal opioid prescription from VA for self-administration at home in FY 2012. We followed retrospectively the 442,544 patients in the population who did not receive any hospice or palliative care during the fiscal year or within 1 year prior to their first take-home opioid prescription for their experience with the provision of VA opioid therapy.

Population

We found that 7.7 percent of VA patients were on take-home opioids. A majority (92.5 percent) of the opioid patients were male, which mirrored the gender composition of VA patients. The average and the median patient age at their first opioid prescription in FY 2012 was 59.4 and 61, respectively. Approximately 1 in every 16 patients had served in Operation Enduring Freedom/Operation Iraqi Freedom. Approximately 87 percent of the opioid patients were diagnosed with a primary pain site of non-cancer origin that could result in pain serious enough to warrant an opioid medication. Six out of 10 patients had been diagnosed with mental health issues, 1 in 3 with mood disorders, 1 of 5 with PTSD, and 1 of 7 with substance use. Nearly 94 percent of the study population had been diagnosed with either pain or mental health issues and 58.4 percent with both. About one third of the opioid patients were on take-home opioids for more than 90 days (chronic users) in FY 2012. Approximately half of the study population were new patients in the sense that they were initiated on take-home opioid therapy during FY 2012 after not having been on take-home opioids for at least more than 1 year. Seven

out of 10 of the non-chronic users were new patients in contrast to 1 in 5 of the chronic users. Nearly 41 percent of the study population had been dispensed with one prescription. This 41 percent was composed entirely of the 61.4 percent of non-chronic users because none of the opioids were allowed to be prescribed for more than 90 days in one prescription. Patients with six or more prescriptions were mainly chronic users, which amounted to 69.3 percent of that group.

Dispensing Patterns and Drug Interactions

Almost all (98.4 percent) patients received their prescriptions from a single VAMC, and three quarters of the patient population had all their (filled) prescriptions issued from a single prescriber. Most (95.0 percent) of the patients were dispensed with a single type of opioid. More than 6 percent of patients received at least one long-acting opioid product, with the percentage of chronic users being four times that of non-chronic users. Opioid dosages with a morphine equivalent of at least 200 milligrams (mg)/day were dispensed to 1.2 percent of the study population. We found that refills of opioids at least 7 days early occurred in 23 percent of the population, with refills of at least 11 days early in 14 percent of the population.

The concurrent use of benzodiazepines and opioids can be dangerous because opioids and benzodiazepines can depress the central nervous system and thereby affect heart rhythm, slow respiration, and even lead to death. We found that take-home benzodiazepines were dispensed to 7.4 percent of the study population, with the percentage of chronic opioid users being 1.6 times that of non-chronic users. We determined that 71 percent of the opioid patients who also received take-home benzodiazepines were dispensed benzodiazepines concurrently with opioids. The percentage of chronic opioid users with concurrent benzodiazepines was 92.6, and the percentage of non-chronic users was 53.6.

Acetaminophen poisoning is a leading cause of liver toxicity. We determined that take-home acetaminophens were given to 92.3 percent of the study patients and that 2.0 percent of them were given an average daily dose of 4 g/day or more. The Clinical Practice Guideline calls for a urine drug test (UDT) prior to initiating opioid therapy and a follow-up contact at least every 2–4 weeks after any change in medication regimen. We determined that 6.4 percent of the new patients who were initiated take-home opioids in FY 2012 after not having been on take-home opioids for at least more than 1 year received both a UDT prior to and a follow-up UDT within 30 days.

Screening and Monitoring

The Clinical Practice Guideline requires routine and random UDTs to confirm the appropriate use of opioids by patients and a follow-up contact either in-person or a telephone encounter at least once every 1–6 months for the duration of opioid therapy. We determined that 37 percent of the existing opioid patients who were on take-home opioids at least from FY 2011 received both an annual UDT and a follow-up contact within 6 months of each filled opioid prescription. We found that VA conducted an annual UDT for 37.9 percent of the existing opioid patients which accounted for 40.9 percent of the chronic opioid users and 33.7 percent of the non-chronic users. We

observed wide variation of VA medical centers' practice on an annual UDT, ranging from 4.4 percent to 87.6 percent.

We found that 13.1 percent of the study population was diagnosed with active substance use. The Clinical Practice Guideline specifies that chronic (for more than 1 month) opioid therapy is absolutely contraindicated in patients with active (not in remission) substance use disorders (SUD) who are not in treatment. It recommends that active substance use patients receive SUD treatment concurrently with urine drug testing as an adjunctive tool at regular intervals. For the active substance use patients who had at least 90 days available for follow-up in FY 2012, we determined that 10.5 percent received both a treatment for substance use and a UDT within 90 days of each filled opioid prescription.

Pain Management Requires Multiple Specialties

Psychotherapy, including cognitive behavioral therapy, is recommended to reduce pain and improve function in chronic pain patients. We found that 45.2 percent of the opioid patients received at least one psychosocial treatment for pain and that 35.1 percent of these patients received this treatment after their first filled opioid prescription in FY 2012. We determined that 8.7 percent of the opioid patients received care from a Pain Clinic. A review of medications by a pharmacist or other health care professional can prevent harmful interactions between these medications. We found that 38.8 percent of the opioid patients received medication management or pharmacy reconciliation during the fiscal year.

Opioid Side Effects

We determined percentages of opioid patients with evidence of a serious adverse effect that may reasonably be expected to be related to opioid therapy for the following six serious adverse effects: (1) opioid overdose, (2) sedative overdose, (3) drug delirium, (4) drug detoxification, (5) acetaminophen overdose, and (6) possible and confirmed suicide attempts. We found that less than 1 percent of the population experienced any one of these adverse effects during the fiscal year, except for the adverse effect of possible and confirmed suicide attempts that was evident in 2 percent of the opioid patients.

OTHER OIG REPORTS

The OIG has published a number of reports that address aspects of the issues when patients are prescribed large doses of opioids. These reports have certain themes:

- The use of high dose opioids in patients with a substance use disorder and mental illness is a common clinical situation.
- Compliance with clinical guidelines is not routine.
- Primary care providers bear the responsibility for managing these complex patients, often with limited support from pain management experts and related specialists.
- The use of high dose opioids causes friction within provider groups, where opinions on the proper use of these medications varies.

- Non-traditional therapies that may offer the benefit of less narcotic use are not fully utilized.

I would like to discuss four reports that highlight these themes.

In our report, *Healthcare Inspection – Medication Management Issues in a High Risk Patient, Tuscaloosa VA Medical Center, Tuscaloosa, Alabama*, we substantiated that facility providers collectively prescribed oxycodone, methadone, and benzodiazepines to a high-risk patient who died of an accidental multi-drug overdose. Three factors contributed to this outcome:

- Providers did not consistently comply with VHA and local policies for the management of chronic pain in this high-risk patient. Additionally, the patient's primary care provider did not conduct key portions of the pain assessment program. These include the requirement to address previous pain treatments and their effectiveness, suicide risk status, and drug overdose history. The primary care provider did not initiate an opioid pain care agreement with the patient or ensure adequate patient monitoring and follow-up after prescribing methadone. Required patient education regarding the specific dangers of methadone was not documented.
- The facility did not ensure access to an interdisciplinary pain management team or a pain clinic to provide needed expert services to this patient.
- Providers did not ensure communication and coordination of care. The primary care provider did not read other providers' progress notes reflecting concerns about prescribing opioids and benzodiazepines, the primary care and mental health providers did not communicate directly about this high-risk patient, and the suicide prevention staff did not assist in coordinating this patient's care although the patient was on the High Risk for Suicide list.

We made seven recommendations and as of March 20, 2015, only Recommendation 7 that the Facility Director ensure access to interdisciplinary pain management care for chronic pain patients who do not respond to standard medical treatment remains open. We will continue to follow-up until VHA provides documentation that planned corrective actions have been implemented.

In our report, *Healthcare Inspection – Alleged Improper Opioid Prescription Renewal Practices, San Francisco VA Medical Center, San Francisco, California*, we addressed several issues related to the group practice of primary care, where opinions vary on the use of high dose narcotic medications. The OIG substantiated the allegation that physicians are tasked with evaluating numerous opioid renewal requests for patients with whom they are unfamiliar. VHA policy requires that certain opioid prescriptions are restricted to a 30-day supply with no refills, which means patients must obtain a new or renewal prescription every month. During the course of our inspection, we found that all clinic physicians were part-time; therefore, patients requiring opioid prescription renewals every 30 days could be subjected to extended periods without their opioid

medication, if required to see one provider. Senior leaders reported that in an effort to avoid such situations, a prescription renewal process was implemented for those instances when a patient requires a medication renewal but is unable to schedule a timely encounter with his or her primary care provider. The renewal process, established in 2006, assigned the attending on duty the responsibility for evaluating all medication renewal requests, including opioids for a period of time. The facility also hired clinical pharmacists who were designated to screen all renewal requests prior to provider evaluation for refills. The physicians we interviewed validated the complainant's allegation that within their on-duty half-day clinics they evaluated multiple opioid renewal requests for patients unknown to them. VHA policy, however, does not prohibit a provider from renewing an opioid prescription for a patient he or she has not evaluated in person.

We partially substantiated that providers do not routinely document patients' opioid prescription renewal problems in the electronic health record. The providers did not consistently document an assessment for adherence with appropriate use of opioids and monitor patients for misuse. The primary care providers did not consistently complete the "narcotic instructions note" in the health record template

We substantiated that there have been patient hospitalizations related to opioid misuse. Seven clinic patients were hospitalized for opioid overdose; however, the primary care provider, Psychiatry Service, and/or the facility's Substance Abuse Program appropriately assessed and monitored the patients. There were no deaths related to opioid overdose.

The report made two recommendations with which the Veteran Integrated Service Network (VISN) and facility directors concurred. We closed our report on April 17, 2014, after receiving documentation from VA that corrective actions were sufficiently implemented.

In an August 21, 2012, report, *Healthcare Inspection – Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic*, we substantiated the allegation that providers did not adequately assess patients who were prescribed opioids for chronic pain. Although providers performed initial pain assessments of patients, reassessments were not consistently documented at the minimum required frequency.

We also substantiated the allegation that providers did not adequately monitor patients who were prescribed opioids for misuse or diversion of the medications. One provider did not properly follow-up on a patient's positive urine drug test, and due to staffing constraints at the clinic, patients often obtained prescriptions from multiple providers.

We substantiated the allegation that facility managers asked providers to write opioid prescriptions for patients whom the providers had not assessed.

We made one recommendation with which the VISN and facility directors concurred. Based on documentation from VA that corrective actions were sufficiently implemented, we closed our report on February 22, 2013.

In a June 15, 2011, report, *Healthcare Inspection – Prescribing Practices in the Pain Management Clinic at John D. Dingell VA Medical Center, Detroit, Michigan*, we substantiated that providers prescribed controlled substances without adequate evaluation of patients and the facility did not have a policy outlining requirements for the ongoing assessment of patients treated with opioid medications. The Clinical Practice Guideline recommends that patients be evaluated every 1–6 months. We reviewed 20 patients' electronic medical records, including those named by the complainant and those with the largest aggregate opioid doses identified from among the 4,445 patients who received these medications during December 2010. We found that during 2010, five patients on chronic opioid therapy had no evaluation and six patients had evaluations more than 7 months apart. For 10 of these patients, prescriptions were written by 1 physician.

We did not substantiate the allegation that clinic supervisors coerced providers to prescribe controlled substances to patients not under their care. A provider had numerous patients who would require medication renewals. Physician coverage for these patients was arranged, after some discussion regarding the proper provision of care, to this population of controlled substance users.

We made two recommendations with which the VISN and facility directors concurred. Based on documentation from VA that corrective actions were sufficiently implemented, we closed our report on November 25, 2011.

CONCLUSION

The use of high dose opioids for the primary treatment of pain conditions is all too common within the veteran population. Patients with mental health or substance use disorders comprise a particularly complex subgroup of patients whose chronic mental health disorders may exceed the competence expected of primary care providers. As the findings in our national report demonstrate, VA was not following its own policies and procedures in six key areas: acetaminophen prescription practices; follow-up evaluations of patients on take-home opioids; concurrent substance use treatment with urine drug tests; prescribing and dispensing of benzodiazepines concurrently with opioids; routine and random urine drug tests prior to and during take-home opioid therapy; and medication reconciliation. We note that VA has taken actions to implement a number of the recommendations in this report, but VA must be vigilant in monitoring facility compliance with opioid prescription policies and in completing outstanding recommendations.

Mr. Chairman, this concludes my statement. I would be pleased to answer any questions you or other Members of the Committee may have.

APPENDIX A

VA Office of Inspector General Reporting on Opioid Prescription Practices

- December 9, 2014 Alleged Inappropriate Opioid Prescribing Practices, Chillicothe VA Medical Center, Chillicothe, Ohio
<http://www.va.gov/oig/pubs/VAOIG-14-00351-53.pdf>
- July 17, 2014 Quality of Care and Staff Safety Concerns at the Huntsville Community Based Outpatient Clinic, Huntsville, Alabama
<http://www.va.gov/oig/pubs/VAOIG-14-01322-215.pdf>
- June 25, 2014 Medication Management Issues in a High Risk Patient, Tuscaloosa VA Medical Center, Tuscaloosa, Alabama
<http://www.va.gov/oig/pubs/VAOIG-13-02665-197.pdf>
- June 9, 2014 Quality of Care Concerns Hospice/Palliative Care Program, Western New York Healthcare System, Buffalo, New York
www.va.gov/oig/pubs/VAOIG-13-04195-180.pdf
- May 14, 2014 VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy
<http://www.va.gov/oig/pubs/VAOIG-14-00895-163.pdf>
- November 7, 2013 Alleged Improper Opioid Prescription Renewal Practices, San Francisco VA Medical Center, San Francisco, California
<http://www.va.gov/oig/pubs/VAOIG-13-00133-12.pdf>
- August 21, 2012 Management of Chronic Opioid Therapy at a VA Maine Healthcare System Community Based Outpatient Clinic
<http://www.va.gov/oig/pubs/VAOIG-12-01872-258.pdf>
- August 10, 2012 Patient's Medication Management, Lincoln Community Based Outpatient Clinic, Lincoln, Nebraska
<http://www.va.gov/oig/pubs/VAOIG-12-02274-244.pdf>
- August 19, 2011 Alleged Improper Care and Prescribing Practices for a Veteran, Tyler VA Primary Care Clinic Tyler, Texas
<http://www.va.gov/oig/54/reports/VAOIG-11-01996-253.pdf>
- June 15, 2011 Prescribing Practices in the Pain Management Clinic at John D. Dingell VA Medical Center, Detroit, Michigan
<http://www.va.gov/oig/54/reports/VAOIG-11-00057-195.pdf>