**STATEMENT OF**
**MICHAEL J. MISSAL**
**INSPECTOR GENERAL**
**DEPARTMENT OF VETERANS AFFAIRS**
**BEFORE THE**
**COMMITTEE ON HOMELAND SECURITY**
**AND GOVERNMENTAL AFFAIRS**
**UNITED STATES SENATE**
**FIELD HEARING ON**
**"THE QUALITY AND CULTURE OF CARE AT**
**THE DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER**
**IN TOMAH, WISCONSIN"**
**MAY 31, 2016**

Mr. Chairman and Members of the Congress, thank you for opportunity to appear today and discuss the Office of Inspector General's (OIG) past inspections at the Tomah VA Medical Center (VAMC), in Tomah, Wisconsin and the OIG's work in the area of pain management and opioid use. I am accompanied by John D. Daigh, Jr., MD, CPA, Assistant Inspector General for Healthcare Inspections.

On May 2, 2016, I was sworn in as the Inspector General. In the past four weeks, I have immersed myself in the work of the OIG to understand better the people, policies, workload, strategic goals and priorities of our office. I have been impressed with the commitment and efforts of the staff of the OIG to achieve its mission of bringing about positive change in the integrity, efficiency and effectiveness of VA operations. While my integration into the OIG has gone very well, I know there is much more to learn.

I recognize and strongly support three overriding principles for the OIG. First, we need to maintain our independence in all of our work, including avoiding even the mere appearance of any undue outside influence. Second, we need to be as transparent as possible in our work, while safeguarding the privacy of veterans, whistleblowers and others involved in our work. Third, we need to produce work of the highest quality. This includes making sure our work is accurate, timely, fair, objective and thorough.

In my first four weeks, I have also reviewed the previous work of the OIG with respect to our healthcare inspections of the Tomah VA Medical Center. Among other actions, I met with the staff of the Homeland Security and Governmental Affairs Committee to ensure they have the information about our work necessary for the issues to be covered in this hearing. My office has learned important lessons from the Tomah healthcare inspections that should help us better meet our mission going forward. The changes that we have made should increase the confidence that veterans, veterans service organizations, Congress and the American public have in the OIG.

## BACKGROUND

In March 2011, the OIG Hotline received a complaint regarding prescription practices at the Tomah VAMC. We referred the allegations to the Director, Veterans Integrated Service Network (VISN) 12, VA Great Lakes Health Care System, who has managerial oversight of the Tomah VAMC. A copy of this referral was also sent to the office of the Veterans Health Administration (VHA) Chief of Staff. The VISN 12 Director provided a detailed response to the allegations on June 22, 2011. This response stated that 16 allegations involving over 30 patients were unsubstantiated. The VISN 12 Director substantiated two allegations involving two patients. As a result of this review, the VISN Director initiated an action plan to:

- Review refill policies at Tomah VAMC.
- Review Tomah VAMC policies regarding lab testing of patients on narcotics.
- Evaluate practice trends and approaches to pain management to ensure the needed variety of pain approaches is available to Tomah VAMC patients.
- Work with the Tomah Chief of Staff to evaluate pain approaches and the effectiveness of such.

Based on the VISN 12 Director's fact-finding efforts and commitment to take corrective action, we closed the complaint.

In August 2011, the OIG Hotline received a new anonymous complaint with similar allegations. Over the course of the next approximately two and a half years, the OIG Office of Healthcare Inspections conducted an extensive inspection of the allegations. This inspection included involvement from the OIG's Office of Investigations, the U.S. Drug Enforcement Administration, and Tomah and Milwaukee municipal police to determine if there was evidence of narcotic abuse at the Tomah VAMC. We reviewed patient medical records, peer reviews of providers' practice and pharmacy records. We conducted an undercover surveillance operation and reviewed email messages and associated files originating from numerous individuals. We interviewed current and former VA employees and conducted a site visit that included touring the outpatient pharmacy to assess security.

We could not substantiate the majority of allegations that the OIG received. Although the allegations dealing with the extensive use of narcotics at the facility may have had some merit, they did not constitute proof of wrongdoing. We did not find any conclusive evidence affirming criminal activity, gross clinical incompetence or negligence, or administrative practices that were illegal or violated personnel policies. We administratively closed the inspection on March 14, 2014 because we believed at the time that given the totality of the facts—paramount of which was that the allegations were not substantiated, the impact disclosure of unfounded allegations could have on an individual's reputation and privacy, and knowing that our forthcoming 2014 national report would highlight the many deficiencies in VA provider's compliance with opioid prescribing guidelines—an administrative closure was appropriate.

We noted several issues of concern and made suggestions to address these concerns to the Tomah VAMC Director and the VISN 12 Director. We conducted a telephone briefing with the Tomah VAMC Director, the VISN 12 Quality Management Officer, and the Organizational Improvement Analyst for the Tomah VAMC on July 3, 2014; and met in person with the VISN 12 Director on July 16, 2014, to discuss the following suggestions:

- The Facility Director should implement a vehicle by which clinicians and staff can openly and constructively communicate concerns and rationale when disagreements arise concerning dispensing of opioid prescriptions.
- The Facility Director should review the reporting structure in the context of safeguarding bi-directional clinical discourse from actual or perceived administrative constraint.
- The Facility Director should ensure development of guidance, parameters, processes, or a specialty clinic-based mechanism to assist clinicians and staff with managing complex patients requesting early opioid refills.
- The Facility Director should consider some variant of the tumor board model as one potential avenue by which to foster collaborative interdisciplinary management when presented with very complex clinical pain cases.
- The VISN should conduct further evaluation and monitoring of relative and case-specific opioid prescribing at Tomah VAMC on both a facility and individual clinician level.

After publication of a news story regarding this work in January 2015, we posted the administrative closure on February 6, 2015. We testified about the 2011 inspection we performed of the Tomah VAMC at a similar field hearing on March 30, 2015. We also provided Chairman Johnson and several other Members of Congress with a "white paper" on June 4, 2015 that was intended to highlight evidence obtained and reviewed during the OIG's 2011 Tomah VAMC inspection.

I do not agree with the tone of the white paper or the gratuitous attacks on the reputation of individuals included in it. Going forward, my office and I will work hard to ensure that all work from the OIG meets the high standards expected of our office.

Since the 2011 inspection, the OIG has conducted two additional inspections regarding allegations at the Tomah VAMC. On June 18, 2015, we issued *Healthcare Inspection – Care of an Urgent Care Clinic Patient, Tomah VA Medical Center, Tomah, Wisconsin*. We made nine recommendations in this report. The recommendations included three directed at the national level to review of policies for acute stroke treatment especially in rural and/or low complexity VA facilities, to improve processes for identifying unauthorized access to VA medical records, and to evaluate rules related to reimbursement for a veteran's emergency care at non-VA facilities.

The remaining six recommendations were directed to the Facility Director. They included providing proper education to veterans and their families about the services an Urgent Care Center is able to provide, providing proper training of staff regarding

treatment of stroke patients and Emergency Department Integration Software training, ensuring routine maintenance on equipment is scheduled during low utilization periods, and ensuring UCC processes are strengthened to improve triage timeliness. As of May 19, 2016, the recommendation that the Facility Director ensure that transfer agreements are established as required remained open.

On August 6, 2015, we issued *Healthcare Inspection – Unexpected Death of a Patient During Treatment with Multiple Medications, Tomah VA Medical Center, Tomah, Wisconsin*. We made four recommendations in this report. Two recommendations are closed. One recommended a further review by VISN leadership of the care provided and a consultation with the appropriate office on any administrative action. The other recommendation for the Acting Facility Director dealt with ensuring that emergency crash carts at the facility are properly stocked with appropriate medications. As of May 9, 2016, two remain open:

- Recommendation 2: The Veterans Health Administration requires written informed consent when administering hazardous drugs including buprenorphine. However, we did not find evidence of written informed consent for buprenorphine treatment. In this case, both psychiatrists involved in the ordering of buprenorphine for the patient acknowledged they did not discuss the risks inherent in off-label use of the drug with the patient. We recommended that the Acting Facility Director ensure compliance with applicable VHA policy that requires informed consent be obtained and documented.

- Recommendation 3: We recommended that the Acting Facility Director review elements needed to respond effectively to medical emergencies including staff training, equipment, and other resources at both the unit and the facility level and take any appropriate actions.

## PAIN MANAGEMENT ISSUES

The use of opioids to treat chronic pain and other conditions continues to be a serious concern not just within VA but throughout the Nation. While opioids are considered an important part of pain management, they are also associated with serious adverse effects. Patients prescribed opioids frequently have complex comorbid conditions, making them more likely to be given multiple medications that can interact dangerously with opioid medications and potentially lead to death. Clinicians vary widely in their chronic opioid therapy prescribing practices within VA and the nation and there is little agreement regarding the appropriate use of opioids for treating pain, especially chronic non-cancer pain.

Recently, the OIG published two inspection reports addressing various aspects of VA opioid prescribing practices.[1] Our recent work on this topic identified many of the same

[1] *Healthcare Inspection—Poor Follow-Up Care and Incomplete Assessment of Disability, VA San Diego Healthcare System San Diego, California* (January 5, 2016); *Healthcare Inspection—Quality of Mental Health Care Concerns, VA Long Beach Healthcare System, Long Beach, California* (March 30, 2016).

issues we previously reported in our May 2014 national review, *Healthcare Inspection—VA Patterns of Dispensing Take-Home Opioids and Monitoring Patients on Opioid Therapy*. 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 the recommendations in this report, but VA must be vigilant in monitoring facility compliance with opioid prescription policies. We are currently working on another national review that will review:

- VA's pain management services.
- VA's substance use treatment programs.
- VA's pain management educational efforts.
- Patterns of use of non-VA treatments.
- VA's opioid prescribing practices.
- Access to state prescription drug monitoring programs.
- Oversight of pain management patients.

We expect to publish our findings by the end of the year.

## CONCLUSION

Yesterday, our nation paid tribute to the sacrifices of the women and men who gave their lives in our defense. It is a valuable reminder for all of us at the OIG to rededicate ourselves to ensuring that our work is independent, accurate, timely, fair, objective and thorough. We will publish the results of our efforts as permissible under law and will ensure that complainant names, patient records, and confidential sources are protected. We will also continue to review our practices and policies and make whatever additional enhancements are necessary to increase the confidence that veterans, veterans service organizations, Congress and the American public have in the work of the OIG. We thank the Committee for the opportunity to testify about these important issues during this most solemn time.