STATEMENT OF
CAROLYN CLANCY, M.D.
INTERIM UNDER SECRETARY FOR HEALTH
VETERANS HEALTH ADMINISTRATION (VHA)
DEPARTMENT OF VETERANS AFFAIRS (VA)
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
U.S. HOUSE OF REPRESENTATIVES

MARCH 30, 2015

Good morning, Chairman Johnson, Chairman Miller, and Members of the Committee. Thank you for the opportunity to participate in this hearing and to discuss the quality of care at the Tomah VA Medical Center. I am accompanied today by Renee Oshinski, Veterans Integrated Service Network (VISN) 12 Acting Network Director, and Mario DeSanctis, Director of the Tomah VA Medical Center.

At VA, we care deeply for every Veteran we have the privilege to serve. One of our most important priorities is to keep our patients free from harm while receiving care at our facilities. I am saddened by any adverse consequence that a Veteran might experience while in, or as a result of, our care, and I would like to express my sincere sympathy to the families of those Veterans we have lost here in Tomah.

VA is committed to providing the highest quality care, but it is not perfect and there are always areas that need improvement. We can, and we must do better. The identification, mitigation, and prevention of vulnerabilities within our health care system are ongoing processes. Where challenges occur, VA takes direct action to review each incident and puts in place processes to correct system issues and improve quality of care. We incorporate lessons learned to avoid and mitigate future incidents throughout the entire health care system. VA also takes any allegations about patient care or employee misconduct very seriously and will hold employees accountable if there is wrongdoing.

Chronic Pain across the Nation

Chronic pain affects the Veteran population, but this is not an issue limited to Veterans. Chronic pain is a national public health problem as outlined in the 2011 study by the Institute of Medicine (IOM). At least 100 million Americans suffer from some

form of chronic pain. The IOM study describes in detail many concerns of pain management, including system-wide deficits in the training of our Nation's health care professionals in pain management; the problems caused by a fragmented health care system; the general public's lack of knowledge about pain leading to inadequate self-management; and the need for care planning that is personalized for the individual patient. While about 30 percent of the Nation's adult population experiences chronic pain, the problem of chronic pain in VA is even more daunting, with almost 60 percent of returning Veterans from the Middle East and more than 50 percent of older Veterans in the VA health care system living with some form of chronic pain. The treatment of Veterans' pain is often very complex. Many of our Veterans have survived severe battlefield injuries, some repeated, resulting in life-long moderate to severe pain related to damage to their musculoskeletal system and permanent nerve damage, which cannot only impact their physical abilities but also impact their emotional health and brain structures.

VA's Progress in Pain Management

Chronic pain management is challenging for Veterans and clinicians -- VA continues to focus on identifying Veteran-centric approaches that can be tailored to individual needs that may also include physician therapy, acupuncture, chiropractic treatments, and other modalities in addition to medications. Opioids are an effective treatment, but their use requires constant vigilance to minimize risks and adverse effects. VA launched a system-wide OSI in October 2013, and has seen significant improvement in the use of opioids as discussed later in the testimony. Most recently, in March 2015, we launched the new Opioid Therapy Risk Report tool which provides detailed information on the risk status of Veterans taking opioids to assist VA primary care clinicians with pain management treatment plans. This tool is a core component of our reinvigorated focus on patient safety and effectiveness.

VA's own data, as well as the peer-reviewed medical literature, suggest that VA is making progress relative to the rest of the Nation. In December 2014, an independent study by RTI International health services researcher, Mark Edlund, MD, PhD and colleagues, supported by a grant from the National Institute of Drug Abuse,

was published in the journal *PAIN*[1] ()the premier research publication in the field of pain management. This study, using VHA pharmacy and administrative data, reviewed the duration of opioid therapy, the median daily dose of opioids, and the use of opioids in Veterans with substance use disorders and co-morbid chronic non-cancer pain. Dr. Edlund and his colleagues found that:

- First, half of all Veterans receiving opioids for chronic non-cancer pain, are receiving them short-term (i.e.: for less than 90 days per year);
- Second, the daily opioid dose in VA is generally modest, with a median of 20 Morphine Equivalent Daily Dose (MEDD), which is considered low risk; and
- Third, the use of high-volume opioids (in terms of total annual dose) is not increased in VA patients with substance use disorders as has been found to be the case in non-VA patients.

Dr. Edlund and the other authors concluded "this suggests appropriate vigilance at VA, which may be facilitated by a transparent and universal electronic medical record." Although it is good to have this information, a confirmation of our efforts for several years, starting with the "high alert" opioid initiative in 2008 and multiple educational offerings, by no means is VA's work finished. In fact, although we are well along in implementing our plan, VA is also working with other Federal agencies and VAMC experts to implement the National Institutes of Health-Department of Health and Human Services National Pain Strategy, an outgrowth of the IOM study, which recommends a transformation in the education of physicians and other health care professionals in pain management. By virtue of VA's central national role in medical student education and residency training of primary care physicians and providers, we will be playing a major role in this national effort. But we have already started with our robust education and training programs for primary care, such as SCAN-ECHO, Mini-residency, Community of Practice calls, two JIF training programs with DoD, and dissemination of the OSI Toolkit.

[1] Edlund MJ et al, Patterns of opioid use for chronic noncancer pain in the Veterans Health Administration from 2009 to 201. PAIN 155(2014) 2337-2343

The Opioid Safety Initiative

The OSI was chartered by the Under Secretary for Health in August 2012. The OSI was piloted in several VISNs. Based on those results of the pilot programs, OSI was implemented nationwide in August 2013. The OSI objective is to make the totality of opioid use visible at all levels in the organization. It includes key clinical indicators such as the number of unique pharmacy patients dispensed an opioid, unique patients on long-term opioids who receive a urine drug screen, the number of patients receiving an opioid and a benzodiazepine (which puts them at a higher risk of adverse events), and the average MEDD of opioids. Results of key clinical metrics for VHA measured by the OSI from Quarter 4, Fiscal Year 2012 (beginning in July 2012) to Quarter 1, Fiscal Year 2015 (ending in December 2014) are:

- 91,614 (13%) fewer patients receiving opioids (679,376 => 587,762);
- 29,281 (24%) fewer patients receiving opioids and benzodiazepines together (122,633 => 93,352) ;
- 71,255 more patients on opioids that have had a urine drug screen to help guide treatment decisions(160,601 => 231,856);
- 67,466 (15%) fewer patients on long-term opioid therapy (438,329 => 370,863);
- The overall dosage of opioids is decreasing in the VA system as 10,143 (17%) fewer patients are receiving greater than or equal to 100 MEDD (59,499 => 49,356); and
- The desired results of OSI have been achieved during a time that VA has seen an overall growth of 75,843 (2%) patients who have utilized VA outpatient pharmacy services (3,959,852 => 4,035,695).

The changes in prescribing and consumption are occurring at a modest pace and the OSI dashboard metrics indicate the overall trends are moving in the desired direction. OSI will be implemented in a cautious and measured way to give VA time to build the infrastructure and processes necessary to allow VA clinicians to incorporate new pain management strategies into their treatment approaches. A measured process will also give VA patients time to adjust to new treatment options and to mitigate any patient dissatisfaction that may accompany these changes.

While these changes may appear to be modest given the size of the VA patient population, they signal an important trend in VA's use of opioids. VA expects this trend to continue as it renews its efforts to promote safe and effective pharmacologic and non-pharmacologic pain management therapies. Very effective programs yielding significant results have been identified (e.g., Minneapolis, Tampa), and are being studied as strong practice leaders.

State Prescription Drug Monitoring Programs

Another risk management approach to support the Veterans' and public's safety is VHA participation in state Prescription Drug Monitoring Programs (PDMP). During this administration, VA implemented a regulatory change to enable VA prescribers to access information contained in these databases. These programs, with appropriate health privacy protections, allow for the interaction between VA and state databases, so that providers can identify potentially vulnerable at-risk individuals. VA providers who register with the State PDMP can now access the state PDMP for information on prescribing and dispensing of controlled substances to Veterans outside the VA health care system. When fully deployed, non-VA providers will also be able to identify their patients who may be receiving controlled substances from VA. VA is working on policy to require PDMP use by controlled substance prescribers in accord with the Administration's 2011 Prescription Drug Abuse Prevention Plan recommendations. Participation in PDMPs will enable providers to identify patients who have received non-VA prescriptions for controlled substances, which in turn offers greater opportunity to discuss the effectiveness of these non-VA prescriptions in treating their pain or symptoms. More importantly, information available through these programs will help both VA and non-VA providers to prevent harm to patients that could occur if the provider was unaware that a controlled substance medication had been prescribed elsewhere already.

Opioid Therapy Risk Report

In conjunction with the OSI, a population-based provider report and feedback tool has recently been developed and is now available to all primary care providers and their teams. This report, easily accessible through a direct link in the electronic health record, assists the PACTs to manage their entire panel of patients prescribed pharmacotherapy for acute or chronic pain; this tool makes it easy to ensure Veterans receiving safe, quality care. This resource provides a quick but thorough assessment of their patients' opioid risk for adverse outcomes. Included in the report is the current opioid dose, concomitant use of benzodiazepines, and presence of associated high-risk diagnoses such as substance use disorder or posttraumatic stress disorder. Urine drug screens, recent mental health and primary care visits, and the presence of a signed opioid agreement are also tracked. By clicking on the patient's name in the report, the provider can immediately pull up graphs showing the relationship between the patient's opioid dose and pain score over the past 12 months. This tabular and graphical information alerts the provider to situations where closer follow up may be needed or to settings where opioid withdrawal or dose reduction may be opportune. To better inform decision making, links to practical pain presentations and opioid clinical guidelines are also embedded.

This report was developed in late 2014 and released in early 2015. A comprehensive training program for primary care was launched in February 2015 reaching over 2,000 PACT providers and their teams. This tool will also assist in the monitoring of opioid prescribing behavior of our primary care workforce over time.

Complementary and Integrative Medicine

The number one strategic goal of VHA is "to provide Veterans personalized, proactive, patient-driven health care." Integrative Health includes Complementary and Alternative Medicine approaches, provides a framework that aligns with personalized, proactive, patient-driven care. There is growing evidence in the effectiveness of non-pharmacological approaches as part of a comprehensive care plan for chronic pain which includes acupuncture, massage, yoga and spinal manipulation. VA is establishing the Integrative Health Coordinating Center (IHCC) within the Office of Patient-Centered

Care and Cultural Transformation to build the infrastructure (e.g. establishing new occupations) to support the delivery of these services.

VA's Opioid Education and Naloxone Distribution Program

In certain situations, opioids are the best choice for pain. Naloxone is an antidote to respiratory depression which can cause fatal overdose. With opioid use, risks are involved, and VA is taking precautionary steps to mitigate these risks. In May 2014, a VHA team developed and implemented VA's Overdose Education and Naloxone Distribution (OEND) program. Although VA's national OEND program is less than 1 year old, as of March 8, 2015, over 2,400 naloxone kit prescriptions have been dispensed to at-risk Veterans throughout the United States. As a result of these efforts, 33 individuals' life-threating opioid overdoses were reversed as a direct result of the OEND program.

Tomah VA Medical Center

VA is actively reviewing allegations of improper opioid prescribing practices and retaliatory behavior at the Tomah VAMC.

Accountability and allegations of misconduct by employees are taken seriously. On January 15, 2015, a physician and nurse practitioner of greatest interest were relieved of their clinical care duties and the ability to prescribe any medications pending the outcome of all investigations. In response to whistleblower allegations of unsafe clinical care and prohibited personnel practices at the Tomah VAMC, on January 23, 2015, I charged a clinical review team to assess practice patterns, controlled substance prescribing habits, and administrative interactions between subordinates and clinical leadership related to opioid prescribing practices. The clinical review team was comprised of subject matter experts in mental health, pain management, pharmacy, and addictive disorders. The team completed the on-site portion of the review during the week of January 27, 2015, and completed phase one on February 26, 2015.

On March 10, 2015, the VA released key findings and recommendations of its initial clinical review into opioid prescription practices at the Tomah VA Medical Center.

The team made specific findings relating to overall opioid utilization at Tomah and found that an apparent culture of fear at the facility compromised patient care and impacted staff satisfaction and morale. Based on these preliminary findings, the team recommended that VA consider a more in-depth evaluation of the clinical and administrative practices at the Tomah VAMC. Additional cases were brought to the review team's attention, and a second in-depth clinical review being conducted by Lumetra, an external quality improvement organization, began on March 11, 2015. It will be completed within 30 days. Investigators from the independent VA Office of Inspector General and the Department of Justice's Drug Enforcement Agency have also been on site.

We are deeply concerned and distressed about the allegations that employees who sought to report deficiencies at the Tomah VAMC were either ignored, or worse, intimidated into silence. VA will not tolerate an environment where intimidation or suppression of concerns occurs. An administrative review team from VA's Office of Accountability Review (OAR) is continuing to look at allegations of retaliation against employees and other accountability issues related to Tomah VAMC leadership.

Both the internal VHA clinical review and Lumetra's in depth review, are confidential under 38 United States Code § 5705 and the implementing regulations. However, we can provide information on the broad themes noted during the VHA clinical review. The team identified patient safety concerns for some patients at Tomah based on opioid prescribing practices outside generally-accepted standards of care. Currently, certain personnel have been detailed out of patient care areas, and their prescribing privileges have been suspended during the ongoing investigations.

In response to the allegations and in order to create a more transparent culture and improve communication with VAMC employees, medical center leadership has taken a number of actions to include town hall meetings, supervisory forums, and expanded all employee communications. The focus of these actions were designed to provide staff support and guidance on how employees can directly and confidentially contact and communicate with the team conducting the investigations. In addition to actions taken to address culture and communication, Tomah initiated a number of actions to address opioid/pain management issues. Providers transitioned to using an

expanded urine drug screen, and facility clinical leadership is updating their pain management policies. Electronic patient record tools for providers are being deployed nationally. This will make pain management information more easily accessible during patient visits. As mentioned previously, prescribers can offer naloxone to patients and their families or caregivers to mitigate risk for overdose, as appropriate

The current situation in Tomah is unfortunate, but I want to acknowledge the many dedicated staff members, nurses and doctors, who are bearing the brunt of these issues We rely on their concern for care and recognize the toll this situation is taking on them and the Tomah Veteran community.

Conclusion

In conclusion, we are continuing to investigate the situation at the Tomah VAMC and will update you on our findings. We at the Department take any concerns regarding the safety of our patients very seriously. Therefore, the safety and continued care of our Veterans is our focus throughout this situation. At VA, we depend on the service of employees and leaders who place the interests of Veterans above and beyond self-interest. Accountability, delivering results, and honesty are key to serving our Veterans. If employee misconduct is identified, VA will take appropriate action and hold those responsible accountable. These investigations are an opportunity to get to the bottom of any issues so that moving forward, these actions are not repeated elsewhere.

Mr. Chairman, we appreciate this Committee's support and encouragement in identifying and resolving challenges. My colleagues and I are prepared to respond to any questions you or the Committee may have.