RECORD VERSION

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ON OVERMEDICATION: PROBLEMS AND SOLUTIONS

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Chairman Sanders, Ranking Member Burr, and Distinguished Members of this Committee – thank you for the opportunity to appear before you to discuss some of the Army Medicine's initiatives to address healthcare needs of our Soldiers, specifically as they relate to the challenges the entire Nation is facing with pain management and the use of opioids. On behalf of the over 150,000 dedicated Soldiers and civilians that make up Army Medicine, I want to extend our appreciation to Congress for the support given to military medicine, which provides the resources we need to deliver leading edge health services to our Warriors, Families and Retirees. I'm accompanied today by Colonel Kevin Galloway, Director for Army Medicine's Pain Management Program.

The Army has been engaged over the last 13 years in combat operations and related activities that have challenged the bodies and spirits of our Soldiers and their families. Throughout this intensive period of military operations, Army Medicine, along with our Sister Services and the Veterans Health Administration (VHA), have been evolving and adapting to meet the emerging medical needs of our wounded, ill, and injured Service members and Veterans. While some of the medical challenges facing Service members and Veterans are unique to the military and military medicine, the challenges related to pain management and the potential overuse, abuse, and diversion of pain medications are shared by the nation at large. These complex issues impact patients, providers, leaders and organizations across the military health system, the VHA, and civilian medicine. Consequently, effective solutions and strategies will involve patients, providers, leaders and organizations across military, VHA and civilian medicine. I would like to share some of our innovative strategies, comprehensive solutions, and collaborative efforts with you today as well as emphasize our commitment to continuous improvement and research efforts.

Pain Management

First, I'd like to place the challenges of pain management in some context. Treating pain is one of medicine's oldest and most fundamental responsibilities, yet modern medicine continues to struggle in its efforts to understand pain mechanisms and to relieve pain and suffering for our patients. Pain is an enigmatic issue for medicine

that places significant burdens on patients, families, medical providers, and employers. Pain is the most frequent reason patients seek medical care in the United States. A 2011 Institute of Medicine (IOM) Report noted that more than 116 million Americans suffer from chronic pain. The annual cost of chronic pain in the U.S. is estimated at $560 billion, including health care expenses, lost income, and lost productivity. The Centers for Disease Control identified prescription medication abuse as an “epidemic” in the United States. The military is not immune to these challenges.

In 2010, the Army-led Pain Management Task Force was chartered to develop a comprehensive, holistic, multidisciplinary, and multimodal strategy utilizing state of the art/science practices in the field. Comprised of representatives from the Uniformed Services and VHA, the Pain Management Task Force examined staff education, clinical practice, and the structure of pain management in military medicine, the VHA, and in civilian medicine. I would like to emphasize that the Task Force benefited immensely during this analysis from the VHA’s previous and ongoing initiatives to develop and implement pain management strategies.

The 2010 Pain Management Task Force Report has been widely circulated and recognized across U.S. Medicine and abroad. The American Academy of Pain Medicine recognized the Pain Management Task Force with its Presidential Commendation. One year after the release of the report, the IOM released its own report entitled, “Relieving Pain in America,” which acknowledged and referenced the work of the Pain Management Task Force. More importantly, the IOM report’s findings and recommendations largely paralleled those contained in the Pain Management Task Force Report. When the IOM report was released in June 2011, the Army was already operationalizing the Pain Management Task Force’s recommendations through the Comprehensive Pain Management Campaign Plan. Since the release of the IOM report, the Army has been representing the Department/* of Defense on the National Institutes of Health (NIH) Interagency Pain Research Coordinating Committee, the federal advisory committee created by the Department of Health and Human Services to enhance pain research efforts and promote collaboration across the government.

The Comprehensive Pain Management Campaign Plan provides a roadmap for this holistic, multimodal, multidisciplinary pain management strategy. Army Medicine's pain strategy includes several lines of effort: first, to implement a culture of pain awareness, education, and proactive intervention; second, to provide tools and infrastructure that support and encourage practice and research advancements in pain management; and lastly, to build a full spectrum of best practices for the continuum of acute and chronic pain, based on a foundation of the best available medical evidence.

The foundation of the MEDCOM pain management program is developing a tiered or "Stepped Care" strategy that provides the appropriate level of pain management capability, provider education and access to consultative/referral support at each level of care (i.e. from Primary Care to Specialty Care). Interdisciplinary Pain Management Centers (IPMC) are being established at each of the Army's eight medical centers. IPMCs provide the highest tier of pain management delivered by a multidisciplinary team of providers working together to provide consultation, care, and expertise for interventional pain medicine. Our goals are rehabilitation and functional restoration through these integrative medicine modalities.

The Army Pain Management Extension for Community Healthcare Outcomes (ECHO) tele-mentoring initiative leverages the model developed by the University of New Mexico (UNM) Project ECHO initiative. The Army is completing a two-year collaboration with UNM to adapt this best practice for use in the Army's pain program. ECHO's objective is to complement the capacity, competence and confidence of remote primary care providers. Utilizing weekly video tele-conferencing to create regional communities of practice, ECHO links the IPMC specialty teams (i.e. hubs) with their designated Patient Centered Medical Homes (i.e. spokes). This improves provider knowledge, increases care coordination, and decreases the need for continued specialty referrals to the direct and purchased care systems.

Complementary Integrative Medicine Modalities

As recommended by the Pain Management Task Force, the integrative medicine modalities in our IPMCs include acupuncture, movement therapy/yoga, medical

massage, and bio-feedback. The use of these modalities in our IPMCs provides our patients with non-medication pain management options. The Army has been collaborating with several organizations with a common interest in expanding the utilization of complementary integrative medicine modalities. The National Center for Complementary and Alternative Medicine at NIH, the Bravewell Collaborative, and the Samueli Institute have all been extremely helpful in this effort.

Army clinicians are participating with the Air Force, Navy, and VHA in a $5.4 million Joint Incentive Fund Project to field a standardized basic acupuncture training and sustainment model across DoD and VHA medical facilities. Training teams have already started traveling to Army, Navy, Air Force, and VHA medical facilities to deliver this training. The response from providers and patients has been overwhelmingly positive.

Army Medicine, along with the Navy and Air Force, is collaborating through the Defense and Veterans Center for Integrative Pain Management on research studies related to the use of acupuncture and yoga as non-medication complements/alternatives to standard pain management therapies. Initial evidence indicates these can be effective complements and sometimes an alternative to medications.

Pain Outcomes Measurement

In response to the 2010 National Defense Authorization Act and the recommendations in the Pain Management Task Force Report, the DoD began development of the Pain Assessment Screening Tool and Outcomes Registry (PASTOR). PASTOR was designed as a tool to reduce the burden of questionnaires during clinical contact through modern information technology, make use of well-established pain assessment tools already available, and provide a framework for development of new assessment tools. Furthermore, PASTOR is envisioned as a critical first step in realizing the vision of outcomes driven pain care across the DoD and VHA health care systems.

The PASTOR prototype results in a clinician report, displaying alerts for concerning responses to questions covering PTSD, depression, anxiety, and alcohol use. These alerts are intended to prompt further individualized evaluation by the clinician. Areas of greatest pain are mapped on an image of a body, and self-reported pain values are tracked over time. When these scores are analyzed in concert with validated measures of emotional (anxiety, depression, anger) and physical (sleep, physical function) health domains, trends are easily identified. Additionally, each patient has an opportunity to list and rate ability on activities that are important to that individual. This functional data provides practical indicators of pain management success. A new set of opioid use measures are also under development and will be field tested in both civilian and military setting later this year.

A significant advantage in the PASTOR development program is its collaborative partnership and development strategy with the NIH Patient Reported Outcomes Measurement Information Systems, or PROMIS. PROMIS represents an existing Federal investment of approximately $100 million, over 8 years of research and development, and the product of 150 scientists at 15 primary research sites. PROMIS created more than 80 royalty free instruments which can be used to capture numerous components of health related quality of life including physical health, mental health and social health. Computerized adaptive testing (CAT) - enables computer-based delivery of measures which can obtain clinical accuracy in five items or less. Scientists at Northwestern University have teamed with the the military to integrate brief PROMIS measures with the needs of military personnel and their families who require pain management. This reduction in patient burden, without loss of clinical reliability, enables PASTOR to frequently assess multiple facets of pain and opioid use.

Thus far, a working prototype has been constructed, pain threshold values for appropriate initiation of PASTOR have been identified, and a pilot test of the system has begun in two military treatment facilities, with more to follow in the coming months.

Army Medicine is adopting the Defense and Veterans Pain Rating Scale (DVPRS). Something as simple as changing how we ask our patients about their pain

can impact the prevalence of medication use. The scale was developed by the Pain Management Task Force and validated through DoD/VHA research studies. It recalibrates the pain discussion along the lines of: "How is pain affecting your function and quality of life?" The scale includes supplemental questions on pain's effect on sleep, mood, stress and activity. The Army is integrating DVPRS into the Patient Centered Medical Home workflows.

Pain Management Transition to VHA

Another area I'd like to highlight with regard to pain management is our ongoing collaboration with the VHA to ensure the smooth transition of care for Soldiers who will be receiving care in the VHA health system. Prominently positioned on the Pain Management Task Force Report cover is the overarching Task Force objective: "Providing a standardized DoD and VHA vision and approach to pain management to optimize the care for Warriors and their Families." Army Medicine has continued to engage with the Air Force, Navy and VHA to move our organizations in that direction. The Army Pain Management Program's incorporation of the VHA's Stepped Care approach synchronizes provider education with the expectations of our patients. Not only do our military providers and patients benefit from a standardized approach to pain management while they are in uniform, but this also makes the transition to VHA care far less disruptive.

DoD and VHA collaboration has also resulted in standardized prescription medication formularies to ensure Soldiers with chronic pain are able to continue effective care plans after their transition to the VHA. Lastly, military and VHA providers are engaged in a project to develop and implement a common pain management education curriculum for both providers and patients. The curriculum will be fully developed within the next twelve months, and will be implemented across VHA and DoD within the next eighteen months. These initiatives will take us closer to the standardized DoD and VHA vision and approach to pain management referenced by the Pain Task Force.

In addition to the Pain Management Campaign, Army Medicine is addressing the potential overuse, abuse and diversion of opioids through a comprehensive strategy that integrates several other initiatives including Polypharmacy, Substance Abuse, Behavioral Health, and Warrior Transition Care.

Polypharmacy

Soldiers with complex injuries often require the use of multiple medications (i.e. polypharmacy) which can place them at greater risk for medication-related adverse events. The Army seeks to reduce risk, enhance safety and optimize care by including the Soldier, Family members, healthcare providers, pharmacists and commanders as part of the healthcare team. Army policies also establish procedures to identify polypharmacy trends that could lead to misuse by Soldiers and Wounded Warriors.

Army Medicine uses best practices that are comparable to, or exceed, civilian programs, such as prescription drug monitoring to identify polypharmacy cases. Positive interventions include comprehensive medication reviews, sole provider programs, limiting the dispensed supply of medication, restricting high-risk patients to the utilization of one pharmacy, informed consent, use of non-drug treatment options, clinical pharmacist referrals, and patient and provider education.

The Army trains its providers on the risks of prescription opioid overuse and ways to prevent medication misuse. The US Army Public Health Command and the Uniformed Services University of the Health Sciences developed an interactive storyline-based training aimed at increasing the knowledge and skills health professionals need to better interact with Soldiers in a clinic setting. Army Medicine has implemented systems and procedures our clinicians regularly use to prevent and detect issues of opioid overuse. These tools include the ability for our clinicians to review all prescriptions paid for by the Defense Health Agency (DHA) pharmacy benefit regardless of the point of service (Military, Home Delivery or Retail Pharmacy). The DHA Pharmacoeconomic Branch website allows clinicians to identify concerning use of opioids dispensed under the TRICARE Pharmacy Benefit through the use of prescription screening tools such as the Medication Analysis and Reporting Tools.

Army Medicine is expanding the role of clinical pharmacists to address national concerns with polypharmacy and adverse drug events that lead to hospital admissions. The Army Surgeon General supports evidence-based enhancements drawing on the expertise and contributions of pharmacists embedded in Patient-Centered Medical Homes. The addition of clinical pharmacists to the patient care team translates into decreased overall costs, fewer adverse drug-related events, reduced hospital admissions, and improved medication-related patient outcomes and appropriate adherence to medications. Clinical pharmacists improve readiness of the force through policy and practice, systematically identifying Soldiers with polypharmacy risk and communicating these concerns to health care providers. The Army uses an automated polypharmacy screening tool to screen all Active Duty Service Members monthly to identify Soldiers prescribed different combinations of high risk medications. These reports are provided to the medical team for review and follow-up. Clinical pharmacists embedded in Army medical homes optimize patient adherence to appropriate drug therapy by conducting medication reviews, resolving medication problems and recommending cost effective treatment alternatives.

Current Army initiatives aimed at reducing adverse outcomes and harm due to prescription drug abuses include informed consent for polypharmacy, sole provider program, limiting authorized use of prescriptions to six months following the prescription fill date, adjusting the panel of drugs in random urine drug testing to include prescription drugs and polypharmacy education for healthcare providers and patients.

Healthcare providers must review identified risks and potential interactions with the Soldier, provide education on detection and management of interactions, and must document informed consent in the medical record. Informed consent includes a brief description of discussed risks and whether or not the indication for which the medication is being used is a Food and Drug Administration (FDA) approved indication or the medication is used off-label.

The Army policy instructs healthcare providers to have a low threshold for referring patients to Behavioral Health resources and the Sole Prescriber Program.

Healthcare providers enroll Soldiers at increased risk of adverse effects, drug interactions, or inappropriate medication use in the Sole Prescriber Program to optimize care. Once enrolled, only a Soldier's designated provider or alternate provider is authorized to prescribe controlled substances for the Soldier. If necessary, the Soldier may be restricted to a specific pharmacy or pharmacies by activating the Prescription Lock-out Program.

In addition to Soldiers who are identified as having intentional or unintentional risk for medication overdose, healthcare providers will refer Soldiers who present with polypharmacy-related concerns to a clinical pharmacist. The pharmacist will identify medication-related problems, develop a medication action plan, and provide medication education to the patient. Clinical pharmacists document patient encounters and consultations for medication therapy management in an electronic medical record template to improve communication with providers.

Army policy limits authorized use of prescriptions to six months following the prescription fill date. In addition, Army medical providers may prescribe only the minimum quantity of controlled substances necessary to treat an acute illness or injury, and quantities of controlled substances used to treat acute conditions are dispensed as a 30-day supply. Prescribers and pharmacists inform Soldiers that, per Army policy, controlled substance prescriptions have an expiration date of six months from the dispensed date, and that a positive urinalysis test for the drug after six months from dispensing may result in a "no legitimate use" finding.

Polypharmacy education and training is available to healthcare providers and beneficiaries to improve appropriate prescribing and use of medications, respectively. Patient-specific training is available to Warrior Transition Units (WTU) to improve awareness of safe medication use, proper medication disposal, and promotion for the bi-annual drug take back events.

Army Medicine has participated in all Drug Enforcement Agency (DEA) National Prescription Drug Take Back Day events since their inception in 2010. Thirty-six Army Military Treatment Facilities participated in the Take Back Day on 25 and 26 October

2013, with over 2,000 patients participating and 7,491 pounds of unused medications collected. The Army will continue to participate in bi-annual Take Back events in an effort to maintain attention on the importance of appropriate disposal of medications that are no longer needed. Army Medicine provides support through coordinated public affairs communications and education directed at medical staff, patients, Families and military leadership, to include on-site presence at every designated event.

Substance Abuse Programs

The Army continues to synchronize clinical care and processes provided through the Army Substance Abuse Program and Army Medical Command's primary care providers, pain specialists, and behavioral health specialists. The Army uses the DoD's drug testing program to test not only for illegal drugs, but also for prescribed medications taken inappropriately (that is without an active prescription). Identified Soldiers are referred to the Army Substance Abuse Program where they are assessed and enrolled for treatment. Commanders and clinicians support this treatment process regardless of the Soldier's disposition, because we recognize that we have an obligation to ensure our Soldiers remain effective on active duty or make their transition from active service with drug use properly managed.

Behavioral Health Program

Army Medicine's Behavioral Health Service Line is an interconnected group of standardized programs delivering a wide variety of Behavioral Health services to Soldiers and beneficiaries. For the treatment of substance abuse disorders, the Army has five Addiction Medicine Intensive Outpatient Programs. There are currently 187 beds designated for long-term Substance Use Disorder treatment in the Military Health System, 22 of which are in the Army. These Military Health System facilities have consistently had 85% or higher utilization rates for the past 18 months. Purchased care inpatient substance use disorder treatment accounts for approximately 70 Soldiers per month. Demand for network inpatient substance use disorder treatment has decreased sharply with the implementation of the NDAA 2010, Section 596, but continues to

remain high enough to justify increases in capacity in the coming years to recapture inpatient substance use disorder care going to the network.

Army Medical Command conducted an analysis of all health care and pharmacy records involving Army Active Duty Service Members, reflecting an annual average population of 657,000 Soldiers from 2007 to 2012. This analysis showed a 65% increase in the number of Soldiers seeking behavioral health services (151,620 in 2007 to 250,410 in 2012), and a corresponding 44% increase in the number of Soldiers prescribed any medication within the broad psychiatric category (101,914 in 2007 to 147,197 in 2012). In other words, there has not been any disproportionate increase in medication use. There are multiple safeguards in place to ensure that psychiatric medications, including antipsychotic medications, are prescribed safely and judiciously according to accepted clinical practice guidelines and nationally recognized standards of care.

Medical Home and Warrior Transition Clinics

Optimizing the use of medications through pharmacist interaction as part of a Patient Centered Care Team is best exemplified by their work within the Wounded Warrior Clinics. Of the 22 Warrior Clinics in support of Army Medicine Warrior Transition Units, 21 Clinics are currently supported by approximately 25 clinical pharmacists and 5 pharmacy technicians. These Warrior Clinics are consistent with the Medical Home model, where pharmacists manage complex medication regimens and mitigate risks for Wounded Warriors.

The Risk Assessment Management within the Warrior Care and Transition Program enables WTUs to monitor the safety of Soldiers. WTU Commanders, in coordination with the Soldiers' interdisciplinary team, conduct risk assessments for every Soldier. The initial risk assessment occurs within 24 hours of the Soldier's arrival at the WTU, ongoing assessments are regularly made throughout the Soldier's stay, and additional assessments occur during key events such as during quarterly scrimmages as directed by the Soldier’s personalized Comprehensive Training Plan. Risk assessments focus on therapy adherence, behavioral health history, substance

abuse history, and access to care patterns. The intent is to assess whether Soldiers on these medications need additional monitoring and assistance with medication management. If a Soldier is identified as needing additional monitoring and assistance, the interdisciplinary team determines what risk mitigation strategies are needed to maintain the Soldier's safety. If needed, the Soldier is entered into the Army Medical Department's Sole Provider Program. Soldiers enrolled in the Sole Provider Program may only receive medications from their assigned provider, and receive no more than a 7-day supply of narcotics or psychotropic medications. Clinical Pharmacists also provide oversight as they review the medication profiles of all Soldiers in a WTU, who are determined to be at high risk. These reviews occur at least weekly.

Army Medicine has engaged in a comprehensive campaign to address the pain management needs of Soldiers and their Families. Our strategy involves developing and implementing solutions with our DoD, VHA, and Civilian Medicine partners. Thank you again for the opportunity to testify before the committee and for your support to our Soldiers and Veterans.