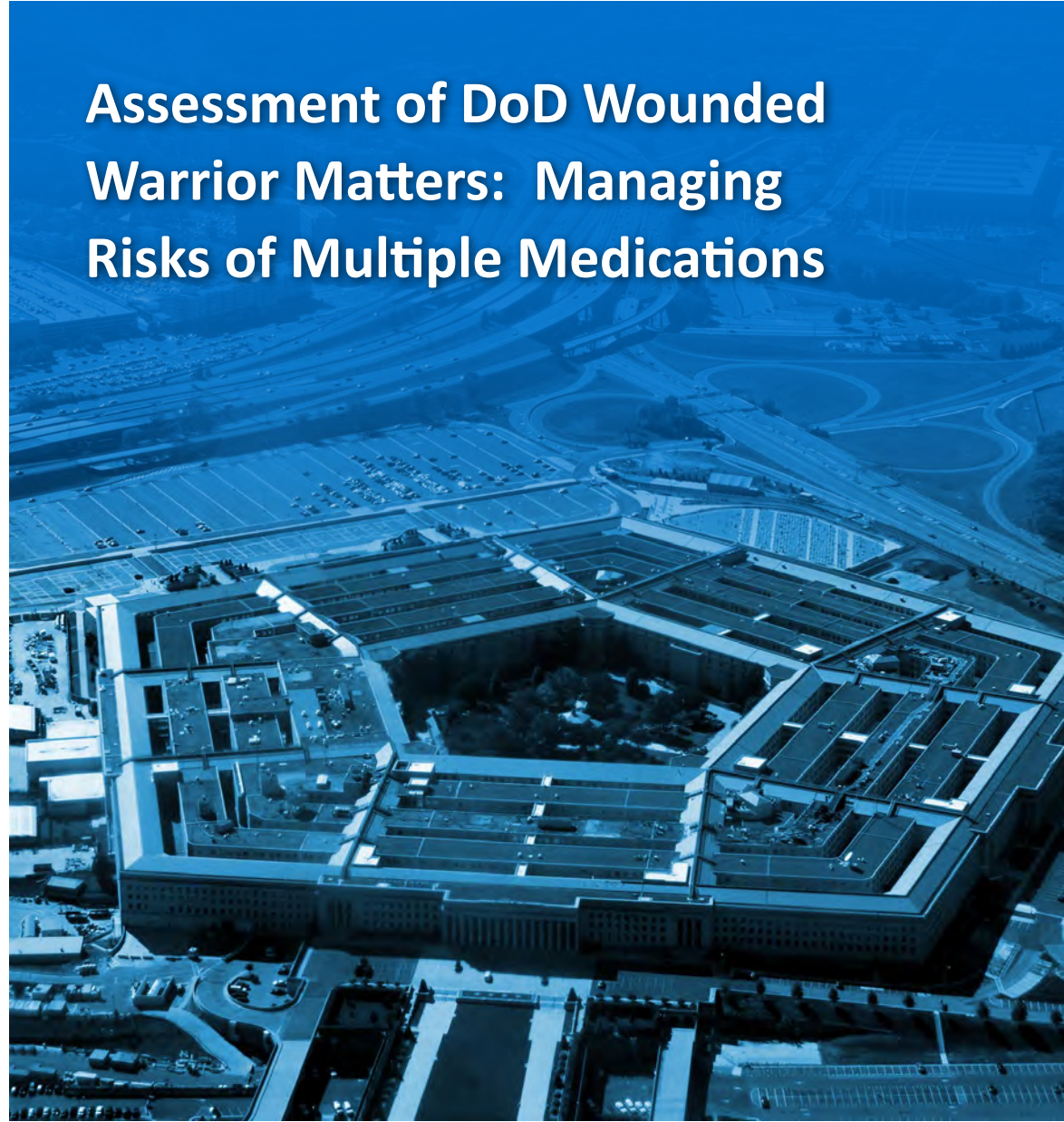




INSPECTOR GENERAL

Department of Defense

FEBRUARY 21, 2014



Assessment of DoD Wounded Warrior Matters: Managing Risks of Multiple Medications

INTEGRITY ★ EFFICIENCY ★ ACCOUNTABILITY ★ EXCELLENCE

Report Documentation Page

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Mission

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Results in Brief

Assessment of DoD Wounded Warrior Matters: Managing Risks of Multiple Medications

February 21, 2014

Objective

During the fieldwork for the assessment of Wounded Warrior programs, we identified challenges pertaining to medication management practices. This follow-on assessment focused on DoD and Service policies and programs intended to manage the risks associated with Wounded Warriors who were prescribed multiple medications during the course of their treatment and recovery. Specifically, we examined the policies related to reducing adverse drug events such as unanticipated side effects, decreased drug effectiveness, accidental overdose, and death. We also examined the procedures related to disposing of medications that are expired or no longer needed for treatment. Misuse of unneeded medications can result in similar adverse drug events.

Findings

We found that the Department of Defense did not have overarching policies and procedures to ensure consistent medication management and reconciliation practices in the Wounded Warrior population. The Services have adopted policies at various command levels; however, there is wide variance across the Services in the policies and standards for medication reconciliation.

Additionally, Wounded Warriors did not have a reliable, safe, accessible, and accountable method to dispose of medications that were no longer needed for treatment. As a result, Wounded Warriors may be at risk for overdose or misuse of unneeded medications that could result in unnecessary hospitalization and death.

Recommendations

We recommend the Department of Defense create Military Health System policy to address the risks for Wounded Warriors who may use multiple medications in the course of their treatment; and the Services update policies to address the unique needs of the Wounded Warrior population. We also recommend the Secretary of Defense request the U.S. Attorney General expedite the Drug Enforcement Administration decision for issuance of authority for Department of Defense medical treatment facility pharmacies to conduct routine take-back of unnecessary prescription medication, and that the Services create implementation policy if that authority is given by the Drug Enforcement Administration. Finally, we recommend the Department of Defense develop additional education and information initiatives on the proper disposal of expired or unneeded medications.

Management Comments and Our Response

The Office of the Secretary of Defense, Army Surgeon General, and Navy Surgeon General provided comments to this report. Management concurred with all the recommendations. At the time of this publication, the Air Force Surgeon General had not provided management comments. We request the Air Force provide management comments to Recommendation A.2., by March 21, 2014. The full reproduction of the comments received is included in this report.

Recommendations Table

Management	Recommendations Requiring Comment	No Additional Comments Required
Secretary of Defense		1.a
Assistant Secretary of Defense for Health Affairs		1.a, 2.b, 2.c
Army Surgeon General		1.b
Navy Surgeon General		1.b
Air Force Surgeon General	1.b	

Total Observations and Recommendations in this Report: 2 and 5.

Please provide comments by March 21, 2014.



**INSPECTOR GENERAL
DEPARTMENT OF DEFENSE
4800 MARK CENTER DRIVE
ALEXANDRIA, VIRGINIA 22350-1500**

February 21, 2014

MEMORANDUM FOR DISTRIBUTION

SUBJECT: Assessment of DoD Wounded Warrior Matters: Managing Risks of Multiple Medications (Report No. DODIG-2014-040)

The Deputy IG, Special Plans and Operations (SPO) is providing this report for your review and comment. This is the seventh Wounded Warrior report published by the DoD IG in the past three years. This report provides an assessment of Wounded Warrior medication management practices across all the Services.

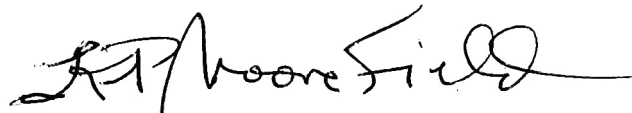
We considered management comments on a draft of this report when preparing the final report. Comments from the Office of Secretary of Defense, the Assistant Secretary of Defense for Health Affairs, the Army Surgeon General, and the Navy Surgeon General were responsive. However, the Air Force Surgeon General did not provide comment on Recommendation A.2 by the release of this publication. We therefore request the Air Force comment to the final report.

Please provide comments that conform to the requirements of DoD Directive 7650.3. If possible, send your comments in electronic format (Adobe Acrobat file only) to SPO@dodig.mil. Copies of your comments must have the actual signature of the authorizing official for your organization. We are unable to accept the / Signed / symbol in place of the actual signature. We should receive your comments by March 21, 2014.

Your comments should state whether you agree or disagree with the observation(s) and recommendation(s). If you agree with a recommendation, clearly state that you “concur” or “concur with comment” and describe what actions you have taken or plan to take to accomplish the recommendation and include the completion dates of your actions. Send copies of documentation supporting the actions you may have already taken. If you disagree with the recommendations or any part of them, please clearly state your “non-concur” and give specific reasons why you disagree and propose alternative action if that is appropriate.

Three of this report’s five recommendations concern reviewing and/or developing medication management policy. SPO will monitor the progress of these recommendations through semiannual updates.

We appreciate the courtesies extended to the staff. Please direct questions to [REDACTED].
We will provide a formal briefing on the results, if management requests.



Kenneth P. Moorefield
Deputy Inspector General
Special Plans and Operations

Distribution:

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Under Secretary of Defense for Personnel and Readiness

Assistant Secretary of Defense for Health Affairs

Warrior Care Policy

Director, Joint Staff

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Senate Committee on Appropriations, Subcommittee On Defense

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House Committee on Oversight And Government Reform

House Committee on Appropriations, Subcommittee On Defense



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Introduction

Medication safety is an issue of national importance that also has military significance. The Centers for Disease Control and Prevention (CDC) reported 700,000 emergency department¹ visits and 120,000 hospitalizations in the United States annually because of adverse drug events (ADE). They estimated that 40 percent of the costs of outpatient medical care related to ADEs are preventable. In November 2011, the CDC stated that deaths from overdose of prescription pain medication had reached epidemic levels.² The CDC reported that nearly 15,000 people die every year from pain medication overdose, and that 1 in 20 people in the United States reported misusing prescription pain medications in the past year.

The White House's 2012 National Drug Control Strategy stated that there were 39,147 drug-induced deaths in 2009. This exceeded the 36,216 motor vehicle deaths that occurred in the same year. Misuse of prescription medications was the second most frequent type of illicit drug used by individuals aged 12 or older in 2010 and 25 percent of young Americans who used illicit drugs for the first time did so by misusing prescription drugs. The strategy identified four main elements for reducing prescription medication misuse.

- Educate healthcare providers on proper narcotic/opioid prescribing practices, and educate patients (and parents) on the risks of medication misuse and the importance of properly securing medication.
- Track medication use through electronic prescription drug monitoring programs that allow healthcare providers and pharmacists to identify patients who engage in "doctor shopping"³ or other medication misuse behavior.
- Dispose of medications that are no longer needed by the patient.
- Enforce medication diversion laws.

¹ A hospital emergency department is also known as an emergency room or ER.

² These overdose deaths can be the result of accidental overdose from legitimately prescribed medication or illicit use of medication that was not prescribed.

³ The CDC states that the term "doctor shopping" has traditionally referred to a patient obtaining controlled substances from multiple health care practitioners without the prescribers' knowledge of the other prescriptions.

The military has experienced similar problems with medication misuse. The Armed Forces Health Surveillance Center reported that the military had almost 13,000 pharmaceutical-related hospitalizations for overdose/poisoning between 2001 and 2010. During this same time, there were more than 2,500 hospitalizations for alcohol or illegal drug overdose/poisoning. Prescription medication overdose happened almost five times more often than alcohol or illegal drug overdose. Pain medications and psychotropic⁴ medications accounted for more than 65 percent of these overdose/poisoning hospitalizations.

Medication Reconciliation Requirement

The Department of Defense requires that all garrison-based medical treatment facilities⁵ meet or exceed standards of appropriate external healthcare accrediting bodies. This includes accreditation of all hospitals by The Joint Commission⁶ or other approved organizations. Accreditation by The Joint Commission includes evaluation of a hospital's compliance with The Joint Commission's National Patient Safety Goals (NPSGs).

In 2002, The Joint Commission established its NPSG program to help accredited healthcare organizations address patient safety. NPSG Goal 3 is "Improve the Safety of Using Medications." In 2011, this goal was modified to include the critical risk points of medication reconciliation.⁷ The elements of performance used to evaluate compliance with the medication reconciliation goal are broad and generic because they are intended for a wide variety of healthcare settings from small outpatient clinics to large medical centers.

Even though The Joint Commission does not mandate the procedures to conduct medication reconciliation, it is widely viewed as a five-step process.

1. Develop a current list of all medications, prescription and over-the-counter, that the patient is taking.
2. Develop a list of proposed medications to be prescribed.

⁴ Psychotropic medications are used to treat behavioral health conditions such as depression, anxiety, post-traumatic stress, obsessive behavior, etc.

⁵ Garrison-based refers to permanently established military bases in the United States or overseas but excludes military bases in an operational theater.

⁶ The Joint Commission is an independent, not for profit organization that is a standards-setting and accrediting body in healthcare. Accreditation and certification by The Joint Commission is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.

⁷ Medication reconciliation is a process of comparing the medications an individual is taking (and should be taking) with newly ordered medications. This comparison addresses duplications, omissions, and interactions, and the need to continue current medications.

3. Compare the medications on the two lists to identify omissions, duplications, incorrect doses, conflicts in timing, or potential adverse drug interactions.
4. Make clinical decisions based on this information—consult with specialty providers and other clinical experts as necessary.
5. Communicate the new list with appropriate healthcare providers and the patient.

The military's Wounded Warrior population is particularly vulnerable to medication management challenges and issues. Wounded Warriors are likely to be routinely prescribed medications that have a high potential for ADEs and/or misuse due to the medical conditions most common in this population. For example, the high prevalence of orthopedic injuries and behavioral health issues, or a combination of the two, often result in Wounded Warriors having to take several medications concurrently. It is also common for Wounded Warriors to frequently change medications or dosage. This creates medication management issues that should be addressed to mitigate the risk of ADEs and/or misuse.

Background

The Military Services formed the Wounded Warrior programs because of the increased number of service member casualties incurred during military operations in Iraq and Afghanistan. Initial programs were formed as early as 2004 and 2005. The programs expanded following media and congressional interest over Wounded Warrior issues identified at Walter Reed Army Medical Center in February 2007. There have been many oversight hearings, special commissions, task forces, and reports related to Wounded Warrior recovery, rehabilitation, and reintegration over the past 6 years.

While the criteria for admission into Wounded Warrior programs vary somewhat by Service, there are similarities across these programs. All the programs assist Wounded Warriors who are navigating through the complex DoD and Veterans Affairs (VA) disability evaluation processes. They all provide career, education, and readiness transition support. Most provide care coordination and/or nonclinical case management. The Army provides clinical case management within the Wounded Warrior unit while the other Services provide it through the medical treatment facility. According to the Office of Warrior Care Policy, the overall objective of Wounded Warrior programs is to “ensure wounded, ill, injured, and transitioning service members receive high-quality care and seamless transition support.”

In June 2010, the DoD Inspector General's (IG) Office of Special Plans and Operations began a series of site visits to Army and Marine Corps Wounded Warrior units. The purpose of the site visits was to determine whether the DoD programs for the care, management, and transition of recovering service members wounded during deployment in Operation Iraqi Freedom or Operation Enduring Freedom were managed effectively and efficiently.

DoD IG has produced the following six reports related to Wounded Warrior programs based on site visits to four Army and two Marine Corps Wounded Warrior units.

- DoD IG Report No. SPO-2011-004, "Assessment of DoD Wounded Warrior Matters–Fort Sam Houston," March 17, 2011.
- DoD IG Report No. SPO-2011-010, "Assessment of DoD Wounded Warrior Matters–Fort Drum" September 30, 2011.
- DoD IG Report No. DODIG-2012-067, "Assessment of DoD Wounded Warrior Matters–Camp Lejeune," March 30, 2012.
- DoD IG Report No. DODIG-2012-120, "Assessment of DoD Wounded Warrior Matters–Wounded Warrior Battalion–West Headquarters and Southern California Units," August 22, 2012.
- DoD IG Report No. DODIG-2013-087, "Assessment of DoD Wounded Warrior Matters–Joint Base Lewis-McCord," May 31, 2013.
- DoD IG Report No. DODIG-2013-113, "Assessment of DoD Wounded Warrior Matters–Fort Riley," August 6, 2013.

We noted medication management issues during all of the Wounded Warrior site visits.

Objective

The objectives of this assessment were to determine whether DoD:

- had policies and programs in place to help manage the risks associated with Wounded Warriors who may be on multiple medications; and
- addressed issues concerning medication management including, but not limited to, medication reconciliation and proper disposal of medications.

Scope

This assessment is intended to specifically address the theme of medication management observations from previous oversight work completed at the installation level. It draws on conclusions based on observations made regarding Wounded Warrior-related policies and practices of the Department of Defense, Assistant Secretary of Defense for Health Affairs (ASD[HA]) and the Services.

Methodology

We reviewed documents such as Federal laws and regulations, the National Defense Authorization Act, Chairman of the Joint Chiefs of Staff instructions, DoD directives and instructions, and relevant civilian and military scientific literature pertinent to the topic of Wounded Warriors taking multiple medications. We reviewed data from previous Wounded Warrior assessments. Additionally, we reviewed information on medication reconciliation and proper disposal of medications, to include documentation of site visits, interviews, and briefings to the DoD IG concerning medication management in the Wounded Warrior population.



Noteworthy Practices

There have been several notable accomplishments to improve medication management and reconciliation within the Department of Defense. These innovations include using the Pharmacy Data Transaction Service (PDS) to increase situational awareness of prescription medications in the electronic medical record.⁸ The policies and guidelines described in this section appear to have improved medication oversight. These innovations should be monitored, sustained, and improved as necessary.

DoD Information Technology Support to Medication Management

Within the PDS, the DoD Pharmacoeconomic Center (PEC) developed the Warrior Transition Unit (WTU) Prescription Medication Analysis and Reporting Tool (P-MART) in July 2008. The WTU P-MART provides an automated tool for primary care providers and nurse case managers to monitor high-risk medications in all Wounded Warrior populations. The WTU P-MART identifies an “individual who may require a more intensive medical review, to identify potential at-risk patients, or to monitor adherence to a sole provider program.” There are two types of reports available from the WTU P-MART: 1) by-name reports of each Wounded Warrior’s medications, and 2) by-medication reports listing all the Wounded Warriors taking a specific type of medication.

The WTU P-MART can provide by-name reports of each Wounded Warrior and lists all their prescribed medications. These reports specifically highlight high-risk medications (medications with significant potential for adverse effects), controlled substances (medications with an increased possibility for addiction or abuse), and chronic medications (for example, blood pressure, allergy medicine). This by-name list of all the Wounded Warriors’ prescribed medications allows the primary care providers and nurse case managers to identify potential medication conflicts and recognize potential abuse.

The WTU P-MART can also produce by-medication reports for particular medications or combinations of medications listing the names of all the Wounded Warriors taking that medication. This report is useful when a primary care provider or nurse case

⁸ The PDS is a centralized data repository that tracks all medical treatment facility, civilian, or mail-order pharmacy prescription medications for all DoD beneficiaries. The data is available for all medical treatment facility pharmacies.

manager is interested in a particular medication (for example, concerned about potential misuse or over prescribing). It allows clinicians to identify changes in prescribing patterns of particular medications that may indicate a change in the health of the Wounded Warrior population.

With the increased situational awareness gained from the WTU P-MART, primary care providers, or nurse case managers, have the ability to determine that a Wounded Warrior is at risk for adverse drug events. This situational awareness is required to successfully implement any policies or programs to improve medication management.

The PEC's Medication Restriction Program uses the PPTS to constrain who can prescribe medications for the Wounded Warrior, restricts the pharmacies that the Wounded Warrior may use, and prohibits use of certain medications by the Wounded Warrior. This is also called the "1-1-1" program because it restricts a Wounded Warrior to one prescribing healthcare provider (also known as "sole provider program"), one pharmacy for obtaining medications, and one emergency department for off-duty care.

As an additional control measure, Wounded Warriors who are enrolled in the "1-1-1" program may also be restricted in the quantity of medication they receive if they are identified as high risk. This medication restriction reduces the opportunity for misuse or abuse, and allows the healthcare team to monitor medication use closely.

Both the "1-1-1" and medication restriction programs are enabled by the electronic messaging capability of the Armed Forces Health Longitudinal Technology Application (AHLTA). The AHLTA is the electronic health record used in military hospitals, outpatient clinics, and pharmacies. The electronic messaging capability informs a provider or pharmacist when a Wounded Warrior has been enrolled in the "1-1-1" program.

The increased situational awareness provided by these clinical tools and policies supports more timely decisions and improves medication management. DoD should continue to support the use of these tools and practices across the Military Health System⁹ (MHS).

⁹ The Military Health System consists of the DoD medical and dental programs, personnel, facilities, and other assets whereby they provide healthcare services and support to the Military Services during military operations and under TRICARE to members of the Military Services, their family members, and others entitled to DoD medical care.

Service-Specific Medication Management Policies

Commanders at various levels in the military health system have implemented policies to address medication management issues. Some of these policies can serve as best practices across DoD for reducing the challenges in managing medications in this high-risk population.¹⁰

Selected Army policies are described below. This list is not all-inclusive, but demonstrates that the Army has worked to mitigate the risk involved in managing multiple medications for Wounded Warriors.

- U.S. Army Office of the Surgeon General (OTSG)/Medical Command (MEDCOM) Policy Memo 10-076,¹¹ “Guidance for Enhancing Patient Safety and Reducing Risk via the Prevention and Management of Polypharmacy¹² Involving Psychotropic Medications and Central Nervous System Depressants,”¹³ November 9, 2010—provided policy guidance to reduce adverse drug events. Specifically, this policy defined and described the process for medication reconciliation when there are four or more prescribed medications that include one or more psychotropic agents and/or central nervous system depressants.
- OTSG/MEDCOM Policy Memo 11-029, “Warriors in Transition High-Risk Medication Review and Sole Provider Program,” April 7, 2011—provided guidance for reviewing high-risk medication use and provided instructions for the sole provider program. This policy required high-risk Wounded Warrior soldiers to be entered into the sole provider program and receive no more than a 7-day supply of medications.
- Warrior Comprehensive Transition Program (WCTP) Policy Memo 12-004, “Warrior Transition Unit/Community Based Warrior Transition Unit (WTU/CBWTU) Risk Assessment and Mitigation Policy,” September 12, 2012—identified actions and processes to:
 - reduce high-risk outcomes which may result in harm to soldiers and others,

¹⁰ Risk is defined by the Army as the probability of harm or injury.

¹¹ This was the policy during most of the DoD Wounded Warriors assessment site visits and medication management interviews. OTSG/MEDCOM Policy 13-032 replaced this policy on May 21, 2013. However, this report only addresses the policy that was in place during site visits and interviews.

¹² Polypharmacy refers to patients who are treated for multiple conditions with a variety of medications prescribed by several health care providers.

¹³ Central Nervous System Depressants are medications which can result in suppression of respiratory drive and therefore require close medical supervision.

- direct risk assessment and reassessments of all soldiers, and
- outline mitigating actions for soldiers assessed as high-risk.

This policy identified the minimum requirements for medication reconciliation.

Neither the Navy nor the Air Force has adopted Service-wide medical policies addressing medication management in their Wounded Warrior population. However, both Services encouraged regional or installation commanders to establish policies. Selected Navy Bureau of Medicine and Surgery subordinate medical commands are described below.

- Navy Medicine West Instruction 6320.1, “Provision of Medical Care and Support Services to Wounded, Ill and Injured Service Members Enrolled in Wounded Warrior Programs,” November 10, 2011—promulgated guidance and standards for the care of Wounded Warriors within Navy Medicine West Medical Treatment Facilities. This policy identified the requirements for a deliberate medication review and reconciliation which is conducted by a clinical pharmacist.
- Navy Hospital Camp Lejeune Instruction 6320.55C, “Pain Assessment and Management,” May 17, 2011—established policies and guidelines for healthcare professionals to ensure optimal patient comfort through a proactive pain-control plan which is mutually established with the patient, family members, and members of the healthcare team.
- Navy Hospital Camp Lejeune Instruction 6710.5A, “Controlled Medication Utilization Review and Intervention Protocol,” May 9, 2012—assigned responsibility and established guidance for monitoring controlled medication use, in order to identify potential controlled medication misuse and/or high risk patients. This policy required the use of the PEC’s Controlled Drug Management Analysis and Reporting Tool to identify patients who:
 - received five or more controlled medication prescriptions within a 2-month period,
 - received controlled substances from three or more different pharmacies within a 2-month period, and

- received controlled substances from three or more different providers within a 2-month period.

Clinical Guidelines and Other Tools

The Defense Centers of Excellence (DCoE) for Psychological Health (PH) and Traumatic Brain Injury (TBI) works with a network of military and civilian experts to identify and disseminate clinical best practices. This network includes Federal agencies, civilian organizations, advocacy groups, clinical experts, and academic institutions. Their products related to medication management for Wounded Warriors include:

- VA/DoD Clinical Practice Guidelines that assist healthcare providers in integrating evidence-based treatments for PH and TBI with their clinical judgment. These guidelines included recommendations for appropriate medication therapy.
- Co-Occurring Conditions Toolkit (pamphlet) that assists healthcare providers find additional resources for improving basic elements of pain and pharmaceutical management. This toolkit states: “While medications can be very effective, this patient population (Wounded Warrior) is at high risk for polypharmacy which may lead to significant drug-drug interactions.”

The development of information technology tools that enable comprehensive medication management policy has proven beneficial for managing medications prescribed for high-risk Wounded Warriors. There appears to be a synergistic effect when combining comprehensive policy with information technology tools. We believe this combination increased medication situational awareness among healthcare providers and provided them an improved ability to preempt adverse drug events. We suggest these innovations be monitored, sustained, and improved as necessary.



Observation 1

Medication Reconciliation

Service policies varied for Wounded Warriors' medication reconciliation. Some of the policies were not sufficiently specific to ensure the safety and well-being of the Wounded Warrior population.

This variance in Service policies was caused by the lack of overarching DoD guidance to establish the minimum requirements to properly reconcile and manage Wounded Warriors' use of multiple medications.

As a result, Wounded Warriors were at risk for adverse drug events that could negatively affect their recovery and transition. These adverse drug events could include unanticipated side effects, decreased drug effectiveness, accidental overdose, and death.

Background

The standards for admission into Wounded Warrior units varied by Service. The Army required service members to have medical conditions that demanded at least 6 months of complex medical management.¹⁴ The Marine Corps required service members to have medical conditions that demanded treatment for more than 90 days. The common requirement in both standards was that the medical condition adversely affects the readiness of the service member.

The appropriate treatment for these medical conditions frequently included medication, or combinations of medications, to treat individual symptoms. Additionally, the dosage or type of medication may be altered during the course of a Wounded Warrior's treatment to gain the desired effect and improve their health. Civilian medical literature has extensively documented that "the relationship between increasing number of drugs used and increased number of DRPs [drug-related problems] is strong...polypharmacy stands out as a marked risk factor for developing DRPs."¹⁵ Therefore, it is important to ensure that medications are closely monitored and managed, especially in the Wounded Warrior population.

¹⁴ The National Committee for Quality Assurance defines complex case management as "(t)he systematic coordination (and) assessment of care (and) services provided to members who have experienced a critical event or diagnosis that requires the extensive use of resources (and) need help navigating the system to facilitate appropriate delivery of care (and) services."

¹⁵ British Journal of Clinical Pharmacology, "Polypharmacy as commonly defined is an indicator of limited value in the assessment of drug-related problems," 30 August 2006, page 193.

The military health system is a joint endeavor. For example, the Joint Task Force National Capital Region Medical Command is responsible for providing a “world-class medical center...serving our military.” The San Antonio Military Medical Center provides inpatient medical care to Wounded Warriors from all Services. The Navy is responsible for delivering healthcare to Marines. Wounded Warriors often receive medical care in specialty clinics from a different Service.

Discussion

While some medical commanders have published medication management policies, the guidance varied significantly from Service to Service and even geographically within a Service. Lacking guidance from Department of Defense, the Services have adopted very different policies. For example, the Army established a policy that describes a threshold for medication reconciliation oversight that was different from what was implemented at Naval Hospital Camp Lejeune. The Army’s threshold was four medications when one was a controlled substance, and the Navy’s Camp Lejeune policy called for five controlled substances. The Camp Lejeune policy also included two criteria to help identify “doctor shopping” behavior that the Army did not address. The hospital policies at Camp Lejeune were different from those at Camp Pendleton, California.

The DoD IG’s report on Wounded Warrior Matters for the United States Marine Corps (USMC) Wounded Warrior Battalion–West noted that the Naval Hospital Camp Pendleton did not have specific medication management policies or procedures for Wounded Warriors. A hospital pharmacist and clinician in the traumatic brain injury clinic confirmed this fact. There was policy for medication reconciliation in the outpatient clinic, but that policy did not specify staff roles and responsibilities or establish medical record documentation requirements. DoD IG personnel noted similar observations during other Wounded Warrior site visits and reports.

These differences might lead to unwarranted medication management distinctions when a Wounded Warrior receives treatment from different medical treatment facilities. For example, an Army Wounded Warrior from Fort Irwin, California, may require specialty care at the Naval Medical Center in Balboa, California. That soldier might receive comprehensive medication management at Fort Irwin, but not receive

the same level of medication oversight at the Navy medical treatment facility. Changing the geographic location of medical care should not alter the level of clinical supervision that DoD provides to a Wounded Warrior.

The ASD(HA) is responsible for ensuring healthcare quality within the MHS. Therefore, it is appropriate for DoD to have consistent policy guidance for medication management, including medication reconciliation. We believe that simply meeting the minimum threshold established by The Joint Commission's NPSGs is insufficient for the high-risk Wounded Warrior population.

Precedence for Overarching DoD Policy

DoD had not issued overarching policy guidance to address the risks involved in managing Wounded Warriors' multiple medications. They have deferred to the Services to create medication management policy. However, the ASD(HA) established precedence for publishing overarching medication management policy when they issued guidance related to the dangers involved in prescribing atypical antipsychotic medications¹⁶ for the treatment of post-traumatic stress disorders. This guidance identified situations when the use of atypical antipsychotic medication might not be appropriate and recommended local medical commanders monitor prescription patterns. This guidance applied to all medical and Service entities within the DoD.

Conclusion

The ASD(HA) does not have specific policies or guidance addressing the risks of managing medications in the Wounded Warrior population. Medication management practices, especially for the high-risk patient population of Wounded Warriors, need to be standardized across DoD. The Services' policies and procedures include aspects that should be considered by ASD(HA) in developing guidance to ensure medications are properly managed in the DoD Wounded Warrior population. An overarching DoD policy for medication reconciliation in the Wounded Warrior population will enable the Services to develop clear and consistent policies for medication management and decrease the risk of adverse drug events and poor patient outcomes.

¹⁶ Atypical antipsychotic medications are the most recent generation of a specific class of behavioral health medications.

Recommendations, Management Comments, and Our Response

Recommendation 1.a.

Assistant Secretary of Defense for Health Affairs publish policy guidance that addresses the risks for Wounded Warriors who may use multiple medications in the course of their treatment and the need for additional safeguards to ensure that these medications are effectively managed and properly reconciled by medical personnel.

Assistant Secretary of Defense for Health Affairs

Assistant Secretary of Defense for Health Affairs concurred with comment to the recommendation. Although the Department of Defense (DoD) has multiple programs and risk mitigation strategies in place, establishing an overarching policy will guide consistent implementation. Use of these programs and strategies require that providers are trained in how to optimize care for patients receiving multiple medications.

Our Response

Comments from the Assistant Secretary are responsive and the actions meet the intent of the recommendation. We acknowledge the necessity of a working group to develop overarching policy. We will request semiannual updates on the progress of the working group until the policy is published. We may choose to assess the implementation and effectiveness of the policy in the future.

Recommendation 1.b.

Military Services' Surgeons General review and update policies and procedures for medication reconciliation to ensure that they are appropriate to address the unique needs of the Wounded Warrior population.

Army Surgeon General and Army Medical Command

The Army Surgeon General concurred with comment to the recommendation. MEDCOM recently updated policies (OTSG/MEDCOM Policy Memo 13-032, 21 May 2013), involving medication reconciliation, as indicated in DoD IG's report. This policy is due to expire 21 May 2015.

Our Response

Comments from the Army Surgeon General are responsive and the actions meet the intent of the recommendation. They have recently reviewed and updated their policy, and have established a deadline for the next policy review. We will continue to monitor and review these policies, and may choose to assess implementation and effectiveness in the future. No further action is required.

Navy Surgeon General and Navy Bureau of Medicine and Surgery

The Navy Bureau of Medicine and Surgery concurred with comment to the recommendation. They acknowledged the importance of medication reconciliation, particularly for Wounded Warriors, who are more likely to be prescribed a variety of medications for various conditions. They concurred that policies regarding medication reconciliation should be reviewed to ensure that they address the unique needs of Wounded Warriors. They noted that all Navy Military Treatment Facilities comply with The Joint Commission's Patient Safety Goals, but the specific policies for conducting medication reconciliation are established in local command instructions. They believe that any centralized policy should allow sufficient flexibility to account for local requirements.

Our Response

Comments from the Navy Bureau of Medicine and Surgery are partially responsive and the actions partially meet the intent of the recommendation because they did not conduct a review of Wounded Warrior medication management policies. We recommend the Navy conduct a review of the local command policies to determine if unnecessary variance exists in those policies; and, if necessary, they should publish Navy policy to minimize that variance. We may choose to assess implementation and effectiveness in the future.

Air Force Surgeon General

As of the release date of this publication, the Air Force Surgeon General has not responded to the DoD IG report or recommendations.

Our Response

As of the date of publication, the Air Force Deputy Assistant Secretary for Financial Operations and the Air Force Surgeon General had not provided a response. In response to the final report, we request that the Air Force Surgeon General respond in accordance with the attached memo no later than March 31, 2014.

Observation 2

Medication Disposal

DoD medical treatment facilities did not have authority to receive unneeded medications for disposal from Wounded Warriors, and had to rely on the patient to discard these medications.

This occurred because current Federal policy restricts “drug take-back” programs to law enforcement entities.

Therefore, Wounded Warriors did not have a reliable, safe, accessible, and accountable to DoD method to discard medications no longer needed for treatment. When medications are misused, it places individuals at increased risk for medical complications, hospitalization, and even death.

Background

As described in Observation 1, Wounded Warriors have complex medical conditions that may require frequent medication changes, including the type and dosage necessary to obtain the intended therapeutic effect. This can result in Wounded Warriors having excess medications in their possession. Additionally, medications may expire during the course of treatment and should be discarded. However, there is no reliable, safe, accessible, and accountable to DoD method for medication disposal available to Wounded Warriors. Access to these unneeded medications increases the risk for illicit use or misuse by the Wounded Warrior, another service member, or a family member.

Methods to Remove Expired or Unneeded Medications

The Food and Drug Administration (FDA) worked with the Office of National Drug Control Policy (ONDCP) to develop consumer guidance for the proper disposal of prescription medications. The ONDCP issued this guidance in February 2007 and updated it in October 2009. This consumer guidance included the following information.

- Follow disposal instructions on the drug label or other patient information that accompanies the medication. Do not flush prescription drugs down the toilet unless specifically instructed.

- Take advantage of community drug take-back programs that allow the public to bring unused drugs to a specific location for proper disposal. The Drug Enforcement Administration (DEA), working with state and local law enforcement agencies, sponsor National Prescription Drug Take-Back Days semi-annually throughout the United States.
- If no instructions are given on the drug label and no take-back program is available in the local area, the medications should be taken out of their original container and mixed with an undesirable substance, such as used coffee grounds or kitty litter. This mixture should be placed in a sealed bag or container and discarded.

The DoD supports these FDA approved methods to remove expired or unneeded medications. The standardized medication information sheet provided with every prescription includes warning about not sharing the medication with others, overdose signs and symptoms, and disposal instructions. The Services have also implemented education programs for healthcare providers and Wounded Warrior leaders. For example, the Army's Polypharmacy and Overdose Medical Education (POME) training program is designed to help healthcare providers educate patients on common side effects, signs and symptoms of overdose, and proper methods of securing medications. Army Medical Command Policy Memo 13-032 (dated May 21, 2013) required at least 90 percent of healthcare providers complete the POME training within 90 days of initial employment.

Impact of Medication Misuse

The high and increasing medication misuse by service members presents a significant risk to their well-being, including to the recovery of Wounded Warriors.

DoD's current healthcare education and patient information approaches regarding unneeded medication have not fully addressed the problem of misuse. This misuse has had a significant negative impact on the military. Almost 1,000 service members were hospitalized for self-inflicted pharmaceutical overdoses in calendar year 2010, and almost 15,000 were hospitalized between 2001 and 2010. Pain medications and behavioral health medication overdoses accounted for over 65 percent of these hospitalizations.

The Army Times reported that there were 32 prescription overdose deaths between 2007 and 2009 in Army and Marine Corps Wounded Warriors units. The Army's January 2012 Gold Book,¹⁷ reported that prescription medications accounted for 142, or 72 percent, of the Army's 197 drug-related accidental deaths between FY 2009 and 2011. Additionally, an Army Warrior Transition Unit epidemiologic analysis established that polypharmacy and overdoses were present in a significant number of Soldier fatalities. In a sample of 63 cases, 30.2 percent involved ingestion of a medication that was not prescribed to that Soldier and approximately 50 percent of the cases involved polypharmacy with multi-drug toxicities or overdoses.

The Army's Gold Book also reported that 21 percent of all positive drug tests from random testing in FY 2011 were for prescription medication. The National Institute on Drug Abuse reported that prescription drug abuse by service members doubled from 2002 to 2005 and almost tripled from 2005 to 2008.

Drug Take-Back Programs

Public Law 111-273, "The Secure and Responsible Drug Disposal Act of 2010," allows a patient to deliver controlled substances to a DEA-authorized entity for disposal. Public Law 111-273 provides the legal authority for establishing take-back programs to dispose of prescription medication. The law states that take-back programs must obtain permission from the DEA and they must arrange for a "full-time law enforcement officer to receive the controlled substance." Public Law 111-273 provides authority to the U.S. Attorney General to publish additional policy authorizing patients to deliver medications to other appropriate entities for disposal.

The DEA has conducted semi-annual Take-Back Days since October 5, 2010. The DoD has encouraged all the Services to participate in these Take-Back Days at military installations. For example, in 2012, 40 Air Force facilities participated in DEA-sponsored National Drug Take-Back events and collected 4,330 pounds of medication, an increase from 2011 when 31 Air Force facilities participated and collected 2,500 pounds of medication. Although the TRICARE Management Activity (TMA) has aggressively marketed the Take-Back Days, DoD IG's Wounded Warrior report for Camp Lejeune noted that the DEA Take-Back Day had low participation rates for the Wounded Warrior population. Participation in semiannual Take-Back Days has not fully addressed the needs of Wounded Warriors.

¹⁷ Full title of the "Gold Book" is "Army 2020, Generating Health & Discipline in the Force Ahead of Strategic Reset, Report 2012.

While these Take-Back Days are beneficial, limiting this activity to voluntary, semi-annual, and anonymous events hinders DoD from collecting, documenting, and disposing of medications that are no longer needed by Wounded Warriors. As described earlier, Wounded Warriors have complex medical conditions that may require frequent medication changes. Based on our assessments, Wounded Warriors could have a significant accumulation of unneeded medication in the 6 months between DEA Take-Back Days. A buildup of unneeded medications further increases the risk for misuse of these medications. Drug take-back should be a routine activity offered by the medical treatment facility pharmacy to mitigate this risk.

Discussion

In January 2011, the Vice Chief of Staff of the Army (VCSA) requested the DEA authorize Army medical treatment facilities to conduct take-back programs in their pharmacies. He expressed his assessment that current Federal regulations on the disposal of controlled substances may have a “detrimental effect on the Army’s ability to reduce unwanted controlled substances in the force ...and limit the possibility for accidental overdose and death related to unauthorized use of controlled substances.” Subsequently, in April 2011, Army representatives met to discuss the VCSA’s request with the DEA’s Office of Diversion Control. The DEA’s office indicated that it was unprepared to act on the Army’s request at that time.

In June 2012, DoD officials interviewed for this report conveyed their commitment to preventing prescription drug misuse, abuse, and accidental poisoning by supporting the DEA Drug Take-Back Days. They notified beneficiaries and medical treatment facilities when DEA Drug Take-Back Days were occurring (i.e., semi-annually) and disseminated information on the TRICARE¹⁸ website, as well as other means, about the importance of disposal of unneeded medications.

Additionally, in the summer of 2012, a DoD working group formed by ASD(HA) began to explore the feasibility and options for a drug take-back program within the DoD. This working group included representatives from the DoD Suicide Prevention office, the Military Services, Patient Safety, Beneficiary Education and Support, and the TMA’s Pharmaceutical Operations Directorate. This work is ongoing.

¹⁸ TRICARE is the healthcare program serving Uniformed service members, retirees, and their families worldwide.

In October 2012, TRICARE Management Activity-Pharmacy Operations Directorate awarded a contract for a technical study related to medication misuse and suicidal behavior. In June 2013, TRICARE Management Activity received the study titled, “Recommendations for the Department of Defense to Reduce Pharmaceutical-Related Suicide Behaviors in Members of the Armed Forces.” This report concluded, “that reduced access (means restriction) to prescription medications will reduce the incidence of accidental or intentional self-harm.” The report also states, “we recommend a program to properly dispose of prescription medications that have reached their expiration date or are no longer needed for their intended purpose.” Finally, this report recommends, “TMA/ASD(HA) should issue a DoD policy for an enterprise program that will ensure MTF [military treatment facility] pharmacies provide a program to take-back medications, including controlled substances, from beneficiaries.”

Although DoD has been taking internal action to help reduce the risk of prescription drug abuse and diversion, they were still limited by the legal constraints of Public Law 111-273.

Proposed Changes in DEA Regulations

In December 2012, the DEA published a notice in the Federal Register requesting comments on proposed rulemaking addressing the secure disposal of controlled substances. This proposed rule would implement Public Law 111-273 by expanding options available to collect controlled substances from users for the purpose of disposal to include: take-back events, mail-back programs, and collection receptacles. Additionally, the proposed rule would allow retail pharmacies to administer mail-back programs and maintain collection receptacles.

This proposed rule would increase the number of “authorized entities,” including retail pharmacies, conducting take-back programs, but did not include DoD pharmacies. The DoD does not have retail pharmacies—medical treatment facility pharmacies are licensed as health system or hospital pharmacies. Therefore, the proposed rule did not provide the authority the DoD has requested to conduct drug take-back programs in its medical treatment facilities, which DoD stated is necessary to “decrease misuse and abuse of these medications”¹⁹ by Wounded Warriors and other DoD medical care beneficiaries.

¹⁹ Assistant Secretary of Defense (Health Affairs) letter to the Drug Enforcement Administration dated February 19, 2013.

DoD's Response to the Proposed DEA Rule Change

In February 2013, the ASD(HA) submitted a response to the proposed DEA rule change, explaining that the proposal would exclude DoD medical treatment facility pharmacies from requesting collector status and “limit the DoD’s ability to accept unused patient medications and reduce the potential effectiveness of efforts to eliminate opportunities for medication misuse, abuse, and tragic adverse events.” Consequently, DoD recommended a modification to the proposed Disposal of Controlled Substances rule to allow medical treatment facility pharmacies registered as hospitals/clinics to receive collector status.

ASD(HA) identified several key issues in their response:

- 1.4 million TRICARE beneficiaries use DoD’s medical treatment facility pharmacies to obtain their prescription medications. An additional 600,000 beneficiaries utilize the TRICARE mail order program.
- Since DoD does not classify its pharmacies as retail pharmacies but rather as hospital pharmacies, they would not be authorized to conduct medication take-back under the proposed DEA rule. This “will limit DoD’s ability to accept unused patient medications in a routine setting and reduce the potential effectiveness of efforts to eliminate opportunities for medication misuse, abuse, and tragic adverse events”²⁰ for 2 million TRICARE beneficiaries.
- Each DoD medical treatment facility out-patient pharmacy has extensive security measures for theft and loss prevention, as well as a secure area to place collection receptacles.
- There are 103 medical treatment facilities with 546 pharmacies throughout DoD. DEA’s pharmacy registration fee is \$731 per pharmacy for 3 years. DoD would need to spend an additional \$399,126 to re-register these out-patient pharmacies every 3 years.

Wounded Warriors obtain most of their medications from medical treatment facility pharmacies. The DEA’s proposed rule would restrict these hospital-based pharmacies from being authorized collectors of unwanted controlled substances. Therefore, left unchanged, the proposed DEA policy will not allow for the routine disposal of unused controlled substances by Wounded Warriors at DoD medical treatment facility pharmacies.

²⁰ Assistant Secretary of Defense (Health Affairs) letter to the Drug Enforcement Administration dated February 19, 2013.

Conclusion

Excess medication poses a risk to the health and well-being of Wounded Warriors and their family members. The availability of the FDA-approved methods to remove expired or unneeded medications has not sufficiently reduced the adverse impact on DoD personnel of medication misuse (see page 13 of this report “Impact of Medication Misuse”). The DEA sponsored semiannual take-back days have not eliminated the problem. Compliance with current DEA policy has hindered DoD from establishing an internal, effective drug take-back program. It is important for the military healthcare system to establish accountability and control with respect to unused medications. Wounded Warriors that are high-risk patients are often prescribed medications that have increased potential for addiction, abuse, or diversion and have no convenient method for returning unneeded and outdated medications. Moreover, these medications can be diverted illegally to others.

Authorizing medical treatment facility pharmacies to become collectors would allow DoD to conduct convenient take-back at the point of dispensing. This would help remove unneeded medications from all at-risk TRICARE patients, especially Wounded Warriors. For high-risk patients, the medical treatment facility pharmacy could then document the medication returned in the military electronic health record. This would help clinicians mitigate medication risks for Wounded Warriors and other high-risk patients by identifying potential medication misuse before adverse drug events occur.

Recommendations, Management Comments, and Our Response

Recommendation 2.a.

Secretary of Defense request that the U.S. Attorney General expedite the Drug Enforcement Administration decision for issuance of authority for the Department of Defense to conduct routine take-back of unnecessary prescription medication in the military medical treatment facility pharmacies serving the Wounded Warrior program population and other Department of Defense beneficiaries.

Secretary of Defense

The Office of the Secretary of Defense concurred with the recommendation and tasked the Acting Under Secretary of Defense for Personnel and Readiness to send a letter to the Attorney General.

Our Response

The letter from the Acting Under Secretary of Defense for Personnel and Readiness is responsive and the actions meet the intent of the recommendation.

Recommendation 2.b.

Subsequently, and upon Department of Defense receipt of authority from the Drug Enforcement Administration to conduct drug take-back programs, Assistant Secretary of Defense for Health Affairs establish Department of Defense policy and coordinate the implementation of a related program across all Services for conducting prescription medication take-back.

Assistant Secretary of Defense for Health Affairs

Assistant Secretary of Defense for Health Affairs concurred with comment to the recommendation. The DoD and DEA are working to establish the authority necessary to allow DoD to conduct drug take-back programs.

Our Response

Comments from the Assistant Secretary are responsive and the actions meet the intent of the recommendation.

Recommendation 2.c.

Assistant Secretary of Defense for Health Affairs should consider additional education and information initiatives to inform patients, healthcare providers, and Wounded Warrior unit commanders on the existing Food and Drug Administration and Drug Enforcement Administration programs and procedures to remove expired or unneeded medications.

Assistant Secretary of Defense for Health Affairs

ASD(HA) concurred with the recommendation. ASD(HA) intends to issue a comprehensive policy for the adoption of optimal methods to reinforce ongoing ASD(HA) activities in patient safety and suicide prevention.

Our Response

Comments from the Assistant Secretary are responsive and the actions meet the intent of the recommendation.



Appendix A

Scope and Methodology

We conducted this assessment from May 2012 to February 2013 in accordance with the Council of Inspectors General on Integrity and Efficiency, “Quality Standards for Inspections and Evaluations,” January 2012. We planned and performed the assessment to obtain sufficient and appropriate evidence to provide a reasonable basis for our observations and conclusions, based on our assessment objectives.

The objective of the prior overarching “Assessment of DoD Wounded Warrior Matters” (Project No. D2010-D00SP0-0209.000) was to assess the DoD programs for the care, management, and transition of recovering service members wounded during deployment in Operation Iraqi Freedom or Operation Enduring Freedom. This follow-on assessment specifically addresses the theme of medication management observed through previous work completed at the installation level, and draws conclusions from observations made regarding policies and practices of Department of Defense, ASD(HA) and the Services.

We stated in our April 16, 2010 project announcement memorandum, as well as the design plan, that additional assessments on Wounded Warrior matters may be conducted as pertinent issues are identified. Once the issue of medication management was identified from multiple site visits and reports, we determined that further description of the methodology outside of what was documented in the original Wounded Warrior project design plan was required.

The objective of this follow-on assessment was to assess if the DoD had policies and programs in place to manage the medication risks associated with Wounded Warriors. Specifically, we addressed in detail issues concerning medication management including medication reconciliation and disposal.

We reviewed documents such as Federal laws and regulations, the “National Defense Authorization Act,” Chairman of the Joint Chiefs of Staff instructions, DoD directives and instructions, and other relevant civilian and military scientific literature pertinent to the topic of Wounded Warriors taking multiple medications.

Additionally, we reviewed observations from previous Wounded Warrior assessments for information on medication reconciliation and proper disposal of medications. This review included documentation of site visits, interviews, and briefings to establish the subject matter of medication management in the Wounded Warrior population.

We also contacted organizations to obtain additional information through interviews and requests for information about current DoD and Service-level medication management practices in order to ensure that we had the most up-to-date information available.

The Medication Management assessment report chronology was:

May-July 2012	Research and fieldwork in CONUS
March-June 2013	Analysis and report writing
November 2013	Draft assessment report issued
December 2013	Management comments received and evaluated
February 2014	Report published

Use of Computer-Processed Data

We did not utilize any computer-processed data in this assessment.

Appendix B

Summary of Prior Coverage

Several reports were issued during the past 5 years about Department of Defense and Department of Veterans Affairs healthcare services and management, disability programs, and benefits. The Government Accountability Office, Department of Defense, Department of Defense Inspector General, and Army Audit Agency have issued 16 reports relevant to DoD Medication Management issues.

Unrestricted GAO reports can be accessed over the Internet at

<http://www.gao.gov>.

Unrestricted DoD IG reports can be accessed at

<http://www.dodig.mil/PUBS/index.html>.

DoD Recovering Warrior Task Force reports can be accessed at

<http://dtf.defense.gov/rwtf/>.

Army Audit Agency reports are not available over the Internet.

GAO

GAO Report No. GAO-13-5, "Recovering Service Members and Veterans, Sustained Leadership Attention and Systematic Oversight Needed to Resolve Persistent Problems Affecting Care and Benefits," November 2012

GAO Report No. GAO-12-676, "Military Disability System: Improved Monitoring Needed to Better Track and Manage Performance," August 28, 2012

GAO Report No. GAO-12-129T, "DoD and VA Health Care: Action Needed to Strengthen Integration across Care Coordination and Case Management Programs," October 6, 2011

GAO Report No. GAO-11-32, "VA Health Care: VA Spends Millions on Post-Traumatic Stress Disorder Research and Incorporates Research Outcomes into Guidelines and Policy for Post-Traumatic Stress Disorder Services," January 24, 2011

GAO Report No. GAO-09-357, "Army Health Care: Progress Made in Staffing and Monitoring Units that Provide Outpatient Case Management, but Additional Steps Needed," April 20, 2009

GAO Report No. GAO-09-31, "Defense Health Care: Additional Efforts Needed to Ensure Compliance with Personality Disorder Separation Requirements," October 31, 2008

GAO Report No. GAO-08-615, "DoD Health Care: Mental Health and Traumatic Brain Injury Screening Efforts Implemented, but Consistent Pre-Deployment Medical Record Review Policies Needed," May 30, 2008. DoD IG

DoD

Department of Defense Recovery Warrior Task Force, 2011-2012 Annual Report, August 31, 2012

Department of Defense Recovering Warrior Task Force, 2010-2011 Annual Report, September 2, 2011

DoD IG

DoD IG Report No. DODIG-2013-113, "Assessment of DoD Wounded Warrior Matters—Fort Riley," August 6, 2013

DoD IG Report No. DODIG-2013-087, "Assessment of DoD Wounded Warrior Matters—Joint Base Lewis-McCord," May 31, 2013

DoD IG Report No. DODIG-2012-120, "Assessment of DoD Wounded Warrior Matters—Wounded Warrior Battalion—West Headquarters and Southern California Units," August 22, 2012

DoD IG Report No. DODIG-2012-067, "Assessment of DoD Wounded Warrior Matters—Camp Lejeune," March 30, 2012

DoD IG Report No. SPO-2011-010, "Assessment of DoD Wounded Warrior Matters—Fort Drum" September 30, 2011

DoD IG Report No. SPO-2011-004, "Assessment of DoD Wounded Warrior Matters—Fort Sam Houston," March 17, 2011

DoD IG Report No. IE-2008-005, "DoD/VA Care Transition Process for Service Members Injured in Operation Iraqi Freedom/Operation Enduring Freedom," June 12, 2008

DoD IG Report No. IE-2008-003, "Observations and Critique of the DoD Task Force on Mental Health," April 15, 2008

Army

Army Audit Report No. A-2011-0008-IEM, "Army Warrior Care and Transition Program," October 21, 2010

Appendix C

Legislative History and Related Activity

The legislative history, congressional initiatives, and DoD actions related to the prescription medication take-back program and DoD include:

1. **October 12, 2010:** Public Law 111-273, “The Secure and Responsible Drug Disposal Act, 2010” is enacted. This law provides authority to the Attorney General to publish rules for implementation.
2. **January 2011:** The VCSA requested the DEA authorize Army treatment facilities to conduct take-back programs in their pharmacies.
3. **April 2011:** Army representatives met with DEA’s Office of Diversion Control to discuss the VCSA’s request. The DEA indicated they were unprepared to act on the Army’s request at that time.
4. **December 4, 2012:** Senate passes Sen. 3254, 112th Cong., 2d sess., the proposed “National Defense Authorization Act for FY 2013.” It contained a provision (section 736) entitled the “Prescription Drug Take-Back Program for Members of the Armed Forces and Their Dependents.” This provision was the result of an amendment offered by Senators Collins, Lieberman and Blumenthal and accepted during Senate consideration and passage of S. 3254.
5. **December 18, 2012:** The resulting conference report (Conference Report No. 112-705) to accompany Public Law 112-239, National Defense Authorization Act for FY 2013 did not contain section 736. In not adopting the legislative provision, conferees stated, “The conferees have been informed that the Drug Enforcement Administration has drafted a comprehensive Notice of Proposed Rulemaking to implement Public Law 111-273. The conferees urge the DEA to ensure the Department of Defense is provided the opportunity to review and provide comment on the rule, and expect that the Department of Justice will keep Congress informed of these efforts.”

6. **December 21, 2012:** To implement Public Law 111-273 (see above), the DEA requested comment and published a notice of proposed rulemaking (Vol. 77 Federal Register No. 246, 21 December 2012, pp. 75784-757817) outlining “requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users.” As a new regulation, the DEA proposed to allow retail pharmacies to administer take-back programs and maintain collection receptacles.
7. **February 2013:** The ASD(HA) submitted a response to the proposed DEA rule change. The ASD(HA) recommended a modification to the DEA’s proposed Disposal of Controlled Substances rule to allow MTF pharmacies, registered as hospitals/clinics pharmacies to receive collector status. MTF pharmacies are registered as hospital/clinic pharmacies and not as retail pharmacies.
8. **June 4, 2013:** Senator Susan Collins introduced Sen. 1089, 113th Cong., 1st sess., “Service Members and Veterans Prescription Drug Safety Act of 2013.” The legislation is co-sponsored by Senators Blumenthal, Boxer, Manchin, Murkowski, and Boozman.



Management Comments

Secretary of Defense



PERSONNEL AND
READINESS

UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, DC 20301-4000

DEC 19 2013

The Honorable Eric Holder, Jr.
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-2000

Dear Attorney General Holder:

Thank you for your Department's continued investment in the removal of controlled substances and other medications from the general public to prevent misuse and abuse. We share your commitment to the removal of unwanted, unused, and expired controlled substances through drug take back programs. A routine drug take back program would reinforce ongoing Department of Defense (DoD) activities in patient safety and suicide prevention.

I am writing to seek your help in providing the Department of Defense the authority to conduct routine take-back of unnecessary prescription medication in the military medical treatment facility (MTF) pharmacies.

As you are aware, the Drug Enforcement Administration (DEA) Proposed Rule, Disposal of Controlled Substances, was published in the Federal Register, Volume 77, Number 246, on December 21, 2012, which would expand the options available for the safe and effective collection and disposal of unwanted and unnecessary prescription drugs. However, this proposed rule excludes the 546 pharmacies located at MTFs. The exclusion of MTF pharmacies from collector status limits DoD's ability to accept unused patient medications in a routine setting and will reduce the potential effectiveness of efforts to eliminate opportunities for medication misuse, abuse, and tragic adverse events.

Our organizations have met, and corresponded, on this issue several times in calendar year 2013. There is general agreement that authority exists for DEA to allow DoD to have a drug take back program which would include MTF pharmacies.

I request that you have DEA grant MTF pharmacies the authority to routinely take back controlled substances notwithstanding the fact that the proposed Final Rule does not grant them collector status. DoD is ready now to work with DEA on adopting guidelines to accomplish this as soon as possible.

Secretary of Defense (cont'd)

Thank you for your interest in the health and well-being of our Service members, veterans, and their families.

Sincerely,


Jessica L. Wright
Acting

Assistant Secretary of Defense for Health Affairs



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

NOV 27 2013

MEMORANDUM FOR THE DEPARTMENT OF DEFENSE INSPECTOR GENERAL

SUBJECT: DOD IG Draft Report D2010-D00SPO-0209.007 Draft Report

This is the Department of Defense response to the Department of Defense Inspector General Draft Report on Project No. D2010-D00SPO-0209.007.

Thank you for the opportunity to review and comment on the Draft Report. Overall, I concur with the findings contained in the Draft Report. The management and reconciliation of multiple medications in the Wounded Warrior population is of importance to the Department of Defense (DOD) in areas of patient safety and suicide prevention. The DOD supports enhanced ability to implement prescription return/take-back and disposal programs to aid in the removal of unwanted, unused, and expired controlled substances. My specific responses to Recommendations A.1, B.2, and B.3 are attached.

My points of contact on this issue are [REDACTED] (Functional) who can be reached at [REDACTED] or via e-mail at [REDACTED] or [REDACTED] (Audit Liaison) at [REDACTED] or via email at [REDACTED].

Jonathan Woodson, M.D.

Attachments:
As stated

Assistant Secretary of Defense for Health Affairs (cont'd)

**DEPARTMENT OF DEFENSE INSPECTOR GENERAL DRAFT REPORT ON
PROJECT NO. D2010-D00SPO-0209.007 "ASSESSMENT OF DOD WOUNDED
WARRIOR MATTERS: MANAGING RISKS OF MULTIPLE MEDICATIONS"**

RESPONSE TO RECOMMENDATIONS

Recommendation A.1: Assistant Secretary of Defense for Health Affairs publish policy guidance that addresses the risks for Wounded Warriors who may use multiple medications in the course of their treatment and the need for additional safeguards to ensure that these medications are effectively managed and properly reconciled by medical personnel.

DOD Response:

We concur with the recommendation. Although the Department of Defense (DOD) has multiple programs and risk mitigation strategies in place as further described below, establishing an overarching policy will guide consistent implementation and use of these programs and strategies and require that providers be trained in how to optimize care for patients receiving multiple medications.

The culmination of more than 10 years of war and advanced medical practices and medical evacuation has resulted in combat injury survival rates that had previously been impossible. These factors have contributed to emotional and physical challenges for many combat injured warfighters. Despite the challenges military personnel remain resilient and motivated for continued military service. Unfortunately, many of psychological and physical wounds of war are chronic conditions whose long-term treatment requires complicated pharmacotherapy.

Scientific evidence over the past several decades shows that appropriately selected and timed medications, or combinations of medications, can limit the severity and duration of mental illness, while medication to treat chronic physical conditions (e.g. chronic pain) is essential to the physically injured undergoing rehabilitation. While the use of multiple medications is medically indicated, efficacious, and compassionate for the purpose of alleviating pain and suffering, it is an area requiring pharmacological risk management strategies within any health system.

The DOD has undertaken several actions to mitigate the risk of adverse outcomes related to the prescribing of pharmaceuticals which include:

- The DOD Pharmacy Operations Division (POD) uses the Pharmacy Data Transaction Service (PDTS), an online centralized prescription data repository that automatically checks new prescriptions against the patient's computerized medication history for possible adverse events or therapeutic duplications before the new drug is dispensed. In addition, prescriptions filled at retail, mail order and MTFs are also screened against theater prescriptions. PDTS provides a single, comprehensive patient drug profile for DOD beneficiaries and it permits the Department to monitor and conduct surveillance for drug usage patterns of concern. PDTS has helped to avoid more than 171,000 potentially life-

Assistant Secretary of Defense for Health Affairs (cont'd)

threatening drug interactions ensuring our patients receive medication that is safe and medically indicated.

- There are existing policies that require coordination between prescribing providers and for those providers to document those intentions in a patient's treatment plan.
- When a suspicion of patient drug-seeking behavior is a concern, the Sole Provider Program is available to providers in all Services. This program requires periodic reviews of all prescriptions for controlled substances, and seeks to identify suspicious patterns of drug use. Should patterns of drug use be validated or remain of concern, the issuance of prescriptions can be assigned to a single provider.
- Prescribing safeguards include guidelines in clinics that limit the number of pills dispensed to potentially high-risk patients, warning flags that appear in electronic drug dispensing menus which require physician attention, and the Military Treatment Facility (MTF) prescription restriction program.¹ We have also increased our reviews of the circumstances of manual overrides of system warning flags by physicians.
- Pharmacists throughout the MHS provide consumers with a medication information sheet on each new and renewed prescription. DOD evaluates for drug-drug interactions on every prescription filled at mail order, a retail pharmacy or MTF, ensuring our patients receive safe medications. Additionally, the Provider and Prescription Program is an integrated program between medical and pharmacy which focuses on utilization management of narcotics. Pharmacy identifies high utilizers of narcotics and refers these beneficiaries to their primary care medical provider or MTF. The medical contractor or MTF reviews the profiles to determine if the beneficiary has a medical condition that supports increase use of narcotics and offers the appropriate case management or pain management options. A PDTS warning flag was recently added to advise MTF providers and pharmacies of restricted patients.

The misuse or abuse of prescription drugs is not consistent with military service and may be indicative of psychiatric conditions that require treatment. In order to identify personnel engaged in such activities all Service members undergo random drug testing for both licit and illicit substances. Presence of drug metabolites in urine in the absence of a bona fide prescription or other evidence of therapeutic use (e.g. anesthesia) is grounds for punitive legal action. These actions involve due process for the Service member and nearly always occur while treatment

¹ **MTF Prescription Restriction Program/ MTF Lock-in Edit** Military Treatment Facility (MTF) providers may identify beneficiaries who may have "drug seeking behavior" or are at high risk of harming themselves through accidental overdose of narcotics and/or other high risk medications. Once identified, the provider may consider placing certain limits on the pharmacy benefit. One way to allow this limit is by utilizing the Pharmacy Data Transaction Service (PDTS). The provider has the option to: 1) restrict the beneficiary to all drugs to a specific pharmacy(s) and/or provider(s) 2) restrict the beneficiary to control meds to a specific provider(s) 3) exclude control meds or specific non- control med at mail order or retail pharmacy. The POD will enter the restriction into PDTS which provides a means to manage the pharmacy benefit access.

Assistant Secretary of Defense for Health Affairs (cont'd)

avenues are pursued. Additional measures are in place to mitigate risks that may be associated with abuse of prescribed medications:

- Drug testing has been expanded to identify nearly all prescription opiates and benzodiazepines, which has been the single most important effort we have made in demand reduction for these potentially dangerous medications.
- In November 2010, the Chairman of the Joint Chiefs of Staff sent a memorandum to the Undersecretary of Defense for Personnel and Readiness (USD P&R) describing the new drug threat to military personnel from prescription drug misuse and abuse. USD P&R concurred and moved forward with an initiative to add prescription drug monitoring to the panel of testable drugs within the Military Personnel Drug Abuse Testing Program.

In addition to the aforementioned risk mitigation measures associated with prescription medication, the DOD places equal emphasis on promulgating the use of evidence-based care in pain management and for mental health care. For example, the DOD-Veterans Affairs (VA) Clinical Practice Guideline, "Management of Opioid Therapy (OT) for Chronic Pain" (2010) describes the critical decision points in the management of OT for chronic pain and provides clear and comprehensive evidence based recommendations incorporating current information and practices for practitioners throughout the DOD and VA Health Care systems (<http://www.healthquality.va.gov/cot/>). And, as psychotherapy is the preferred first-line method of providing mental health care numerous working groups and defense centers of excellence within the DOD have been advancing provider training and research of proven psychotherapeutic techniques. Research findings are actively translated into recommendations for clinicians, including the use of effective medication assisted therapies. DOD-VA scientific and clinical working groups have revised and created Clinical Practice Guidelines (CPGs) for several psychiatric illnesses, including Major Depressive Disorder, Substance Use Disorders, and Post-Traumatic Stress Disorder (PTSD). The Assistant Secretary of Defense for Health Affairs has published specific policy guidance addressing the safe practice of using medications during psychiatric treatment, provider training recommendations, and specific provider documentation and patient informed consent when prescribing psychotropic medication (*Clinical Policy Guidance for Assessment and Treatment of Post-Traumatic Stress Disorder*, published August 2012) and policy guidance pertaining to the prescription of antipsychotic medication (*Guidance for Providers Prescribing Atypical Antipsychotic Medication*, http://www.health.mil/libraries/HA_Policies_and_Guidelines/12-003.pdf)

Recommendation B.2.: Subsequently, and upon DOD receipt of authority from the Drug Enforcement Administration (DEA) to conduct drug take-back programs, Assistant Secretary of Defense for Health Affairs establish DOD policy and coordinate the implementation of a related program across all Services for conducting prescription medication take-back.

Assistant Secretary of Defense for Health Affairs (cont'd)

DOD Response:

DOD concurs with the recommendation. The removal of unwanted, unused, and expired controlled substances is of particular importance to the DOD. A drug take back program would reinforce ongoing DoD activities in patient safety and suicide prevention. The DEA Proposed Rule, *Disposal of Controlled Substances*, published in the Federal Register, Volume 77, Number 246, on December 21, 2012, as written allows entities registered as retail pharmacies, including those co-located in a hospital, the opportunity to request collector status. However, the proposed rule did not allow pharmacies registered as hospitals/clinics this option. The DOD military MTF pharmacies are registered with the DEA as hospital/clinic pharmacies. The exclusion of MTF pharmacies to request collector status limits DOD's ability to accept unused patient medications in a routine setting and reduce the potential effectiveness of efforts to eliminate opportunities for medication misuse, abuse, and tragic adverse events. The DOD provided comments to the Proposed Rule recommending modification to the *Disposal of Controlled Substances* proposed rule to allow military treatment facilities registered as hospitals/clinics to receive collector status. In July 2013, the DOD and DEA met with the Department of Justice (DOJ) regarding DOD's ability to engage in controlled substance collection activities. Both agencies agreed that authority exists for DEA to allow DOD to have a drug take back program, and can be accomplished through a Memorandum of Agreement (MOA). DOD is hopeful that such a MOA can be accomplished in the near future.

Recommendation B.3.: Assistant Secretary of Defense for Health Affairs should consider additional education and information initiatives to inform patients, healthcare providers, and Wounded Warrior unit commanders on the existing Food and Drug Administration and Drug Enforcement Administration programs and procedures to remove expired or unneeded medications.

DOD Response:

DOD concurs with the recommendation. Since 2011, DOD has taken a significant step towards preventing prescription drug misuse, abuse, and accidental poisoning through participation in DEA's National "Take Back Day" events to remove unwanted and outdated prescription drugs from our military communities' medicine cabinets. Several military facilities have participated in the National "Take Back Day" events.

The DOD is prioritizing recommendations resulting from a DOD sponsored Drug Take-Back Study entitled "*Recommendations for DOD to Reduce Pharmaceutical Related Suicide Behaviors in Members of the Armed Forces*" (April 2013). Once complete, the DOD intends to issue a comprehensive policy for the adoption of optimal methods to reinforce ongoing DOD activities in patient safety and suicide prevention. The policy will include the activation of patient management programs such as the Patient Centered Medical Home (PMCH) to improve the coordination of care, and management of complex patients such as wounded warriors suffering from polytrauma and behavioral health issues. With the implementation of PCMH there will be increased attention on the education of healthcare professionals regarding medication reconciliation, counseling patients on their current, discontinued, and adjusted medications reconciliation, formally recommending the best ways to prevent misuse and abuse

Assistant Secretary of Defense for Health Affairs (cont'd)

of medications, and obtaining formal informed consents from patients as it relates to their medications. During the informed consent process healthcare professionals will highlight the different types of controlled substances take back programs that are currently available to them.

Army Surgeon General, Army Military Command

REPLY TO
ATTENTION OFDEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042-5140

02 DEC 2013

DASG-CS

MEMORANDUM FOR Department of Defense Inspector General (DoDIG), Special Plans and Operations, [REDACTED] 4800 Mark Center Drive, Alexandria, VA 22350-1500

SUBJECT: Response to DoDIG Assessment of DoD Wounded Warrior Matters: Managing Risks of Multiple Medications (Project No. D2010-D00SPO-0209.007), dated 1 November 2013

1. Thank you for the opportunity to review this report.
2. The US Army Medical Command (MEDCOM) concurs with the report as written, and with recommendation A-2. MEDCOM recently updated policies involving medication reconciliation, as indicated in DoDIG's report.
3. In addition, the Drug Enforcement Agency (DEA) has agreed to grant MEDCOM Military Treatment Facilities (MTF) dual registrations (hospital/clinic and retail pharmacy). This added retail registration will allow them to meet the definition of a "collector" to maintain collection receptacles on site as proposed in 77 Fed. Reg. 75784 (Dec. 21, 2012). Patients could then have the option to dispose of Schedule II-V controlled substances and other medications at MTF locations. MEDCOM is evaluating the implications of dual status and potential conversion of existing hospital/clinic registrations into dual registrations.
4. The point of contact is [REDACTED] Internal Review and Audit Compliance Office, [REDACTED], or email: [REDACTED]

FOR THE SURGEON GENERAL:



ULDRIC L. FIORE, JR.
Chief of Staff

Navy Surgeon General and Navy Bureau of Medicine and Surgery



DEPARTMENT OF THE NAVY
BUREAU OF MEDICINE AND SURGERY
7700 ARLINGTON BOULEVARD
FALLS CHURCH, VA 22042

IN REPLY REFER TO
12 December 2013

MEMORANDUM FOR Department of Defense Inspector General

SUBJECT: Assessment of DoD Wounded Warrior Matters: Managing Risks of Multiple Medications.

Thank you for the opportunity to review your document. Bureau of Medicine and Surgery has reviewed the material and attached you will find our response. This letter serves as a notice of approval for the attached comments.

My point of contact is [REDACTED]

at [REDACTED]

A handwritten signature in black ink, appearing to read "J. A. Ralph", written over a circular stamp or seal.

J. A. RALPH
Assistant Deputy Chief, Wounded Ill and Injured

Navy Surgeon General and Navy Bureau of Medicine and Surgery (cont'd)

Recommendation A.2. - "Military Services' Surgeons General review and update policies and procedures for medication reconciliation to ensure that they are appropriate to address the unique needs of the Wounded Warrior population."

BUMED concurs with the importance of medication reconciliation, particularly for Wounded Warriors, who are more likely to be prescribed a variety of medications for various conditions. We concur that policies regarding medication reconciliation should be reviewed to ensure that they address the unique needs of Wounded Warriors.

As stated in the report, there is no overarching BUMED policy governing medication reconciliation. In the past, Navy Medicine has refrained from mandating specific medication reconciliation processes given important differences that exist at the local level, including unique patient populations at our various MTFs, differences in facility capabilities, staffing variations, and other characteristics. Navy Medicine has also historically placed a great deal of importance on individual provider autonomy and the professional judgment of prescribers when interacting with individual patients, which could be impacted by the imposition of enterprise-wide standards.

However, medication reconciliation is emphasized at every Navy MTF, in accordance with The Joint Commission (TJC) National Patient Safety Goals. All of our prescribing providers are required to review and confirm with patients the list of medications a patient is taking, and to take this into account in their prescription practices and clinical decision-making. All of our MTFs are encouraged to use the SF-508 form to perform medication reconciliation during each clinic visit. Many of our sites use an electronic version of the SF-508 that is populated with a list of active medications from CHCS. Again though, the specific policies for conducting medication reconciliation are specified in local command instructions.

This recommendation seems to endorse a more centralized medication management policy for Wounded Warrior patients, similar to the development of a Clinical Practice Guideline. BUMED does not object to this, but we believe that any centralized policy should be sufficiently flexible to account for variations in practice that are necessary given differences in the circumstances at each local site. BUMED concurs with the concept of standardization and is very active in this regard with many initiatives currently ongoing to decrease variation across Navy Medicine. These standardization efforts are inclusive of Wounded Warrior patients but also extend to the beneficiary population at large. We also recognize the risks of polypharmacy, particularly with regard to controlled substances, and to that end have implemented the DoD/VA approved CPG on Chronic Opioid Therapy. We believe this will address many of the concerns raised in the report and benefit not only our Wounded Warriors, but all of our patients.



Acronyms and Abbreviations

ADE	Adverse Drug Events
AHLTA	Armed Forces Health Longitudinal Technology Application
ASD (HA)	Assistant Secretary of Defense for Health Affairs
CBWTU	Community-Based Warrior Transition Unit
CDC	Centers for Disease Control and Prevention
DCoE	Defense Centers of Excellence
DEA	Drug Enforcement Administration
DRP	Drug Related Problems
MEDCOM	Medical Command
MHS	Military Health System
NPSG	National Patient Safety Goals
ONDCP	National Office of Drug Control Policy
OTSG	Office of the Surgeon General
PDTS	Pharmacy Data Transaction Service
PEC	Pharmacoeconomic Center
PH	Psychological Health
P-MART	Prescription Medication Analysis and Reporting Tool
TBI	Traumatic Brain Injury
TMA	TRICARE Management Activity
USMC	United States Marine Corps
VCSA	Vice Chief of Staff of the Army
WCTP	Warrior Comprehensive Transition Program
WTU	Warrior Transition Unit



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U.S. DEPARTMENT OF DEFENSE

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